University of Michigan Clinical Criteria

Revised: June 1, 2024

This policy compendium is published on a regular basis. The University of Michigan and Magellan Rx Management make a good faith effort to keep this document up to date. Prior authorization policies may be updated and are subject to change. All criteria are evidence based. References are available upon request. For any questions regarding this information, please contact Magellan Rx Management at 888-272-1346.

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PLAN INFORMATION

Website: https://hr.umich.edu/benefits-wellness/health-well-being/prescription-drug-plan

Member/Provider Portal: https://umich.magellanrx.com/

Phone Numbers

- Clinical Contact Center (PA Line): 1-888-272-1346
- Clinical Fax Number: 1-800-424-7648

Billing Information

- **BIN:** 017449
- **PCN:** 3387647000
- **GROUP:** MRHUOM
- **ID Sample:** U01234567

Formulary

- Custom formulary
- University of Michigan Formulary Look up Tool: https://magellan.adaptiverx.com/webSearch/index?key=cnhmbGV4LnBsYW4uUGxhblBkZlR5cGUtNTcy

Drug Tiers

- **T0:** TIER 0 – $0
- **T1:** TIER 1 – Generic (low co-pay, generic drugs)
- **T2:** TIER 2 – Preferred Brand (intermediate co-pay, preferred brand drugs)
- **T3:** TIER 3 – Non-Preferred Brand (high co-pay, non-preferred brand drugs and brands with generic equivalent; the member may also be subject to a product selection penalty)
- **NF:** TIER 4 – Non-Formulary
- **EXL:** TIER 5 – Not Covered (Plan Exclusions)
- NOTES:
  - Tier exception requests are not allowed. Requests should be **admin denied** as plan benefit exclusions. Note: Plan benefit exclusions and tier exceptions may not be appealed.
  - DAW penalty exception requests follow Medical Necessity for Brand clinical criteria.

Days' Supply

- Retail Day Supply
  - Claims up to 34-days' supply = 1 co-payment
  - Claims for 35–60 days' supply = 2 co-payments
  - Claims for 61–90 days' supply = 3 co-payments
- Mail Day Supply
  - Any claim up to 91-day supply = 2 co-pays
  - No mandatory mail
  - NoviXus is the preferred mail order pharmacy
- Specialty Day Supply
  - Specialty drugs are limited up to 34 days' supply at Michigan Medicine Pharmacies.
  - Exceptions to the 34-day limit include:
    - Stelara, Cosentyx, Tremfya, Skyrizi, Prograf, and Envarsus, which can be filled up to a 90 days' supply based on diagnosis and directions.
    - Immunosuppressive drugs and drugs to treat HIV are covered for up to 90 days per fill. Refer to HIV MEDICATIONS and IMMUNOSUPPRESSIVE DRUGS sections for more information.

Specialty Medications

- All specialty claims are mandated to fill at Michigan Specialty Pharmacies:
  - Ambulatory Care Pharmacy, Taubman Pharmacy and Cancer Center NPI: 1003967035
  - East Ann Arbor Pharmacy NPI: 1366484933
  - Brighton NPI: 1477031185
  - Kellogg Eye Center Pharmacy NPI: 1508197419
- If a specialty medication is processed outside the University of Michigan Specialty Pharmacy Network, the claim will reject IE 50207 / NCPDP R6 and display the error message: "MUST FILL AT MICHIGAN MED."
- If Michigan Medicine cannot fill a medication due to the member being out of state, the requested medication will process at NoviXus without an override.
- If neither Michigan Medicine nor NoviXus have the medication in stock or cannot ship to the member, plan approval is required to place an override to allow the claim to pay at Magellan Rx Specialty or another In-Network Specialty Pharmacy.

HIV Medications

- Allow up to 34 days' supply, first fill anywhere with POS message, "2nd fill covered only at Michigan Medicine Specialty Pharmacies 855-276-3002."
- Second fill must be filled at Michigan Specialty Pharmacies or NoviXus Mail Order NPI:1639310600 for a 90 days' supply.
- Members can continue filling at U of M Health Service Pharmacy NPI:1790891026 (Student Health Services) up to a 34 days' supply.

Immunosuppressive Drugs

- Allow up to 34 days' supply, first fill anywhere with POS message, "2nd fill covered only at Michigan Medicine Specialty Pharmacies 855-276-3002"
- Second fill must be filled at Michigan Specialty Pharmacies or NoviXus Mail Order up to a 90 days' supply.

CRM

- Carrier ID: MRHUOM
- Coverage Codes:
  - MRHUOM0001 – Plan 1
  - MRHUOM0002 – Plan 2

Plan Exclusions

Length of Authorization:	Refer to client
Initiative:	EXC: Drug Exclusion (IE 31011 / NCPDP 70 – GSN)

- Medications not covered (EXL) by University of Michigan (Plan Exclusions) will reject 31011/70
  - External Reject Message: "Product/Service Not Covered"
  - Internal Error Message: "Error List NDC not covered. Plan Exclusion."
- Drugs classified as excluded by the plan are administratively denied (ADMIN denied) by the pharmacist as a plan benefit exclusion. Note: Plan benefit exclusions may not be appealed.
  - Technicians: Set up contact detail and PA, then escalate to the pharmacists following the PA Process
- If pharmacy is processing a medication under an excluded NDC and an included NDC is available, please change to included NDC and advise pharmacy to process using the included NDC if approvable.
- Use the FirstTrax℠ internal rejection 31011/70 to determine if a medication is excluded by the plan. In general, excluded products include the following:
  - Stimulant-based weight loss products
  - Blood products
  - Diagnostic agents
  - Swabs
  - Blood Glucose Test Strips – medical benefit
  - Lancets
  - Urine test strips
  - Items approved as devices by the FDA do not go through the same review and approval process as drugs.
  - Cosmetic products or any drug used for cosmetic purposes such as treating facial wrinkles or hair loss.
  - Drugs that lack substantial evidence of safety and efficacy for the proposed use. These include but are not limited to experimental, investigational, or unproven drugs, or drugs being used for indications that have not been approved by the FDA. Exceptions may be considered using the standard appeal process as allowed under the Affordable Care Act.
  - Injectable medications, except those listed in this website as covered; injections that must be administered by a health care professional are not covered.
  - In general, new drugs and medicines that have not been reviewed by the plan.
  - Prescription products that offer no additional clinical benefit over existing available therapies or existing therapeutically equivalent products in the drug class.
  - Generally, prescription products that are the main active metabolite, the isolated enantiomer, prodrug, or an alteration of an existing product where no added clinical benefits have been shown by published, scientific, peer-reviewed, head-to-head comparative studies.
  - Medical foods.
  - Enteral Feeding
  - Infant Formula
  - Vitamins, other than select prescription prenatal vitamins, vitamin D, K, injectable B-12, and those specified in the Affordable Care Act.
  - Therapeutic devices, appliances or medical equipment, support garments, or ostomy supplies.
  - Most Over the Counter (OTC) medications, any prescription medication that contains the same active ingredient(s) as an existing OTC medication, or kits that are packaged with an OTC medication. Select preventive OTC drugs and products are covered at $0 co-pay under the Affordable Care Act with a written prescription by your physician.
  - Compounded prescription medications that contain bulk chemicals.
  - **Azelastine 0.1% (137 mcg) spray** is only covered for patients 5yo and under, it is a **plan exclusion** for patients **over 5**.
- **Internal note:** Rozerem (ramelteon) is excluded by the plan for members below the age of 65.

Medication Request Form (MRF)

- Drug specific clinical prior authorization forms are available in FirstTrax℠ (send a fax) and on the provider portal: https://umich.magellanrx.com/
- The drug specific MRFs are not required to be used. It is acceptable to review requests submitted on alternatives MRFs.
- PA requests can be made via FAX, ePA, or phone.
  - For phone requests, if physical documentation (e.g., chart notes, labs, etc.) is required under the "Required Medical Information" section of clinical criteria, documentation must be faxed in and reviewed prior to determination made.

Clinical Criteria

- Each drug or drug class has a clinical policy to follow for prior authorization requests. The drug/drug classes are listed in alphabetical order.
- Each clinical policy page(s) contains the following:
  - Drug/drug class name
  - Length of authorization
  - Initiative/internal rejection code
  - Information about the drug/drug class (not required for PA approval):
    - FDA-Approved Indications
    - FDA-Recommended Dose
    - How Supplied
  - Information required for PA approval:
    - Utilization criteria
  - For initial review
  - For continuation
    - Exclusion Criteria: Applied on initial and renewal requests
    - Required Medical Information (general): Information that must be collected before PA approval. Requires either verbal/written attestation of information or physical documentation (ex: chart notes, labs, etc.).
      - Example: Treatment history – may be verbal or written attestation of trial by the provider, chart notes/pharmacy documentation not required unless specifically noted in the policy.
      - Example: "Medical records" defined as anything in the patient's medical record or in a letter of medical necessity signed by the provider
      - Example: When the criteria notes that documentation is required, the intent is not to accept information received verbally or on the PA cover sheet. Example: needs medical records, chart notes, lab results, or claims.
    - Required Medical Information (lab documentation): Unless otherwise stated in criteria, labs should be from within 6 months of the PA start date for new starts. For renewals, labs should be from within the initial approval timeframe.
      - Example: For an initial review, labs should be from within the last 6 months.
      - Example: For a renewal review, the labs should be from between the start date and date of renewal request.
    - Age Restrictions: PA limited to patients that meet the age restrictions for the drug
    - Prescriber Restrictions: Limits who can request the PA
      - Ex: "Must be prescribed by or in consultation with a rheumatologist."
    - Reviewer Requirements: Limits who can review and approve/deny the PA
      - Ex: "All coverage requests must be reviewed by a licensed pharmacist or physician," means the request must be forwarded to the pharmacist team for review.
    - Coverage Duration:
      - Ex: 6 months (initial), 12 months (continuation)
    - Quantity/Partial-Fill Restrictions: Quantity limitations for initial/renewal, if applicable
    - Operational Instructions/Additional Information: Any additional information pertinent to the review

Interpreter Services

- Translation Services:
- Many of our customers are of diverse backgrounds and do not speak English as their first language. To better serve these individuals, Magellan Rx Management has negotiated a contract with **Voiance LLC** to provide confidential language interpretation via telephone.
- Requesting Services:
  - Dial the following toll-free number: 1-833-409-4473. A Voiance Customer Service Agent (CSA) will answer.
  - Enter the Magellan Rx Management Contact Center Access Code: 1873425003.
  - You will be prompted to verify the Magellan Rx Management Contact Center Access Code you entered.
  - A prompt will ask for the language needed. If the language is Spanish, press 1. For all other languages, verbally state the language needed. If you do not know the language the caller is speaking, press 0 for agent assistance.
  - An interpreter will come on the line and provide their name and agent ID number.
  - Provide the caller's information in three to four sentences for the interpreter to relay. This will help the interpreter retain the information and relay it to the caller.
  - Proceed with standard documentation of the call. Note that an interpreter was used, as well as the interpreter's name and agent ID number.
  - When communication has finished, state "Interpreter no longer needed." The Interpreter will sign off.

Performance Guarantees

- Initial Prior Authorization (PA) Turnaround Times:
  - Expedited (Urgent): Request must be resolved within 24 hours or less
  - Standard: Request must be finalized within 72 hours or less
- First and Second Level Internal Appeals Turnaround Times:
  - **Expedited (urgent):** Appeal must be resolved **within 72 hours** of receipt
  - **Standard:** Request: Appeal must be resolved **within 15 days** of receipt

Medication Shortages

KNOWN SHORTAGES

- Known drug shortages will be identified in the University of Michigan Drug Look up tool by the "B4G" indicator.
  - If the pharmacy processes a claim using DAW8 for a drug marked "B4G," the claim will process.
  - If the pharmacy processes a claim using DAW8 for a drug NOT marked "B4G," the claim will reject.

REPORTED SHORTAGES

- Please have the caller check at least 3 other pharmacies, at least one with a different wholesaler, to see if the medication is in stock at another pharmacy.
- Technicians check the ASHP and FDA websites below for known shortages:
  - https://www.ashp.org/shortages
  - https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
- If the caller has checked other pharmacies with different wholesalers AND the drug cannot be found, tell the caller the request is being investigated and Magellan will call/fax once completed. Normal turnaround time is 24-48 hours.
- Technician sends an email with the reported findings using the appropriate email template.
- Save notes from call, including other pharmacies checked and results from looking on the ASHP and FDA websites, in the work log notes.
  - Leave request in progress in MAP: Pharm queue.
  - Assign to: "DAS Request"
- Overrides due to reported drug shortages should only be made by direct notice from the Sr. RPh, Pharmacist Account Manager, or Client.
- The override will be entered for date of service only.

Service Level Agreement (SLA)

- SLA Type
  - Expedited (Urgent)
    - Fax or caller must indicate Expedited, Urgent, ASAP, etc., for a request to be marked expedited. Do not review claims data to make this determination.
    - Provider attests a standard review period may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.
  - Standard
    - A regular request or one not marked expedited (urgent).
- SLA Service Type
  - Preservice
    - Requests for medications prior to the member getting the medication.
  - Postservice
    - Requests for medications received after the member picked up the medication. Direct Member Reimbursement (DMR) requests only.
    - Postservice request are always marked standard.

Early Refill Tolerance

- 75% for all pharmacies

Early Refill and MSC Overrides

Length of Authorization: Day of Service
Initiative: ADM: Early Refill (IE ER / NCPDP 88 – GSN)

- Refill Too Soon (RTS) overrides may not override benefit monthly (erectile dysfunction), yearly (erectile dysfunction) or lifetime (infertility) limits on the medication.
  - Magellan Rx Management may override RTS for the following reasons:
  - Overrides are allowed one time per medication, per year (up to 34-day supply) in the following situations:
    - Incorrect days' supply on previous claims because directions (SIG) changed, data entry error, or different product under the same coding.
    - In a situation where a pharmacy processes two separate claims to satisfy the total dosage written by the physician (i.e., the medication does not come in a 7 mg strength. The pharmacy must bill two separate claims – one for the 5 mg strength and one for the 2 mg strength), the member is responsible for each co-pay per claim. There are no exceptions.
    - Facility admission or discharge
      - Enter a one-time refill-too-soon override when the member is admitted to or discharged from a facility or there is a change in directions and the member's previous fill had to be destroyed.
      - Override may include quantity restrictions, as long as there is no lifetime or yearly limit on the medication and the quantity does not exceed the limit allowed per month as defined in the member's benefit.
      - **NOTE:** Facilities include nursing homes, rehabilitation centers and hospitals.
  - Overrides are allowed one time per medication, per six months (up to a 34day supply) in the following situations:
    - Member took/consumed the medication incorrectly
    - Lost/stolen/spilled
    - Natural disaster
    - Additional supply for school/daycare
    - Vacation
- Change in Dose Requests:
  - Overrides are allowed for any RTS claim in which therapy change request is for a quantity/days' supply equal to or below the existing quantity limit.
- Sabbatical (extended medication supply) Requests:
  - NoviXus can ship to all 50 states, members must be leaving the U.S. to get an extended supply.
  - Any extended supply request needs to come through UofM Shared Services Center 734-615-2000. Approvals will be sent to Account Management to be overridden.
- Special Packaging:
  - If the medication cannot be dispensed with a smaller quantity/days' supply based on the package size (e.g., cream tubes, drops, inhalers, etc.) please override the amount/days' supply as prescribed by the physician.
- Compounds:
  - Inactive ingredients included in multiple different compounds (e.g., sterile water for irrigation) may reject for refill too soon. Set up the PA using the rejecting inactive ingredient included in both compounds and override for day of service.

Backdating

- Magellan Rx Management may backdate an existing clinical prior authorization up to 30 days from the date of the request. Any request for more than 30 days back is not applicable.
- **Internal note for clarification:** existing clinical prior authorizations may be backdated up to 30 days prior to the start date of the PA, even if requested more than 30 days from the original request.

Samples

- Samples do not count toward tried and failed medications. Generally, use of drug samples does not meet the criteria for having been established on therapy.
- Drug samples may only be considered in cases where a member has initiated use of a non-formulary (NF) product for the treatment of a psychiatric illness, and the provider attests that the member may decompensate if therapy is interrupted or modified.
- In general, medications received through a patient assistance program, with no historical claims, do not meet the criteria for having been established on therapy. If initial criteria are NOT met, but renewal criteria are met, email case summary to Sr. RPh for review with client. Unless directed otherwise by the client, requests not meeting initial criteria should be denied.

Trialed and Failed Medications

Provider attestation, pharmacy fill history, and claims history can be used for documentation of previous trials and failures of medication, unless otherwise noted in the drug-specific clinical criteria.

New To Market

- In the interim of a drug coming to market and not yet having gone through P&T or having criteria, these products should be excluded until directed otherwise.
- Technicians: set up contact detail and PA, then escalate to the pharmacists following the PA Process.
- Pharmacists: place an ADMIN denial (plan benefit exclusion).

Drugs Without Criteria

If a request for a medication without criteria is rejecting for prior authorization, the request should be escalated to account management. Gather the case details and email them to the current Clinical Account Manager, CC the Lead Clinical Pharmacist.

Contraceptive Tier Exception Policy

Updated: May 8, 2023

POLICY OVERVIEW

The University of Michigan Prescription Drug Plan (PDP) allows coverage of non-preferred single source brand (tier 3) formulary contraceptive products at zero cost share (tier 0) when the product is the only medically appropriate agent for the member as attested to by the member's provider.

COVERAGE CRITERIA

- For multisource brand contraceptive products:
  - Refer to the Medical Necessity for Brand Policy.
- For non-formulary contraceptive products:
  - Refer to the Non-Formulary Policy.
- For non-preferred (tier 3) single source brand contraceptive products with no available interchangeable generic:
  - Approve at tier 0 if the member's provider attests that the requested contraceptive product is the only medically appropriate agent for the member.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

If a drug is classified as "excluded" by the PDP, the member and provider are both to receive a denial letter with instructions on how to appeal the decision to the State of Michigan.

Email erxresponseteam@magellanhealth.com with the following information and let them know that the patient is meeting for a contraceptive tier exception (tier 0) so the override can be entered in FirstRx℠.

Follow up with the ERX team after 2 days to ensure the override has been completed if there has been no response of completion.

Member Name

Member DOB

Member ID

Drug Name

Opioid Policy

- As of July 1, 2018, consistent with Michigan's Public Act 251 of 2017, opioid prescriptions for acute pain are limited to a 7-day supply.
- Drugs included in this limit include all dosage forms and products combined with other ingredients (e.g., acetaminophen, aspirin, caffeine, etc.) that contain buprenorphine, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, morphine sulfate, nalbuphine, oxycodone, pentazocine, tapentadol, and tramadol.
- For more information, refer to the University Human Resources website at https://hr.umich.edu/benefits-wellness/health-well-being/prescription-drug-plan/coverage-drug-information.
- For a summary of all new opioid laws in Michigan, please refer to the Department of Licensing and Regulatory Affairs (LARA) and the Michigan Department of Health and Human Services (DHHS)'s Frequently Asked Questions document: (https://www.michigan.gov/documents/lara/LARA_DHHS_Opioid_Laws_FAQ_05-02-2018_622175_7.pdf.
- Opioid naïve edit
  - 7-day limit for opioid naïve patients
  - Lookback: Will not reject opioid naïve if claims for opioids or antineoplastics in past 180 days.
  - Rejection: IE 7004 / NCPDP 75
  - Messaging: "Opioid I patient > 7 ds max. Enter PPS codes or call 888-272-1346"
  - Pharmacy can override at point of sale with ICD10 code for sickle cell only: D57. Instruct pharmacy to enter ICD10 code on the claim.
  - Pharmacy can also override at point of sale using Reason Service Codes (RSC) applicable to the patient's diagnosis: 4B (palliative), 4C (hospice), 4D (cancer), or 4J (patient not opioid I).
  - Magellan Rx Management cannot override this rejection at the call center. If the pharmacy is unable to override using the diagnosis provided or applicable RSC, refer them to their software vender.

Step Therapy Exception Policy

Updated: May 26, 2023

Length of Authorization:	3 months
Initiative:	STP: (choose drug specific initiative) (IE 31121 / NCPDP 608 – GSN)

POLICY AND PRODUCT INFORMATION

- The University of Michigan Prescription Drug Plan (PDP) utilizes step therapy (ST) edits as a core utilization management strategy. Drugs with ST requirements are covered only if certain formulary alternatives have been tried first. If the preferred alternative ("Step") drug(s) have been tried, as evidenced by claim history on the member's profile, the requested drug will automatically approve at the point of sale (POS) without manual intervention. If there is no claim history for the step drug(s) within the drug-specific look-back period, the claim for the requested drug will deny at POS. When a denial occurs at POS for a drug with ST requirement, the member or member's provider has the opportunity to submit a request for an ST exception.
- The ST exception procedure applies to all drugs that have ST requirements on the UM PDP's formulary that do not have drug-specific coverage criteria policies.
- Internal Note: The ST exception procedure applies to all drugs that have ST requirements on the PDP's formulary that do not have drug-specific coverage criteria policies designated for the override of the given ST denial.

UTILIZATION PROCEDURE

For Initial Coverage Requests:

- The member has documentation supporting trial and failure of, or contraindication/intolerance to, **ALL** required step drugs; **AND**
- The member has an indication supported by the requested product's FDA-approved label or meets the plan's off-label use policy.

For Continuation Coverage Requests:

- The member has an indication supported by the requested products FDA-approved label or meets the plan's off-label use policy, **AND**
- One of the following:
  - The member is new to the PDP within the last 6 months **and** the member has previously tried and failed the required step drug(s) as evidenced by provider documentation or submitted pharmacy claim records; **OR**
  - The member was previously established on the requested drug through a different insurance plan as evidenced by provider attestation or submitted pharmacy claim records.

COVERAGE DURATION

Three months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

- Continued use of the requested drug will satisfy the ST look-back requirement. If the member has not filled the product in 180 days, the request should be treated as an initial request.
- The member's use of drug samples does not meet the criteria for having been established on therapy and does not count towards tried and failed medications.
- If multiple strengths/formulations of the same medication are listed as step drugs, trial and failure, contraindication, or intolerance of just one strength/formulation of each medication listed is sufficient.

INTERNAL NOTE: VIEWING STEP THERAPY AND REQUIRED STEP DRUG(S)

1. Open the University of Michigan Formulary Look up Tool: https://magellan.adaptiverx.com/webSearch/index?key=cnhmbGV4LnBsYW4uUGxhblBkZlR5cGUtNTcy
2. Search for the requested medication.
3. Left click on the **"ST" indicator** for the requested drug under "Limits & Restrictions" to view Step Therapy details.
   - Required step drug(s) are listed on the left side of the Details window.
   - All Step 2 drugs (drugs that require step therapy) will be listed on the right-hand side of the Details window.

INTERNAL NOTE: KAZANO (BRAND NAME ONLY) – STEP THERAPY EXCEPTION

- Initiative: STP: Kazano (IE 31121 / NCPDP 608 – GSN; IE 50076 / NCPDP 70 – GSN)
- Although rejecting for STEP and Non-Formulary, brand name Kazano does not follow the STEP policy. Refer to Non-Formulary criteria.Plan Information (Continued)

Quantity Limits

Length of Authorization:	Varies
Initiative:	EXC: Quantity Limit: Per Day (IE 2641, 15110 / NCPDP 76 – GSN); EXC: Quantity Limit: IE 7001 (IE 7001 / NCPDP 76 – GSN); EXC: Quantity Limit: IE 7007 (IE 7007 / NCPDP 76 – GSN)

- Allowable quantity limits are referenced on the formulary or within the drug specific clinical PA policy.
- Refer to the Off-Label Use policy for quantity requests beyond that allowable per formulary or the PA policy. If Off-Label Use policy criteria are met, or if the requested dose is on-label for the diagnosis provided, the member must also try and fail up to the formulary limit prior to approval of quantities above the listed formulary limit.
  - Technicians: Set up contact detail and PA, then escalate to the pharmacists following the PA Process.
- Dose titration – If the member is titrating up to the next maintenance dose, technician or pharmacist may approve quantity PA x 1 month to allow for dose titration.

Dose Optimization

Length of Authorization:	Varies, refer to clinical policy
Initiative:	PAR: Loading Dose (IE 15110, 2641, 7001 / NCPDP 76 – GSN)

- Medications with a loading dose and maintenance dose require two different PAs for initial approval. The metric quantity and day supply must be entered in the PA.
  - Enter the MAINTENANCE dose using the drug-specific initiative FIRST, for the full duration of the approval. Use the appropriate CTI and send the letter.
  - Enter the LOADING dose using "PAR: Loading Dose" initiative SECOND. Approve the loading dose for the loading period, entering the loading strength, metric quantity, and day supply in the PA.
    - Select CTI reason code: 2nd O/R for Existing PA Approved.
    - No approval letter is sent with second PA.

Gender Dysphoria

- Refer to drug specific clinical policy.
- In general, University of Michigan is supportive of this diagnosis and support medication therapy needs.

Infertility Medications

- Refer to drug specific clinical policy
- Select infertility drugs are limited to 5 fills per family, per lifetime, after the 5th fill member will pay 100% out of pocket.
- Included fertility drugs are marked as "INF – Infertility Max 5 Fills" in the drug lookup tool:
  - Gonal-F 1,050 unit and 450 units vial
  - Gonal-F RFF 75 units vial
  - Gonal-F RFF REDI-JECT 300 unit, 450 unit, and 900 unit
  - Follistim AQ 300 unit, 600 unit, and 900 unit cartridge
  - Menopur 75-unit vial
- Requests for above the max benefit limit will reject 50076/70 with the supplemental language "Max of 5 lifetime infertility fills have been met." These requests are **admin denied** by the pharmacist as a plan benefit exclusion.

Cost Exceeds Maximum

Length of Authorization:	Determined by client
Initiative:	ADM: Cost Exceeds Maximum: Plan Review (IE 3024 / NCPDP 78 – GSN, IE 50084 / NCPDP 78 – GSN) ADM: Compound: DOS Cost Override (IE 3024 / NCPDP 78)

- Cost exceeds maximum requests days that are escalated to the client for review are carved out of Performance Guarantees.
- All cost exceed maximum rejections are escalated to the pharmacist team for review.
- The University of Michigan Prescription Drug Plan (PDP) must be consulted for all Cost Exceed Maximum overrides for which the anticipated cost per claim exceeds:
  - $250 for Compounds
  - $2,000 for Non-Formulary drugs
  - $5,000 for traditional drugs (Should bypass if there is a Prior Authorization or Quantity Limit on the product)
  - $10,000 for specialty drugs (Should bypass if there is a Prior Authorization or Quantity Limit on the product)

TECHNICIANS:

- Collect directions for use and diagnosis, if available. Ensure pharmacy is processing claim correctly. If the pharmacy is not processing correctly, have them rerun the claim with the correct quantity and days' supply.
- If pharmacy is processing claim correctly, set up contact detail and PA, then escalate to the pharmacists following the PA Process.
  - Select CTI: MAP Exception Inquiry → MAP Exclusion Exception → In Progress Exception

INTERNAL NOTES FOR PHARMACISTS:

- Send via email using the cost exceeds email template
  - **Note:** Cost Exceeds Max requests may be resolved internally (without client review) if the "Total Paid" on the pricing tab of trial adjudication OR "Total Amount Paid" under the Pricing → Client tab on the rejected claim is less than the cost threshold for the category (specialty, traditional, compounds, non-formulary).
  - Include summary in email (note patient name and ID are not required): Drug, Quantity, Days' Supply, Cost, Directions for use, information researched regarding dosing, and diagnosis. Send what information is available, do not pend for more information from the physician.
- When escalated to the client for review, select the following CTI:
  - MAP Exception Inquiry → MAP Exclusion Exception → Sent to Client
- When decision from client received, select the following CTI:
  - MAP Exception Inquiry → MAP Exclusion Exception → Approved by Client/Denied by Client

OPERATIONAL NOTES AND OTHER INFORMATION

- For compound approvals, place the Cost Exceeds Max override only. **Do not place overrides for excluded compound ingredients.**
- If the compounded medication contains an excluded ingredient (other than those marked as 'CMPD Only' on the formulary), the pharmacy can process with SCC 08 to receive a paid claim (the plan only pays for covered ingredients).

NON-FORMULARY REQUESTS EXCEEDING $2,000

Length of Authorization:	Shorter of 12 months or planned duration of therapy, determined by client
Initiative:	EXC: Non-Formulary Product (IE 50076 / NCPDP 70 – GSN, IE 50084 / NCPDP 78 – GSN)

- Non-Formulary requests exceeding the maximum cost limit of $2,000 per claim that are escalated to the client for review are carved out of Performance Guarantees.
- Refer to the NON-FORMULARY POLICY
- Technicians:
  - Collect directions for use and diagnosis, if available. Ensure pharmacy is processing claim correctly. If the pharmacy is not processing correctly, have them rerun the claim with the correct quantity and days' supply.
  - If pharmacy is processing claim correctly, set up contact detail and PA, then escalate to the pharmacists following the PA Process.
  - For Non-Formulary requests exceeding $2,000 per claim, select CTI: MAP Exception Inquiry → MAP Exclusion Exception → In Progress Exception
- Pharmacists:
  - If Non-Formulary Policy criteria are **not** met, deny the request.
    - **Note:** if the request is denied and **not** sent to the client for review, resolve using the appropriate CTI starting with Call Category: *MAP PA Inquiry.*
  - If criteria are met and the cost per claim exceeds $2,000, University of Michigan Prescription Drug Plan (PDP) must be consulted prior to placing a clinical approval (for initial review, reconsiderations, AND appeals).
    - Send via email using the appropriate template in the Health Plans OneDrive.
      - **Note:** Cost Exceeds Max requests may be resolved internally (without client review) if the "Total Paid" on the pricing tab of trial adjudication **or** "Total Amount Paid" under the Pricing → Client tab on the rejected claim is less than the cost threshold for the category (specialty, traditional, compounds, non-formulary).
    - Include summary in email: Drug, Quantity, Days' Supply, Cost, Directions for use, information researched regarding dosing, and diagnosis. Send what information is available, do not pend for more information from the physician.
    - When escalated to the client for review, select the following CTI:
      - MAP Exception Inquiry → MAP Exclusion Exception → Sent to Client
    - When decision from client received, select the following CTI:
      - MAP Exception Inquiry → MAP Exclusion Exception → Approved by Client/Denied by Client

INTERNAL NOTES

The PDP does **not** need to be consulted for NF contraceptive overrides where the anticipated cost per claim exceeds $2,000 (example, Annovera does not need to go to the client for approval).

COMPOUND REQUESTS EXCEEDING $250

Length of Authorization:	Determined by client
Initiative:	ADM: Compound DOS Cost Override (IE 3024 / NCPDP 78 – GSN) ADM: Cost Exceeds Maximum: Plan Review (IE 3024, 50084 / NCPDP 78 – GSN)

- Compound requests exceeding the maximum cost limit of $250 per claim that are escalated to the client for review, are carved out of Performance Guarantees.
- Refer to the COMPOUND POLICY
- Technicians:
  - Collect directions for use and diagnosis, if available. Ensure pharmacy is processing claim correctly. If the pharmacy is not processing correctly, have them rerun the claim with the correct quantity and days' supply.
  - If pharmacy is processing claim correctly, set up contact detail and PA, then escalate to the pharmacists following the PA Process.
  - For Compound requests exceeding $250 per claim, select CTI: MAP Exception Inquiry -> MAP Exclusion Exception -> In Progress Exception
- Pharmacists:
  - If Compound Policy criteria are NOT met, deny the request.
    - **NOTE:** If the request is denied and NOT sent to the client for review, resolve using the appropriate CTI starting with Call Category: *MAP PA Inquiry*.
  - If criteria are met and the cost per claim exceeds $250, University of Michigan Prescription Drug Plan (PDP) must be consulted.
    - Send via email using the Compound Cost Exceeds Maximum email template
      - **Note:** Cost Exceeds Max requests may be resolved internally (without client review) if the "Total Paid" on the pricing tab of trial adjudication OR "Total Amount Paid" under the Pricing →Client tab on the rejected claim is less than the cost threshold for the category (specialty, traditional, compounds, non-formulary).
    - Include summary in email (note patient name and ID are not required): Drug, Quantity, Days' Supply, Cost, Directions for use, information researched regarding dosing, and diagnosis. Send what information is available, do not pend for more information from the physician.
    - When escalated to the client for review, select the following CTI:
      - MAP Exception Inquiry → MAP Exclusion Exception → Sent to Client
    - When decision from client received, select the following CTI:
      - MAP Exception Inquiry → MAP Exclusion Exception → Approved by Client/Denied by Client

COMPOUNDS

Length of Authorization:	Shorter of 12 months or planned duration of therapy
Initiative:	ADM: Compound: DOS PA Override (IE 2462 / NCPDP 75) ADM: Compound: DOS Cost Override (IE 3024 / NCPDP 78)

UNIVERSITY OF MICHIGAN'S PRESCRIPTION DRUG PLAN

- The University of Michigan (U-M) Prescription Drug Plan (PDP) utilizes an evidence-based medicine approach to formulary management. Resources used include, but not limited to, published clinical trial data, meta-analyses and/or review articles, FDA-approved product labeling, treatment and/or consensus guidelines, University subject matter experts, and other clinical resources.
- The Pharmacy Benefits Advisory Committee (PBAC) acts as an independent advisory panel of physicians, pharmacists, and PDP staff charged to evaluate drug products for coverage on the U-M PDP formulary. All PBAC members are required to submit annual conflict of interest disclosures.
- The U-M PDP is responsible for the final determination of recommendations, implementation, operations, coordination, and follow up of drug review decisions recommended by PBAC with the contracted pharmacy benefit manager (PBM).
- Drug formulary coverage is evaluated on several criteria including efficacy, safety, clinical appropriateness, place in therapy, treatment guidelines, clinical expert opinion, therapeutic alternatives, cost, and projected utilization.
- **Note:** Compounds cannot be filled at NoviXus Mail Order.

COVERAGE OF COMPOUNDED DRUG PRODUCTS

- Compounded medications are prepared to meet the needs of individual patients and are not FDA-approved. They are covered only if they meet **all** of the following criteria:
  - The compounded medication must contain at least **two** covered ingredients
  - **Note**: Covered compounds may include one active, covered ingredient and one covered inactive ingredient. Covered inactive ingredients may appear as "excluded" on the plan's formulary but are noted as payable when used as a compound (listed as "CMD" on the drug look up tool).
  - At least one active ingredient must require a prescription by federal law pursuant to an FDA review and approval process
  - The compounded medication does not require administration by a healthcare professional
  - The active ingredient(s) must be approved by the FDA for medicinal use in the United States
  - The compounded medication is not a copy of a commercially available FDA-approved product
  - The safety and effectiveness for the intended use is supported by FDA-approval or adequate medical and scientific evidence in the medical literature, or if requested for off-label indication, the off-label guidelines **must** be met
  - The compounded medication is not intended to replace a drug that has been withdrawn from the market for safety reasons
  - If a drug included in the compound requires PA, all drug-specific prior authorization criteria must be met
  - The compounded medication must **not** contain an excluded ingredient (other than those marked as 'CMPD Only' on the formulary) **or** must only process with SCC 08 (only covered ingredients pay).
- Compounded medications require a prior authorization of the cost is greater than $250 or if any component of the compound requires a clinical prior authorization.
- Compounded medications process at a tier 2 copay.

INTERNAL NOTES

- **Technicians** – Ensure the pharmacy is processing the compound using Submission Clarification Code 8. If claim still does not pay, escalate to the pharmacists for clinical review.
- If compound is **not** rejecting for cost, escalate using appropriate CTIs following the PA Process.
- For Compound requests exceeding $250 per claim, select CTI: MAP Exception Inquiry → MAP Exclusion Exception → In Progress Exception
- Compound requests exceeding the maximum cost limit of $250 per claim that meet clinical criteria, are escalated to the client for review. Refer to COMPOUND REQUESTS EXCEEDING $250.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

Signatures and Prior Authorization Requests

- Fax requests must be signed by the requesting provider/provider's representative to be processed for PA. If unsigned, fax will not be processed for PA and will be sent back for missing signature. (**Note:** This does not apply to ePA or verbal requests. A signed PA form is not required to process ePA or verbal requests).
- Prior authorization may be requested by the provider/provider's representative **or** patient.
  - For patient-initiated PA requests, do the following:
    - Technician gathers information from the patient, including the provider's information.
    - Technician will reach out to the physician's office to attempt to gather and verify any information needed on the patient-initiated PA request.
      - If criteria are met and technician can approve the request, approve noting information gathered from the call to the physician's office in the PA notes.
      - If request is not approvable, transfer the physician call to the RPh line and place the PA in the MAP: Pharmacist queue
- Prior authorization may be requested by the pharmacy IF the pharmacy is working as the provider's representative. Example: pharmacy is located within the same location as the provider's office, or pharmacy has access to patient chart notes.
- Any pharmacy may call to request an override due to cost exceeded. If pharmacy is billing correctly, the request is sent to University of Michigan for review, if applicable. Refer to the COST EXCEEDS MAXIMUM Process.

PA Process

INITIAL CLINICAL PRIOR AUTHORIZATION REVIEW

- Technicians:
  - If there is no previous denial within 180 days, treat as an Initial PA review.
  - Start a prior authorization (PA). Document the pertinent information in the Clinical Decision Module (CDM) or clinical notes.
  - If the CDM recommends approval – approve the request. Inform the caller or fax back the approval to the provider. Send the approval letter to the patient.
  - If the request is a fax, and there is missing information to complete the review: Leave the PA "In Progress." Follow the pending procedure for EXPEDITED and STANDARD requests.
  - If there is no missing information and the request is not approvable, WARM transfer the call to the RPH line or escalate the fax to the MAP: Pharmacists queue:
    - Prior to transferring the call or escalating the fax, save issue as follows:
    - Select the following CTI:
      - Call Category: *MAP PA Inquiry*
      - Call Type: MAP PA Request
      - Response Code: *In Progress PA OR Outreach: Information Received* (if request was previously pended for more information)
    - Leave the issue in the MAP: Pharmacist Queue.
    - Assigned Individual field: leave blank for standard requests, mark as "URGENT," for expedited requests.
    - Select Issue Status: **IN PROGRESS**.
    - Click **Save**.

MORE INFORMATION RECEIVED

- Technicians:
  - Update the CTI Response Code to "Outreach: Information Received."
  - Update the Release Date
    - Fax requests: Highlight the new fax received on the Fax- Related to Issue Tab. Press "Update Release Date."
    - Call requests: Enter in the time and date the call was received on the SLA-SLA for Current Issue Tab.
    - If the **Release Date** field is blank and the *Outreach: Information Received* **Response Code** is selected, an error message box will appear. The user needs to either manually enter the date and time in the **Release Date** field if the information is received via telephone or click the **Update Release Date** button with the most recent fax highlighted.
  - Review and document new information received in the clinical notes.
  - If the request is a reconsideration or first and second level internal appeal – escalate to the MAP: Pharmacist queue following the RECONSIDERATIONS AND INTERNAL FIRST AND SECOND LEVEL APPEALS process.
  - If the request is an external third level IRO review, refer to the EXTERNAL THIRD LEVEL REVIEW – IRO REVIEW process.
  - If the request is a fourth level appeal – State review, refer to the FOURTH LEVEL APPEAL – STATE REVIEW process.
  - If the request is an initial PA review (no previous denial within 180 days), continue with the review.
    - Review the previous information and new information together and compare to the CDM questions and clinical criteria document.
    - Determine if there is a reviewer requirement by checking the clinical policy section under the drug/drug class.
      - If Reviewer Requirements states "N/A" – a technician can review and approve the PA if criteria are met.
      - If Reviewer Requirements states "All coverage requests must be reviewed by a licensed pharmacist or physician," – request must be escalated to the pharmacist queue. Refer to the PA Process above.
    - If the initial PA request is approvable with the new information provided and the reviewer request section says "N/A," approve the request following the length of authorization outlined in the clinical policy.
    - If the initial PA request is NOT approvable with the new information provided OR the review requirement states it must be reviewed by a pharmacist or physician, escalated to the pharmacist queue. Refer to the PA Process above.

Pending Procedure

STANDARD REQUESTS

- Technicians:
  - Start a prior authorization (PA). Document the pertinent information in the Clinical Decision Module (CDM) or clinical notes and leave the PA "In Progress." Send a fax back to the requester for missing information using the canned fax backs responses.
  - Select the following Category, Type, Item (CTI):
    - Call Category: MAP PA Inquiry
    - Call Type: MAP PA Request
    - Response Code: Outreach 1: Additional Info Requested; OR Outreach 2: Additional Info Requested; OR Outreach 3: Additional Info Requested
  - Leave the issue in the **MAP: Pharmacists Queue**.
  - Leave the Assigned Individual field blank.
  - Click Outreach.
  - Select Issue Status: **IN PROGRESS.**
  - Change SLA pend hours to 48
  - Click Save.
- Aging Issues:
  - Dedicated pharmacists review the MAP: Pharmacists Pending Queue daily for requests still awaiting MD response.
  - Deny the request before the SLA end time. Use the reason code: Insufficient Information to Determine Medical Necessity. If it is an initial PA request, use the Denial – Initial, No Response canned faxback that includes the reconsideration message. Include the missing information.
  - If more information is received via phone/fax before the SLA end time – approve or deny the request if it is an initial PA review (no previous denial in 180 days).

EXPEDITED (URGENT) REQUESTS

- Technicians:
  - Start a prior authorization (PA). Document the pertinent information in the Clinical Decision Module (CDM) or clinical notes and leave the PA in progress. If there is missing information, DO NOT PEND the request or fax back.
  - Save issue as follows:
    - Select the following CTI:
      - Call Category: *MAP PA Inquiry*
      - Call Type: MAP PA Request
      - Response Code: *In Progress PA*
  - Leave the issue in the MAP: Pharmacist Queue.
  - Change the Assigned Individual field to "URGENT."
  - Select Issue Status: **IN PROGRESS**.
  - Click **Save**.
  - ***For Expedited/Urgent requests:
    - **Calls:** WARM transfer the call to the RPH line indicating it is an urgent request.
- Pharmacists:
  - Fax and call immediately on all Expedited requests to attempt to gather missing information.
  - After the outreach has been made and documented in the PA clinical notes, the request may be denied at any time before the SLA end time. Use the reason code: Insufficient Information to Determine Medical Necessity. If it is an initial PA request, use the "Denial – Initial, No Response" canned faxback that includes the reconsideration message. Include the missing information.
  - If more information is received via phone/fax before the SLA end time – approve or deny the request if it is an initial PA review (no previous denial in 180 days).

Reconsiderations and Internal First and Second Level Appeals

OVERVIEW

- Technicians:
  - Start a prior authorization (PA). Document the pertinent information in the Clinical Decision Module (CDM) or clinical notes.
  - All reconsiderations and Internal 1st and 2nd level appeals are escalated to the MAP: Pharmacist queue for pharmacist review.
  - Timeframes:
    - Reconsideration reviews can be requested within 90 days of an initial denial.
      - If there is an initial denial within 90 days of the request, and the new request does not specify whether an appeal or reconsideration is requested, treat the request as a reconsideration.
      - If the request is made more than 90 days after an initial denial, it must be considered an appeal.
      - The request does not have to state "reconsideration" to be treated as a reconsideration.
      - The member or provider can initiate the reconsideration review.
      - If an **appeal** is requested at any time during or after the 90-day window, the request will be treated as an appeal and will not go through the reconsiderations process.
      - The reviewer for a reconsideration can be the same pharmacist who reviewed the original denial.
    - Internal Appeals:
      - A first and second level internal appeal can be requested within 180 days of an initial PA denial.
      - Urgent internal appeals may be requested orally or in writing when:
        - The provider believes the appeal decision is urgently needed; **OR**
        - In the opinion of the physician or other prescriber, deciding the appeal within the standard timeframe could seriously jeopardize the patient's life, health, or ability to regain maximum function or cause the patient pain that cannot be adequately controlled.
      - Standard Internal Appeals must be requested in writing.
  - Save issue as follows:
    - Select the following CTI:
      - Reconsiderations: MAP PA Inquiry → MAP Reconsideration Request → In Progress
      - Internal Appeals: MAP PA Inquiry → MAP PA Appeal → In Progress
    - Leave the issue in the MAP: Pharmacist Queue.
    - Assigned Individual field: Mark as "reconsideration" or "appeal" for standard requests, mark as "URGENT reconsideration or URGENT appeal," for expedited requests.
    - Select Issue Status: **IN PROGRESS**.
    - Click **Save**.
  - ***For Expedited/Urgent requests:
    - Calls: WARM transfer the call to the RPH line indicating it is an urgent request.
- Pharmacists:
  - For reconsideration request, review the request as an initial PA review.
  - For internal first and second level appeals, follow the **University of Michigan Appeals Guide**.

RECONSIDERATION FAX BACKS

- Denial – May Appeal
  - General denial message already used when faxing back a denial to the provider:
  - "The patient does not meet the criteria for approval of this medication. The request has been denied allowing pursuit of the appeal process. The patient will receive an official denial letter, complete with instructions regarding the appeal process, if applicable."
- Reconsiderations – Duplicate Fax
  - If a duplicate fax is received with information identical to the original fax within 90 days of the initial denial, close as informational and fax back the following message:
  - "A duplicate fax was received with no additional information provided after a recent denial was placed. Please note, a reconsideration review is available if missing/additional information is received within 90 days following the initial denial. Reconsiderations received more than 90 days after initial denial will be treated as an appeal in accordance with the guidelines presented in the initial denial correspondence. The initial review was denied due to the following: {enter reason for denial}"
- Reconsiderations – General
  - Add the general reconsiderations message to the return fax with the "Denial – May Appeal" message, when appropriate, after an initial denial is placed:
  - "Please note, a reconsideration review is available if missing/additional information is received within 90 days following the initial denial. Reconsiderations received more than 90 days after initial denial will be treated as an appeal in accordance with the guidelines presented in the initial denial correspondence. The initial review was denied due to the following: {enter reason for denial}"
- Denial Initial, No Response
  - If a denial is issued due to not receiving a response from the provider, use the following message that includes the "Denial – May Appeal" message as well as information on the reconsiderations process:
  - "The patient does not meet the criteria for approval of this medication. The request has been denied to allow pursuit of the appeal process. The patient will receive an official denial letter, complete with instructions regarding the appeal process, if applicable.

    NOTE: a reconsideration review is available if missing/additional information is received within 90 days following the initial denial. Reconsiderations received more than 90 days after initial denial will be treated as an appeal in accordance with the guidelines presented in the initial denial correspondence. The initial review was denied due to lack of response. The missing information includes the following: {enter missing information}"

External Third Level Appeal – IRO Review

- Technicians:
  - **If anyone other than the member** requests the external third-level appeal, the member must fill out, SIGN (section 4), and submit to Magellan Rx Management the "Authorized Representative Form," available under Forms and Information on the member portal: https://umich.magellanrx.com/ and available under "Send A Fax" in FirstTrax.
    - Note – If member is a minor, form may be filled out by a parent or guardian.
  - External third level appeals – IRO reviews are escalated to the MAP: Pharmacist queue.
  - Timeframes:
    - External third level appeals may be requested within 4 months of the final internal appeal determination.
      - Within 4 months of the Internal Second Level Appeal denial; **OR**
      - Within 4 months of the internal first level appeal denial AND the member is not eligible for the Internal Second Level Appeal due to it being >180 days since initial denial.
      - If requesting an external appeal but the member has not exhausted internal first-level and second-level appeals rights (and is still eligible), process as an internal appeal.
      - If the member has exhausted first-level and second-level internal appeal rights and it is more than 4 months after the final internal appeal determination, treat as an initial PA review.
    - Urgent external third level appeals may be requested orally or in writing
      - Available when:
        - The provider believes the appeal decision is urgently needed; **OR**
        - In the opinion of the physician or other prescriber, deciding the appeal within the standard timeframe could seriously jeopardize the patient's life, health, or ability to regain maximum function or cause the patient pain that cannot be adequately controlled.
    - Standard external third level appeals must be requested in writing.
  - Save issue as follows:
    - Select CTI: MAP IRO Inquiry → Third Level External Appeal → In Progress
    - Leave the issue in the MAP: Pharmacist Queue.
    - Assigned Individual field: Mark as "appeal" for standard requests, mark as "URGENT appeal," for expedited requests.
    - Select Issue Status: IN PROGRESS.
    - Click Save.
  - ***For Expedited/Urgent requests:
    - Calls: WARM transfer the call to the RPH line indicating it is an urgent Third Level External Review request.

    Pharmacists:
  - Determine eligibility for External Third Level Review, and submit request to IRO, if eligible, following the **University of Michigan Appeals Guide**

Fourth Level Appeal – State Review

MEMBER OR PROVIDER REQUESTS

- Technicians:
  - Prior to starting a PA, determine if the member has exhausted his or her internal and external appeal rights:
    - A first- and second-level internal appeal can be requested **within 180 days** of an initial PA denial.
    - An external third level appeal – IRO Review can be requested **within 4 months** of the final internal appeal determination.
  - Timeframe:
    - A fourth level appeal – state review can be requested **within 60 days** of final determination on external third level (IRO) appeal.
  - Magellan Rx Management does not complete the fourth level appeal – State review. Member or authorized representative may send a written request for an external review to DIFS. Request must be mailed, including the required forms that may be obtained from the DIFS Claims Administrator, to:

    Office of General Counsel
    Health Care Appeals Section
    Michigan Department of Insurance and Financial Services (DIFS)
    P.O. Box 30220
    Lansing, MI 48909-7720
    Phone: (877) 999-6442
  - For additional information on the fourth level appeal – State review process, direct members to the University of Michigan Human Resources website under Prescription Drug Plan Prior Authorization Appeals Process. (https://hr.umich.edu/benefits-wellness/health-well-being/prescription-drug-plan/prior-authorization)
  - Resolve issue as follows:
    - Select the following CTI:
      - MAP IRO Inquiry → MI State Appeal → Information Given
    - Leave the issue in the MAP: Technician Queue
    - Assigned Individual field: blank
    - Select Issue Status: **Resolved**
    - Click **Save**.

STATE OF MICHIGAN REQUESTS

- Technicians – Setting up Initial Requests:
  - Select the following CTI:
    - MAP IRO Inquiry → MI State Appeal → CCR Request
  - Leave the issue in the MAP: Supervisor queue
  - Assigned Individual field: blank
  - Select Issue Status: **In Progress**
  - Click **Save**.

- MI State Review Technicians:
  - Gather requested information for IRO from previous Contact Details. Use the CCR Report in FirstTrax℠.
    - Select the following CTI:
      - MAP IRO Inquiry → MI State Appeal → In Progress
    - Leave the issue in the MAP: Supervisor queue
    - Assigned Individual field: blank
    - Select Issue Status: **In Progress**
    - Click **Save**.
  - Attach completed compilation of documents to Contact Detail and sent to IRO
    - Select the following CTI:
      - MAP IRO Inquiry → MI State Appeal → Case Sent to State
    - Leave the issue in the MAP: Supervisor queue
    - Assigned Individual field: blank
    - Select Issue Status: **Resolved**
    - Click **Save**.
- MI State Review Technicians – Entering Decision
  - Once decision received from the State of Michigan, create a new Contact Detail in FirstTrax℠.
    - Approved Appeal:
      - Prior Authorization
        - PA Status: Approved
        - PA Initiative: Use Drug Appropriate One
        - PA Reason Code: Clinical Approval – See Clinical Notes
      - Select the following CTI:
        - *MAP IRO Inquiry → MI State Appeal → Approved*
      - Attach notification from State of Decision.
      - Leave issue in MAP: Supervisor queue
      - Assigned Individual field: blank
      - Select Issue Status: **Resolved**
      - If needed, complete effectuation notice. Attach to Contact Detail and send back to Independent Review Organization (IRO).
      - Click **Save**.
      - **NOTE:** Decision letter should not generate. Decision sent to the patient by the IRO.
    - Denied Appeal:
      - Prior Authorization
        - Since there is already an existing denial on file, there is no need to enter in another denial.
      - Select the following CTI:
        - *MAP IRO Inquiry → MI State Appeal → Denied*
      - Attach notification from State of Decision.
      - Leave issue in MAP: Supervisor queue
      - Assigned Individual field: blank
      - Select Issue Status: **Resolved**
      - Click **Save**.
      - **NOTE:** Decision letter should not generate. Decision sent to the patient by the IRO.

Appeal Review Requirements and Timeframes

Reviewer Requirement	
Reconsideration	The same Magellan Rx Management pharmacist that denied the initial PA Request can review and approve/deny the reconsideration request.
First Level Internal Appeal	Denial will be OVERTURNED: Magellan Rx Management pharmacist can complete. Denial will be UPHELD: Magellan Rx Management pharmacist can complete. The Magellan Rx Management pharmacist must be different than the RPh that completed Initial PA or Reconsideration Denial.
Second Level of Internal Appeal	Denial will be OVERTURNED: Magellan Rx Management pharmacist can complete. The Magellan Rx Management pharmacist must be different than the RPh that completed Initial PA/Recon denial and first level internal appeal denial. Denial will be UPHELD: Physician must complete review. Specialty match is NOT required. Use MRx-PCR (Physician Clinical Reviewer).
External Third Level Appeal – IRO Review	Request submitted to MRIoA or AllMed using the vendor's web portal using the federal external review process.
Fourth Level Appeal – State Review	Magellan does not complete the fourth level appeal – State review. Member or authorized representative may send a written request for an external review to DIFS.

Timeframes to Request Appeal	
IF	**THEN**
Initial denial placed > 180 days ago (and it is not an external third level or fourth level state appeal request)	Process as an initial review request.
Initial denial placed ≤ 90 days ago	Review as a reconsideration. If the request states appeal, then it MUST be treated as an internal first level appeal.
Initial denial placed ≤ 90 days ago and there is already a reconsideration denial on file	Review as an internal first level appeal.
Initial denial placed > 90 days ago but not more than 180 days ago	Review as an internal first level appeal.
Initial denial placed ≤ 180 days ago AND an Internal First Level Appeal Denial is on file	Review as an internal second level appeal.
Final determination of internal (1st and 2nd Level) appeals placed ≤ 4 months ago.	Treat as a third level external (IRO) review. **NOTE:** If there is an internal first level appeal denial on file within 4 months AND the member is not eligible for the internal second level appeal due to it being > 180 days since initial denial, treat as an external review. **NOTE:** Incomplete requests (example: missing an Authorized Representative Form signed by the patient) are resolved as informational, with a message sent back to the requestor indicating what is needed to process the request. The case is escalated to IRO once all required information has been received.

Timeframes to Request Appeal	
IF	**THEN**
Third level external (IRO) appeal denial placed ≤ 60 days ago.	Refer to the fourth level appeal – State review process. Magellan Rx Management does not complete the fourth level appeal – State review. Authorized representative may send a written request for an external review to DIFS.
No previous denial on file	Treat as initial PA
> 180 days from initial PA denial and there is no internal appeal denial on file	Treat as initial PA
> 4 months from final internal appeal determination and there is no third-level external appeal denial on file	Treat as initial PA
> 60 days from third level external appeal denial	Treat as initial PA

Vaccine Coverage and Prescription Drug Plan Policy

Version 1: Effective June 1, 2022

UNIVERSITY OF MICHIGAN'S PRESCRIPTION DRUG PLAN

A. The University of Michigan (U-M) Prescription Drug Plan (PDP) utilizes an evidence-based medicine approach to formulary management. Resources used include — but are not limited to — published clinical trial data, meta-analyses and/or review articles, FDA-approved product labeling, treatment and/or consensus guidelines, University subject matter experts, and other clinical resources.

B. The Pharmacy Benefits Advisory Committee (PBAC) acts as an independent advisory panel of physicians, pharmacists, and PDP staff charged to evaluate drug products for coverage on the U-M PDP formulary. All PBAC members are required to submit annual conflict of interest disclosures.

C. The U-M PDP is responsible for the final determination of recommendations, implementation, operations, coordination, and follow-up of drug review decisions recommended by PBAC with the contracted pharmacy benefit manager (PBM).

D. Drug formulary coverage is evaluated on several criteria including efficacy, safety, clinical appropriateness, place in therapy, treatment guidelines, clinical expert opinion, therapeutic alternatives, cost, and projected utilization.

COVERAGE OF VACCINES ADMINISTERED IN PHARMACY SETTINGS

A. The U-M PDP will cover select vaccines in retail and ambulatory pharmacy settings, in-line with coverage policies under medical vendors.

B. Vaccines for preventative illnesses, as recommended by the United States Preventative Task Force (USPTF) and the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) will generally be covered at $0 cost to members. [i, ii]

   a. For members aged 2-18 years the following vaccines will generally be covered:

      i. Rotavirus (RV)
      ii. COVID-19, ages 5-18
      iii. Diphtheria, tetanus, and acellular pertussis (DtaP, Tdap)
      iv. *Haemophilus influenzae* type b (Hib)
      v. Pneumococcal conjugate (PCV13)
      vi. Pneumococcal polysaccharide (PPSV23)
      vii. Inactivated poliovirus (IPV)
      viii. Influenza (IIV4, LAIV4)
      ix. Measles, mumps, rubella (MMR)
      x. Varicella (VAR)
      xi. Hepatitis B (HepB)
      xii. Hepatitis A (HepA)
      xiii. Human papillomavirus (HPV)
      xiv. Meningococcal, Meningococcal B
      xv. Dengue

b. For members aged 19 years and older, the following vaccines will generally be covered:
    i. Influenza (IIV4, LAIV4, RIV4)
    ii. COVID-19
    iii. Diphtheria, tetanus, and pertussis (Td, Tdap)
    iv. *Haemophilus influenzae* type b (Hib)
    v. Measles, mumps, rubella (MMR), through age 65
    vi. Varicella (VAR)
    vii. Zoster recombinant (RZV)
    viii. Hepatitis B (HepB)
    ix. Hepatitis A (HepA)
    x. Human papillomavirus (HPV), through age 45
    xi. Meningococcal (MenACWY, MenB)
    xii. Pneumococcal (PCV15, PCV20, PPSV23)

C. The following vaccines may by covered by the UM PDP with member cost-share.
    a. Travel vaccines, including those used in the prevention of cholera, Japanese encephalitis, tick-borne encephalitis, typhoid, and yellow fever.
    b. Vaccines used for routine illnesses outside of the USPTF and ACIP age recommendations.
    c. Branded vaccine products used for the treatment of routine preventative care that do not offer additional advantages over alternative, lower-cost vaccine products.

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[i] https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/immunizations-for-adults. Accessed May 4, 2022.
[ii] https://www.cdc.gov/vaccines/schedules/index.html. Accessed May 4, 2022.

ACCRUFER® (FERRIC MALTOL)

Updated: May 10, 2023

Length of Authorization:	Initial: 3 months; Continuation: 12 months
Initiative:	PAR: Accrufer (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of iron deficiency in adults

FDA-RECOMMENDED DOSE

One 30 mg capsule twice daily on an empty stomach

HOW SUPPLIED

30 mg capsules in 60-count bottles

UTILIZATION CRITERIA

For Initial Coverage:

- The member has a confirmed diagnosis of iron deficiency anemia; **AND**
- The member has a serum ferritin < 30 ng/mL or transferrin saturation < 19%; **AND**
- The member has hemoglobin levels greater or equal to 9.5 g/dL, and below 12 g/dL for women and below 13 g/dL for men; **AND**
- The member is not currently receiving, or plans to receive, IV iron treatment; **AND**
- The member has tried and failed three or more of the following over-the-counter iron products:
  - Ferrous sulfate, gluconate, or fumarate
  - Polysaccharide iron complex
  - Ferric citrate
  - Iron bisglycinate

For Continuation of Coverage:

- The member has had a positive clinical response to therapy, as documented by an increase in hemoglobin or reduction in the need for IV iron since initiating treatment.

REQUIRED MEDICAL INFORMATION

- Documentation of most current serum ferritin or transferrin saturation, with dates.
- Documentation of most current hemoglobin levels with dates.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

Must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 3 months
- Continuation: 12 months

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary quantity limits.

OTHER INFORMATION

Approve by GSN

ACTEMRA® (TOCILIZUMAB)

Updated: December 18, 2023

Length of Authorization: 12 months
Initiative: PAR: Actemra (IE 2462 / NCPDP 75, IE 7001 / NCPDP 76 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs).
- For the treatment of giant cell arteritis (GCA) in adult patients.
- For the treatment of active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older.
- For the treatment of active systemic juvenile idiopathic arthritis (SJIA) in patients 2 years of age and older.
- For the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older.
- For slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease.

FDA-RECOMMENDED DOSE

- **RA:**
  - < 100 kg: 162 mg subcutaneous every other week, followed by an increase to every week based on clinical response.
  - ≥ 100 kg: 162 mg subcutaneous every week.
- **GCA:**
  - 162 mg subcutaneous once every week (or every other week)
- **PJIA:**
  - < 30 kg: 162 mg subcutaneous every 3 weeks
  - ≥ 30 kg: 162 mg subcutaneous every 2 weeks
- **SJIA:**
  - < 30 kg: 162 mg subcutaneous every 2 weeks
  - ≥ 30 kg: 162 mg subcutaneous every week
- **CRS:**
  - Not self-administered (IV only)
- **SSc-ILD:**
  - 162 mg subcutaneous every week

HOW SUPPLIED

- For subcutaneous injection
  - Each single-dose prefilled syringe delivers 162 mg/0.9 mL
  - Each single-dose autoinjector (ACTPen) delivers 162 mg/0.9 mL

UTILIZATION CRITERIA

FOR INITIAL REQUESTS

For All Indications:

- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib).

For the Treatment of RA:

- The member has a diagnosis of moderate to severe RA; **AND**
- The member has had an inadequate response to **one** or more, or contraindication to all, of the following:
  - Leflunomide
  - Sulfasalazine
  - Hydroxychloroquine
  - Methotrexate; **AND**
- The member has had a previous trial of **one** or more, or contraindication to all, of the following preferred agents:
  - Adalimumab
  - Enbrel
  - Xeljanz

For the Treatment of GCA:

- The member has a diagnosis of GCA; **AND**
- The member has had a previous trial of or contraindication to a systemic glucocorticoid.

For the Treatment of PJIA:

- The member has a diagnosis of PJIA; **AND**
- The member has had an inadequate response to **one** or more, or contraindication to all, of the following:
  - Leflunomide
  - Sulfasalazine
  - Methotrexate
  - Hydroxychloroquine; **AND**
- The member has had a previous trial of (or contraindication to) **one** of the following preferred agents:
  - Adalimumab
  - Enbrel
  - Xeljanz

For the Treatment of SJIA:

- The member has a diagnosis of SJIA; **AND**
- The member has had an inadequate response, or contraindication to, at least **one** of the following:
  - NSAIDs
  - Systemic Glucocorticoid
  - Methotrexate

For the Treatment of SSc-ILD:

- The member has a diagnosis of SSc-ILD

FOR CONTINUATION REQUESTS

- Member has had a positive clinical response to therapy, as documented by the member's specialist provider; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib).

REQUIRED MEDICAL INFORMATION

For initial requests:

- Claims or medical records demonstrating use of previous therapies.
- For PJIA or SJIA diagnoses: current weight.

For continuation requests:

- For PJIA or SJIA diagnoses: current weight.

AGE RESTRICTIONS

- **RA, SSc-ILD, GCA:** 18 years of age and older
- **PJIA and SJIA:** 2 years of age and older

PRESCRIBER RESTRICTIONS

- For SSc-ILD: must be prescribed by or in consultation with a pulmonologist.
- For all other indications: must be prescribed by or in consultation with a rheumatologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

- **RA, SSc-ILD, or GCA:** Approval should be entered for maximum of 4 autoinjectors or syringes with a minimum day supply of 28. (#4/28 DS)
- PJIA:
  - < 30 kg: approval should be entered for maximum of 1 autoinjector or syringe with a minimum day supply of 21. (#1/21 DS)
  - ≥ 30 kg: approval should be entered for maximum of 2 autoinjectors or syringes with a minimum day supply of 28. (#2/28 DS)
- SJIA:
  - < 30 kg: approval should be entered for maximum of 2 autoinjectors or syringes with a minimum day supply of 28. (#2/28 DS)
  - ≥ 30 kg: approval should be entered for maximum of 4 autoinjectors or syringes with a minimum day supply of 28. (#4/28 DS)

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HSN

H.P. ACTHAR® (CORTICOTROPIN INJECTION)

Updated: May 30.2023

Length of Authorization: 1 month
Initiative: PAR: Acthar (IE 2462 / NCPDP 75, IE 2641 / NCPDP 76, IE 15110 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

- As monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.
- See package insert for other indications.

FDA-RECOMMENDED DOSE

- Infantile Spasms: Daily dose of 150 U/m2 (divided into twice daily IM injections of 75 U/m2) administered over a 2-week period.
- Dosing with corticotropin should be gradually tapered over a 2-week period to avoid adrenal insufficiency. The following is one suggested tapering schedule: 30 U/m2 in the morning for 3 days; 15 U/m2 in the morning for 3 days; 10 U/m2 in the morning for 3 days; and 10 U/m2 every other morning for 6-days.
- See package insert for dosing of other indications.

HOW SUPPLIED

5 mL multi-dose vial (80 USP Units per mL).

UTILIZATION CRITERIA

For All Coverage Requests:

- The member has a diagnosis of infantile spasms confirmed with hypsarrhythmia on electroencephalography (EEG); **AND**
- The member's caregiver intends to administer the product at home.

REQUIRED MEDICAL INFORMATION

- Confirmation of hypsarrhythmia via chart review.
- Date of initiation of corticotropin in the inpatient setting.
- Dosing schedule.

AGE RESTRICTIONS

Less than 2 years of age.

PRESCRIBER RESTRICTIONS

Must be prescribed by, or in consult with, a neurologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

One month

QUANTITY RESTRICTIONS

Two vials maximum.

OPERATION NOTES AND OTHER INFORMATION

- Approve by GSN. Ensure the dosing requested requires 2 full vials.
- **Note:** the use of corticotropin for indications other than infantile spasms is considered experimental or investigational as these indications pre-date the Kefauver-Harris amendment to the Federal Food, Drug, and Cosmetic Act of 1962, and have not since been supported by substantial clinical evidence

ACZONE® (DAPSONE)

Updated: August 2, 2023

Length of Authorization:	12 weeks (initial) 24 months (continuation)
Initiative:	STP: Dermatological Agents (IE 31121 / NCPDP 608 – GSN) PAR: Dermatological Agents (IE 2462 / NCPDP 75 – GSN)

POLICY AND PRODUCT INFORMATION

The prescription drug plan covers dapsone 5% and 7.5% topical gel for patients with acne vulgaris who do not respond to treatment with preferred formulary agents.

FDA-APPROVED INDICATION(S)

For the topical treatment of acne vulgaris.

FDA-RECOMMENDED DOSE

A thin layer applied to affected areas twice daily.

HOW SUPPLIED

30-gram, 60-gram, and 90-gram tubes.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS FOR 5% GEL

- The member is diagnosed with acne vulgaris; **AND**
- The member has tried an adequate trial of benzoyl peroxide or topical retinoids (over the counter or federal legend, as attested to by prescriber).

FOR INITIAL COVERAGE REQUESTS FOR 7.5% GEL

- The member is diagnosed with acne vulgaris; **AND**
- The member has had an adequate trial of benzoyl peroxide or topical retinoids (over the counter or federal legend, as attested to by prescriber); **AND**
- The member has tried and failed an adequate trial of dapsone 5% gel.

FOR CONTINUATION COVERAGE REQUEST

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

9 years of age and older.

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

N/A

COVERAGE DURATION

- 12 weeks (initial)
- 24 months (continuation)

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

ADAGRASIB (KRAZATI)

Updated: January 9, 2024

Length of Authorization: 5 years
Initiative: PAR: Krazati (IE 2462/NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) who have received at least one prior systemic therapy.

FDA-RECOMMENDED DOSE

600 mg orally twice daily.

HOW SUPPLIED

200 mg tablets in 180-count bottles.

COVERAGE CRITERIA FOR INITIAL COVERAGE REQUESTS

- The member has a confirmed diagnosis of one of the following:
  - Non-small cell lung cancer (NSCLC); **OR**
  - Pancreatic adenocarcinoma; **OR**
  - Ampullary adenocarcinoma; **OR**
  - Colon cancer; **OR**
  - Rectal Cancer; **AND**
- The member has evidence of KRAS G12C mutation as determined by an FDA approved test; **AND**

FOR CONTINUATION COVERAGE REQUESTS

The member has had a positive clinical response to therapy, as documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Evidence of KRAS G12C mutation.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by GSN References

ADBRY® (TRALOKINUMAB-LDRM)

Updated: April 1, 2024

Length of Authorization:	Initial: 6 months Continuation: 12 months
Initiative:	PAR: Adbry (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

FDA-RECOMMENDED STARTING DOSE

- 600 mg on day 0, followed by 300 mg administered every other week.
- After 16 weeks of treatment, if clear or almost clear skin is achieved, dose can be dropped to 300 mg every 4 weeks (only for patients with body weight < 100 kg).

HOW SUPPLIED

150 mg/mL pre-filled syringes in packs of two and four.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of moderate-to-severe atopic dermatitis; **AND**
- The member has one of the following:
  - A minimum body surface area (BSA) involvement of at least 10%; **OR**
  - Eczema Area and Severity Index (EASI) score of at least 16; **OR**
  - Physician Global Assessment (PGA) score of at least 3; **AND**
- The member meets **one** of the following clinical scenarios:
  - The member has a greater than 50% of their BSA impacted; **OR**
  - The member has had a previous trial of at least one therapy from at least two of the following preferred therapy categories without adequate response:
    - Topical Calcineurin Inhibitors (e.g., tacrolimus, pimecrolimus)
    - Medium or high potency topical corticosteroids
    - Topical PDE-4 Inhibitors (e.g., crisaborole); **AND**
- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

FOR CONTINUATION COVERAGE REQUESTS

- The member has had a positive clinical response to therapy, as documented by the member's specialist provider; **AND**
- The member has experienced or maintained one of the following:
  - A reduction in BSA involvement of a least 20% from baseline; **OR**
  - A decrease in EASI score of at least 50% from baseline; **OR**
  - A PGA score of 0 or 1.
- If the request is for 300 mg every other week, the member must meet either of the following:
  - The member weighs >100 kg; **OR**
  - The provider attests that the patient is **not** appropriate for a dose reduction to 300 mg every 4 weeks; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

REQUIRED MEDICAL INFORMATION

- Initial: current BSA coverage, EASI score, or PGA score and a treatment plan with all previous and concurrent therapies.
- Continuation: current BSA coverage, EASI score, or PGA score and current weight.

AGE RESTRICTIONS

18 years of age or older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a dermatologist or an allergist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

6 months (initial); 12 months (continuation)

QUANTITY RESTRICTIONS

INITIAL

- Approve a formulary quantity limit override for 1 month to allow a loading dose MDD of 0.22
- Approve a formulary quantity limit override starting after month one, for the length of the remainder of the clinical PA approval to permit an MDD of 0.15.

CONTINUATION

- Refer to formulary unless the member is not appropriate for formulary QPD per weight or provider attestation above.
- If not appropriate for monthly dosing, approve a formulary quantity limit override to permit an MDD of 0.15.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

AFINITOR DISPERZ® (EVEROLIMUS)

Updated: May 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Afinitor Disperz (ID 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- In adult and pediatric patients aged 1 year and older with tuberous sclerosis complex (TSC) for the treatment of subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected.
- For the adjunctive treatment of adult and pediatric patients aged 2 years and older with TSC-associated partial-onset seizures.

FDA-RECOMMENDED STARTING DOSE

- TSC-associated SEGA: 4.5 mg/m2 orally once daily until disease progression or unacceptable toxicity
- TSC-associated partial onset seizures: 5 mg/m2 orally once daily until disease progression or unacceptable toxicity

HOW SUPPLIED

2, 3, and 5 mg tablets for suspension in 28-count blister packs

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member must have a diagnosis of tuberous sclerosis complex (TSC) with subependymal giant cell astrocytoma (SEGA) tumor(s) that require therapeutic intervention but cannot be curatively resected; **OR**
- The member must have a diagnosis of TSC-associated partial-onset seizures.

For Continuation Coverage Requests:

- The member must continue to receive benefit as attested to by their prescribing provider.

REQUIRED MEDICAL INFORMATION

Patient body surface area (or recent height and weight)

AGE RESTRICTIONS

- 1 years of age and older for treatment of SEGA tumors
- 2 years of age and older for TSC-associated partial-onset seizures

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION (MONTHS)

5 years

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

Approve by GSN.

AFREZZA® (INSULIN HUMAN POWDER, METERED)

Updated: July 27, 2023

Length of Authorization:	Initial: 6 months. Continuation: 5 years
Initiative:	PAR: Afrezza (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

To improve glycemic control in adult patients with diabetes mellitus.

FDA-RECOMMENDED DOSE

4 units at each meal, to increase up to 24 units at each meal as needed.

HOW SUPPLIED

4 unit, 8 unit, and 12-unit single-use cartridges. Three cartridges are contained in a single cavity of a blister strip. Each card contains 5 blister strips separated by perforations for a total of 15 cartridges.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of diabetes mellitus; **AND**
- The member does not smoke **or** quit smoking six or more months prior to the request; **AND**
- The member does not have a history of lung cancer; **AND**
- The member does not have a history of asthma, COPD, or pulmonary disease; **AND**
- The member has tried and failed subcutaneous forms of rapid-acting insulin; **AND**
- If the member has type 1 diabetes, the member will use basal insulin concurrently with Afrezza.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy per the treating provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an endocrinologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 6 months.
- Continuation: 5 years.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

AKEEGA® (NIRAPARIB/ABIRATERONE)

Updated: December 22, 2023

Length of Authorization:	5 years
Initiative:	PAR: Akeega (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

With prednisone, Akeega is indicated for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC).

FDA-RECOMMENDED DOSE

200 mg niraparib/1,000 mg abiraterone acetate orally once daily in combination with 10 mg prednisone daily.

HOW SUPPLIED

- 50 mg/500 mg film-coated tablets in 60-count bottles.
- 100 mg/500 mg film-coated tablets in 60-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of castration-resistant prostate cancer; **AND**
- The member meets one of the following clinical scenarios:
  - The member is also receiving a gonadotropin-releasing hormone (GnRH) analog concurrently; **OR**
  - The member has had bilateral orchiectomy; **AND**
- The member has documentation of BRCA positive disease; **AND**
- The member's treatment plan includes concomitant prednisone therapy.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

For initial reviews:

- Claims or medical records demonstrating concurrent use of hormone suppression therapy, as applicable.
- Medical records documenting orchiectomy, as applicable.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by, or in consultation with, an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HSN

ALECENSA® (ALECTINIB)

Updated: April 11, 2023

Length of Authorization:	5 years
Initiative:	PAR: Alecensa (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)

FDA-RECOMMENDED DOSE

600 mg (four 150 mg capsules) orally twice daily

HOW SUPPLIED

150 mg capsules in 240-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **NSCLC:**
  - The member has documented anaplastic ALK-positive metastatic non-small cell lung cancer (NSCLC)
- **Histiocytic neoplasm:**
  - The member has documented symptomatic or relapsed or refractory Erdheim-Chester Disease (ECD); **AND**
  - Alectinib is being used as targeted therapy for ALK-fusion
- **T-cell lymphoma:**
  - The member has documented ALK-positive anaplastic large cell lymphoma (ALCL)
- **Inflammatory myofibroblastic tumor (IMT):**
  - The member has documented inflammatory myofibroblastic tumor (IMT) with ALK translocation
- **B-cell lymphoma:**
  - The member has documented relapsed or refractory ALK-positive large B-Cell lymphoma

For Continuation Coverage Requests:

- The member has had a positive response to therapy, as documented by the member's specialty provider

REQUIRED MEDICAL INFORMATION

ALK-rearrangement test results

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a hematologist or an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OTHER INFORMATION

Approve by GSN.

ALTERNATIVE DOSAGE FORMS

Updated: July 27, 2023

Length of Authorization:	5 years
Initiative:	EXC: Age Limit: Over Maximum (IE 2194 / NCPDP 60 – HICL)

POLICY AND PRODUCT INFORMATION

Coverage for alternative dosage forms (e.g., solutions, suspensions, oral disintegrating tablets) of products commonly available as oral doses (e.g., tablets, capsules) may require prior authorization for members over the age of 10. This policy may also apply to non-oral products that have pediatric formulations or packaging intended for pediatric patients.

UTILIZATION CRITERIA

For All Initial Coverage Requests:

- Modifications to the conventional dosage form (e.g., crushing, chewing, dissolving) are not possible or feasible, per the member's provider; **AND**
- The member has one or more of the following clinical conditions:
  - Documented difficulty in swallowing or dysphagia
  - Requires tube feeding
  - Requires a dosage unobtainable with the conventional dosage form

For Continuation Coverage Requests:

- The member meets the initial coverage criteria; **OR**
- The member is currently established on the alternative dosage form, either through a previous authorization or through coverage from a previous insurer, and the member's provider attests that altering the current treatment plan would result in patient harm or significantly adverse clinical outcomes.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

11 years of age and older (claims should automatically process if 10 years or younger).

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

N/A

COVERAGE DURATION

5 years

QUANTITY/PARTIAL-FILL RESTRICTIONS

N/A

OTHER INFORMATION

Internal note: Applies to medications indicated as “AL Up to 10 years old” on the drug look up tool, unless dosage form is specifically addressed in the drug specific clinical policy

ALUNBRIG® (BRIGATINIB)

Updated: April 28, 2023

Length of Authorization:	5 years
Initiative:	PAR: Alunbrig (IE 2462, NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or intolerant to crizotinib.

FDA-RECOMMENDED STARTING DOSE

90 mg orally once daily for the first 7 days; if tolerated, may increase to 180 mg orally once daily until disease progression or unacceptable toxicity.

HOW SUPPLIED

- 30 mg tablets in 30 count bottles, 90 mg tablets in 7 and 30 count bottles, and 180 mg tablets in 23 and 30 count bottles.
- Also available in a one-month initiation pack containing 7x90 mg tablets and 23x180 mg tablets.

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member has one of the following diagnoses**:**
  - Recurrent or advanced metastatic NSCLC; **OR**
  - Inflammatory myofibroblastic tumor (IMT); **OR**
  - Langerhans Cell Histiocytosis; **OR**
  - Rosai-Dorfman Disease; **OR**
  - Erdheim-Chester Disease; **AND**
- The member has ALK rearrangement positive disease; **AND**
- The member will be using brigatinib as monotherapy.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

ALK tumor status

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years.

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES

Approve be HICL.

AMITIZA® (LUBIPROSTONE)

Updated: November 30, 2023

Length of Authorization:	12 months
Initiative:	PAR: Amitiza (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of chronic idiopathic constipation (CIC) in adults, opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, and irritable bowel syndrome with constipation (IBS-C) in women at least 18 years of age.

FDA-RECOMMENDED DOSAGE

- **CIC and OIC:** 24 mcg twice daily
- **IBS-C:** 8 mcg twice daily

HOW SUPPLIED

8 and 24 mcg capsules in 60-count and 100-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member must meet one of the following:
  - Have clinically diagnosed CIC with symptoms persisting for at least 3 months; **OR**
  - Have clinically diagnosed OIC and receiving opioids for chronic non-cancer pain, with symptoms persisting for at least 3 months; **OR**
  - Have clinically diagnosed IBS-C and is female, with symptoms persisting for at least 3 months; **AND**
- The member has attempted lifestyle changes, including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; **AND**
- The member must not have a known or suspected mechanical gastrointestinal obstruction or perforation; **AND**
- The member must not be taking a diphenylheptane opioid (e.g., methadone); **AND**
- The member must not be on concurrent tenapanor, linaclotide, plecanatide, or prucalopride.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider; **AND**
- The member must not be taking a diphenylheptane opioid (e.g., methadone); **AND**
- The member must not be taking concurrent tenapanor, linaclotide, plecanatide, or prucalopride.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a gastroenterologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

AMPYRA® (DALFAMPRIDINE)

Updated: August 17, 2023

Length of Authorization:	3 months (initial); 5 years (continuation)
Initiative:	PAR: Ampyra (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

To improve walking in adult patients with multiple sclerosis (MS).

FDA-RECOMMENDED DOSE

10 mg orally twice daily, approximately 12 hours apart

HOW SUPPLIED

10 mg extended-release tablets in 60-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of multiple sclerosis; **AND**
- The member is able to walk with or without an assistive device; **AND**
- The member does not have a history of seizures; **AND**
- The member does not have moderate to severe renal impairment (i.e., CrCl ≤ 50 mL/min); **AND**
- The member is not receiving another form of 4-aminopyridine (e.g., compounded 4-AP, fampridine).

For Continuation Coverage Requests:

- The member has had a positive response to therapy, as documented by the member's specialty provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 3 months.
- Continuation: 5 years.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

ARCALYST® (RILONACEPT)

Updated: July 28, 2023

Length of Authorization:	12 months
Initiative:	PAR: Arcalyst (IE 2462 / NCPDP 75 – GSN) PAR: Loading Dose (IE 15110, 2641, 7001 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 years of age and older.
- For the maintenance and remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing at least 10 kg.
- For the treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and pediatric patients 12 years of age and older.

FDA-RECOMMENDED DOSE

Table 1: recommended dose for FDA approved indications

	Loading Dose	**Maintenance Dose**
Adults (CAPS, FCAS, MWS, RP)	320 mg, administered as two 160 mg subcutaneous injections given the same day at different sites	160 mg once weekly
Pediatric patients 12-17 (CAPS, FCAS, MWS, RP)	4.4 mg/kg (max. 320 mg), administered as one or two subcutaneous injections given the same day at different sites	2.2 mg/kg (max. 160 mg) once weekly
Adults (DIRA)	N/A	320 mg once weekly, administered as two 160 mg subcutaneous injections given the same day at different sites
Pediatric patients ≥ 10 kg (DIRA)	N/A	4.4 mg/kg (max. 320 mg) once weekly, administered as one or two subcutaneous injections given the same day at different sites

HOW SUPPLIED

20 mL vials containing 220 mg of dry powder for reconstitution (80 mg/mL after reconstitution)

UTILIZATION CRITERIA

For Initial Review:

- For All Indications:
  - The member must not be taking any concurrent TNF-inhibitors or IL-1 inhibitors, *AND*
  - The member has a negative tuberculosis (TB) test prior to initiating therapy OR has received a complete treatment course for latent/underlying TB
- **For CAPS/FCAS/MWS/RP:**
  - The member must have a one of the following diagnoses:
    - Cryopyrin-Associated Periodic Syndromes (CAPS; positive for the CIAS1/NLRP-3 gene mutation)
    - Familial Cold Autoinflammatory Syndrome (FCAS)
    - Muckle-Wells Syndrome (MWS)

- Recurrent Pericarditis (RP)

- For Recurrent Pericarditis (RP):
  - The member has a confirmed diagnosis of RP; **AND**
  - The member does not have a myeloproliferative disorder; **AND**
  - The member does not have a history of malignancy of any organ system within the previous five years or has had an organ transplant; **AND**
  - The member has tried colchicine.
- For DIRA
  - The member has a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA); **AND**
  - The member must weigh at least 10 kg

For Continuation:

- The member has had a positive clinical response to therapy, as documented by the member's specialist provider.
- The member must not be taking any concurrent TNF-inhibitors or IL-1 inhibitors.

REQUIRED MEDICAL INFORMATION

For Initial Coverage Requests:

- Chart notes to confirm specific diagnosis and TB test results.
- Concurrent medications.

For Continuation Coverage Requests:

- Concurrent medications.

AGE RESTRICTIONS

- 12 years of age for RP, CAPS, FCAS, and MWS
- No age restriction for DIRA

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a CAPS, FCAS, MWS, cardiologist, or DIRA specialist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY/PARTIAL-FILL RESTRICTIONS

- For CAPS/FCAS/MWS/RP:
  - Enter second PA with a metric quantity and days' supply of #5/28 x 1 month for loading dose.
  - If an initial clinical approval is granted, enter a quantity exception override to permit 5 vials per 28 days for 1 month, then defer to the formulary limit.
  - The second approval should have a start date of 3 weeks after the start date of the initial approval to allow for proactive pharmacy refills.
- For DIRA:
  - Enter second PA with a metric quantity and days' supply of #8/28 to match clinical PA for maintenance dose.
- Use initiative PAR: Loading Dose
- Select CTI reason code: 2nd O/R for Existing PA Approved. No approval letter is sent with second PA.

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by GSN.

ARIKAYCE® (AMIKACIN)

Updated: May 10, 2023

Length of Authorization:	Six months (initial); up to three months (renewal). For renewal requests, coverage is limited to 12 months after the date of first negative sputum culture – see below.
Initiative:	PAR: Arikayce (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For use in adults who have limited or no alternative treatment options, for the treatment of Mycobacterium avium complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of six consecutive months of a multidrug background regimen therapy.

FDA-RECOMMENDED DOSE

590 mg once daily via inhalation

HOW SUPPLIED

590 mg/8.4 mL unit-dose vials; each carton contains 28-day supply (28 vials) with one Lamira Nebulizer Handset and four Lamira Aerosol Heads.

UTILIZATION CRITERIA

For Initial Coverage requests:

- The member must have a diagnosis of MAC lung disease with limited or no alternative treatment options; **AND**
- The member must have tried and failed a six-month course of a guideline-based treatment (i.e., a three-drug regimen consisting of a rifamycin, a macrolide, and ethambutol) in the preceding twelve months, unless otherwise contraindicated, as verified through pharmacy claims or medical records; **AND**
- Amikacin will be used concurrently with a three-drug regimen consisting of a rifamycin, a macrolide, and ethambutol, unless otherwise contraindicated.

For Continuation Coverage requests:

- The member has documentation of sputum culture conversion, defined as three consecutive negative monthly sputum cultures by month six; **AND**
- The member has not had a positive M. avium culture after the initial sputum culture conversion; **AND**
- The member's physician has attested to an improvement in the member's symptoms.

REQUIRED MEDICAL INFORMATION

Sputum M. avium cultures collected prior to the initiation of amikacin therapy and for each consecutive month thereafter

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an infectious disease specialist.

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Six months (initial); up to three months (renewal).
- For renewal requests, coverage is limited to 12 months after the date of first negative sputum culture (Figures 1-3).
- If sputum cultures of the preceding month are not yet available for review at the time of the continuation request, but the member has consecutive negative cultures up to the time of the review, one month of coverage may be granted until the culture results become available to prevent gaps in care.

Figure 1 (below): An example scenario of coverage for a member with MAC, with a first negative sputum culture at month four. In this scenario, the total time of coverage would extend to 15 months with 12 months of coverage after the first negative culture.

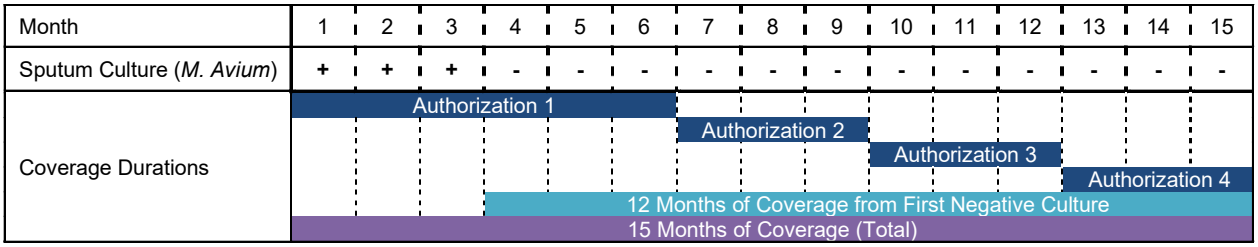

Figure 2 (below): An example scenario of coverage for a member with MAC, with a first negative sputum culture at month two. In this scenario, the total time of coverage would extend to 13 months with 12 months of coverage after the first negative culture.

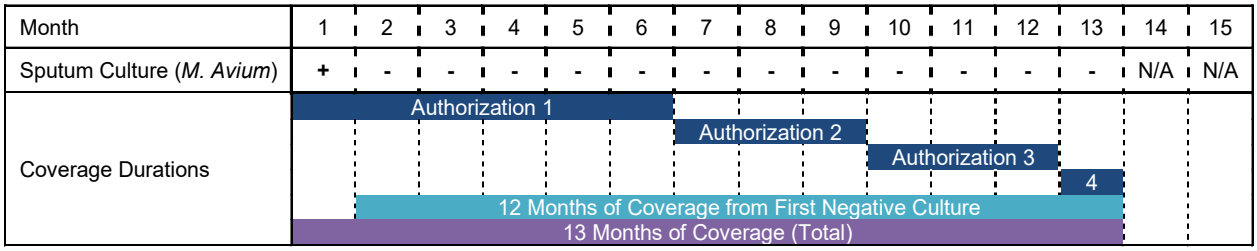

Figure 3 (below): An example scenario of coverage for a member with MAC, with a first negative sputum culture at month three, followed by a positive sputum culture at month four. Regardless of the negative sputum cultures in months five and six, the member does not meet criteria for continuation of coverage.

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Sputum Culture (*M. Avium*)	+	+	-	+	-	-	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Coverage Duration	Authorization 1														
	6 Months of Coverage (Total)														

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve all requests by GSN.

AUBAGIO® (TERIFLUNOMIDE)

Updated: September 19, 2023

Length of Authorization:	Five years
Initiative:	PAR: Aubagio (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

FDA-RECOMMENDED DOSE

7 mg or 14 mg orally once daily.

HOW SUPPLIED

7 mg and 14 mg tablets in cartons of 28 or bottles of 30

COVERAGE CRITERIA

- **For Initial Coverage Requests:**
  - The member must have a diagnosis of relapsing remitting multiple sclerosis (MS); **AND**
  - The member must have tried and failed at least ONE of the following disease-modifying agents for the treatment of their MS:
    - Avonex
    - Betaseron
    - Dimethyl fumarate
    - Fingolimod
    - Gilenya
    - Glatiramer Acetate or Glatopa
    - Mayzent
    - Plegridy
    - Kesimpta; **AND**
- The member must meet one of the following scenarios:
  - The member is not a female of childbearing potential; **OR**
  - The member must be using an effective means of pregnancy prevention as attested to by the member's provider.
- **For Continuation Coverage Requests:**
  - The member has had a positive clinical response to therapy, as documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

Five years

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

N/A

AUGTYRO (REPOTRECTINIB)

Updated: February 1, 2024

Length of Authorization:	Five years
Initiative:	PAR: Augtyro (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC).

FDA-RECOMMENDED DOSE

160 mg orally once daily.

HOW SUPPLIED

40 mg capsules in 60 and 120-count bottles.

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member must have a diagnosis NSCLC; **AND**
- The member must have locally advanced or metastatic disease; **AND**
- The member must have ROS-1 positive disease

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Documentation of tumor status (i.e., ROS-1 NSCLC)

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

Five years

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

Approve by GSN.

AUSTEDO® (DEUTETRABENAZINE)

Updated: August 16, 2023

Length of Authorization:	5 years
Initiative:	PAR: Austedo (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of chorea associated with Huntington's disease in adults.
- For the treatment of tardive dyskinesia in adults.

FDA-RECOMMENDED DOSE

Starting dose: 6 mg administered orally twice daily; the dose may be increased at weekly intervals in increments of 6 mg per day to a maximum recommended daily dosage of 48 mg.

HOW SUPPLIED

- 6 mg, 9 mg, and 12 mg immediate release tablets in 60-count bottles.
- 6 mg, 12 mg, and 24 mg extended- release tablets in 30-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member must have a diagnosis of chorea associated with Huntington's disease or tardive dyskinesia; **AND**
- The member must have tried and failed generic tetrabenazine; **AND**
- The member must not be taking concurrent VMAT2 inhibitor.

For Continuation Coverage Requests:

- Confirmation that the member continues to have a beneficial response to therapy as assessed and documented by the member's specialist provider; **AND**
- The member must not be taking concurrent VMAT2 inhibitor.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist, movement disorder specialist, or psychiatrist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

Five years.

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

Approve by HSN.

AUVIQ® (EPINEPHRINE)

Updated: October 22, 2023

Length of Authorization:	12 months
Initiative:	PAR: Auvi Q (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the emergency treatment of allergic reactions (Type I).

FDA-RECOMMENDED DOSE

- Patients greater than or equal to 30 kg (approximately 66 pounds or more): 0.3 mg.
- Patients 15 to 30 kg (33 to 66 pounds): 0.15 mg.
- Patients 7.5 to 15 kg (16.5 to 33 pounds): 0.1 mg.

HOW SUPPLIED

Cartons containing two auto-injectors with a single device trainer.

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member must be at risk for a life-threatening allergic reaction; **AND**
- The member has a body weight between 7.5 and 15 kg, measured within the previous 60 days.

For Continuation Coverage Requests:

- The member has a body weight between 7.5 and 15 kg, measured within the previous 60 days; **AND**
- The member has used at least one device from the previous fill.

REQUIRED MEDICAL INFORMATION

Member weight with date.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an allergy specialist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

- Coverage is limited to only the 0.1 mg/0.1 mL formulation.
- Approve by GSN.

AYVAKIT® (AVAPRITINIB)

Updated: April 12, 2023

Length of Authorization:	5 years
Initiative:	PAR: Ayvakit (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.
- For the treatment of adult patients with advanced systemic mastocytosis (AdvSM). AdvSM includes patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL).

FDA-RECOMMENDED DOSE

300 mg orally once daily on an empty stomach, at least 1 hour before and 2 hours after a meal. Treatment should be continued until disease progression or unacceptable toxicity.

HOW SUPPLIED

100 mg, 200 mg, and 300 mg tablets in 30 count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **For GIST:**
  - The member must have a diagnosis of unresectable or metastatic GIST; **AND**
  - The member must have documentation of a PDGFRA exon 18 mutation.
- **For AdvSM:**
  - The member must have a diagnosis of ASM, SM-AHN, or MCL; **AND**
  - The member must have platelets ≥ 50 x 10^9/L.
- **For myeloid/lymphoid neoplasm:**
  - The member must have a diagnosis of myeloid or lymphoid neoplasm; **AND**
  - Presence of a FIP1L1-PDGFRA rearrangement; **AND**
  - Presence of a PDGFRA D842V mutation.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy as assessed by their specialist provider.

REQUIRED MEDICAL INFORMATION

Chart notes or medical records supporting PDGFRA exon 18 mutation, platelet level, FIP1L1-PDGFRA rearrangement, and PDGFRA D842V mutation (as applicable).

AGE RESTRICTIONS

18 years of age and older

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

PRESCRIBER RESTRICTIONS

Prescribed by or in consultation with an oncologist or hematologist.

COVERAGE DURATION (MONTHS)

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

AZELEX® 20% CREAM (AZELAIC ACID)

Updated: July 21, 2023

Length of Authorization: 6 months (initial); 24 months (continuation)	
Initiative: PAR: Dermatological Agents (IE 2462 / NCPDP 75 – HICL, IE 2193, 2194 / NCPDP 60 – HICL)	

POLICY AND PRODUCT INFORMATION

The prescription drug plan covers azelaic acid (Azelex) 20% topical cream for patients with acne vulgaris who do not respond to treatment with preferred formulary agents.

FDA-APPROVED INDICATION(S)

For the topical treatment of mild-to-moderate acne vulgaris

FDA-RECOMMENDED DOSE

A thin layer applied to affected areas twice daily

HOW SUPPLIED

30-gram and 50-gram tubes.

UTILIZATION CRITERIA

FOR INITIAL REVIEW

- Member is diagnosed with acne vulgaris; **AND**
- Member has tried an adequate trial of benzoyl peroxide or topical retinoids (over the counter or federal legend, as attested to by prescriber); **AND**
- The member has tried an adequate trial of generic azelaic acid 15% gel.

FOR CONTINUATION

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

12 years of age and older

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 6 months.
- Continuation: 24 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

BALVERSA® (ERDAFITINIB)

Updated: May 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Balversa (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has susceptible FGFR3 or FGFR2 genetic alterations and has progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neo-adjuvant or adjuvant platinum-containing chemotherapy.

FDA-RECOMMENDED DOSE

8 mg (two 4 mg tablets) by mouth once daily, with a dose increase to 9 mg (three 3 mg tablets) by mouth once daily if, at 14 to 21 days, the serum phosphate level is < 5.5 mg/dL and there are no ocular disorders or Grade 2 or greater adverse reactions

HOW SUPPLIED

3 mg tablets in 56- and 84-count bottles, 4 mg tablets in 28- and 56-count bottles, and 5 mg tablets in 28-count bottles

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member has a documented diagnosis of metastatic urothelial carcinoma (mUC); **AND**
- The member has susceptible FGFR3 or FGFR2 genetic alterations, as documented by a positive result from an FDA approved companion diagnostic; **AND**
- The member must have received at least one line of prior therapy for their cancer diagnosis

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's oncologist.

REQUIRED MEDICAL INFORMATION

FGFR genetic alteration test results.

AGE RESTRICTIONS

18 years of age or older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY/RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

BANZEL (RUFINAMIDE)

Updated: May 8, 2023

Length of Authorization:	Initial 12 months, Continuation 5 years
Initiative:	PAR: Banzel (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome in pediatric patients 1 year of age and older and in adults.

FDA-RECOMMENDED DOSE

- Pediatric patients (1 year to less than 17 years):
  - Starting dose of 10 mg/kg/day administered in two equally divided doses.
  - Titrate by approximately 10 mg/kg/day increments every other day until a maximum daily dose of 45 mg/kg/day is reached. Do not exceed 3200 mg/day.
- Adults (17 years and older):
  - Starting dose of 400 to 800 mg per day administered in two equally divided doses.
  - Titrate by 400–800 mg every other day until a maximum daily dose of 3200 mg/day is reached.

HOW SUPPLIED

- 200 mg and 400 mg tablets in 120-count bottles.
- 40 mg/1 mL suspension in a 460 mL bottle.

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of Lennox-Gastaut syndrome; **AND**
- The requested medication will be taken in combination with an anticonvulsant agent (such as topiramate, valproic acid, lamotrigine, etc.).

For Continuation Requests:

- The member has had a positive clinical response to therapy, as documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

1 year of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by a neurologist, or other epilepsy specialist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 12 months
- Continuation: 5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

- Approve by HICL.
- Intention of quantity limits is to limit to a max daily dose of 3200 mg per label.

BEDAQUILINE FUMARATE (SIRTURO)

Updated: January 4, 2024

Length of Authorization:	6 months
Initiative:	PAR: Sirturo (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S):

- As part of combination therapy in the treatment of adult and pediatric patients (5 years of age or older and weighing at least 15 kg) with pulmonary multi-drug resistant tuberculosis (MDR-TB)
- Reserve Bedaquiline fumarate for use when an effective treatment regimen cannot otherwise be provided

FDA-RECOMMENDED DOSE:

Recommended Dosing		
Body weight or age	**Weeks 1 and 2**	**Weeks 3 to 24**
15 kg to less than 30 kg	200 mg (2 of the 100 mg tablets **or** 10 of the 20 mg tablets) orally once daily	100 mg (1 of the 100 mg tablets **or** 5 of the 20 mg tablets) orally three times per week
Greater than or equal to 30 kg (or 18 years of age and older)	400 mg (4 of the 100 mg tablets **or** 20 of the 20 mg tablets) orally once daily	200 mg (2 of the 100 mg tablets **or** 10 of the 20 mg tablets) orally three times per week

HOW SUPPLIED

20 mg tablets in 60-count bottles and 100 mg tablets in 188-count bottles.

COVERAGE CRITERIA

For all coverage requests:

- The member has a confirmed diagnosis of pulmonary multi-drug resistant tuberculosis; **AND**
- The member must be ineligible for alternate treatment MDR-TB treatment as attested to by the health department.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

5 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed in consultation with the applicable government health department.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

6 months

QUANTITY RESTRICTIONS

N/A

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approval by HSN

BENLYSTA® (BELIMUMAB)

Updated: July 27, 2023

Length of Authorization:	12 months
Initiative:	PAR: Benlysta (IE 2462 / NCPDP 75 – GSN) PAR: Loading Dose (IE 15110, 2641, 7001 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of patients aged 5 years and older with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy.
- For the treatment of patients 5 years of age and older with active lupus nephritis who are receiving standard therapy.

FDA-RECOMMENDED DOSE

- SLE: 200 mg once weekly given as a subcutaneous injection in the abdomen or thigh.
- Lupus nephritis: 400 mg once weekly for 4 doses and then 200 mg once weekly thereafter.
- **Note**: only IV admin for patients 5 years to 18 years of age. Subcutaneous injection can only be given if over the 18 years of age.

HOW SUPPLIED

- 200 mg/mL in a single-dose prefilled autoinjector or a single-dose prefilled glass syringe.
- Single dose vials are not a covered benefit.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- SLE:
  - The member must have a diagnosis of systemic lupus erythematosus (SLE); **AND**
  - The member must have a positive antinuclear antibody (ANA) test result of ≥ 1:80 or anti-dsDNA result of ≥ 30 IU/mL; **AND**
  - The member must be receiving standard of care SLE medications, including hydroxychloroquine or chloroquine, unless otherwise contraindicated.
- Lupus Nephritis:
  - The member must have a diagnosis of lupus nephritis; **AND**
  - The member must be receiving standard of care medications unless otherwise contraindicated.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed and documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- For Initial Coverage Requests:
- ANA or anti-dsDNA levels.
- Concurrent therapies.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a rheumatologist or dermatologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

- For SLE: Refer to formulary
- For Lupus Nephritis: Clinical approvals will require a one-time quantity exception override to permit a QPD of 0.3 for one month

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve by GSN.
- Single dose vials are not a covered benefit

BENZNIDAZOLE

Updated: May 8, 2023

Length of Authorization:	60 days
Initiative:	PAR: Benznidazole (IE 2462 / NCPDP 75 – HICL), (IE 2641, 15110 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of Chagas disease (Trypanosome cruzi or T. Cruzi) in patients ages 2–12 years.

FDA-RECOMMENDED DOSE

5 to 8 mg/kg orally in two divided doses (approximately every 12 hours) daily for 60 days.

HOW SUPPLIED

12.5 mg unscored tablets and 100 mg tablets scored for quartering, each in 100-count bottles.

UTILIZATION CRITERIA

For All Coverage Requests:

- The member has serologically confirmed T. Cruzi (Trypanosome cruzi, or Chagas disease); AND
- The member does not have Cockayne syndrome.

REQUIRED MEDICAL INFORMATION

- Chart notes documenting serologically confirmed T. Cruzi.
- Weight (kg)

AGE RESTRICTIONS

Covered for patients between the ages of 2 and 12 years.

PRESCRIBER RESTRICTIONS

Must be prescribed by an infectious disease specialist

REVIEWER REQUIREMENTS

Must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

60 days

QUANTITY RESTRICTIONS

Approve quantity override to the lowest dose per weight-based dosing (5-8 mg/kg daily in 2 divided doses) for 60 days.

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by HSN.

BESREMI® (ROPEGINTERFERON ALFA-2B)

Updated: May 1, 2023

Length of Authorization:	12 months
Initiative:	GSN: Besremi (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adults with polycythemia vera.

FDA-RECOMMENDED DOSE

The recommended starting dose is 100 mcg by subcutaneous injection every two weeks (50 mcg if receiving hydroxyurea). The dose should be titrated by 50 mcg every two weeks (maximum of 500 mcg) until hematological parameters are stabilized.

HOW SUPPLIED

A single-dose prefilled syringe containing 500 mcg/mL ropeginterferon alfa-2b with a 30 gauge, half inch safety needle in a 1-pen carton.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of polycythemia vera; **AND**
- The member has tried and failed:
  - Hydroxyurea; **AND**
  - Either Pegasys or Intron A

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Documentation of diagnosis and previous medication trials and outcomes.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a hematologist or oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

BIMEKIZUMAB (BIMZELX)

Updated 2/26/2024

Length of Authorization:	12 months
Initiative:	PAR: Bimzelex (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

FDA-RECOMMENDED DOSE

320 mg (given as two 160 mg injections) subcutaneously once every 4 weeks for the first 16 weeks, and then every 8 weeks thereafter. For patients weighing ≥ 120 kg, consider a dosage of 320 mg every 4 weeks after week 16.

HOW SUPPLIED

160 mg/mL autoinjector or prefilled syringe in two-count cartons.

UTILIZATION CRITERIA

For initial coverage requests:

- The member has a diagnosis of moderate-to-severe plaque psoriasis; **AND**
- The member has psoriatic lesions that involve greater than or equal to 10% of body surface area (BSA), or that affect the palms, soles, head, neck, or genital area, leading to disability/impact on quality of life; **AND**
- The member has had a previous trial of, or contraindication to, at least **one** of the following:
  - PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B)
  - Topical corticosteroids
  - Calcipotriene
  - Acitretin
  - Methotrexate
  - Cyclosporine; **AND**
- The member has had a previous trial of or contraindication to at least **three** of the following preferred agents:
  - Adalimumab
  - Cosentyx
  - Enbrel
  - Tremfya
  - Stelara; **AND**
- The member has been counseled on the risk of suicidal ideation and behavior associated with this medication in clinical trials; **AND**
- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib), or other potent immunosuppressives (e.g., azathioprine, cyclosporine).

For continuation coverage requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib), or other potent immunosuppressives (e.g. azathioprine, cyclosporine).

REQUIRED MEDICAL INFORMATION

For initial coverage requests:

- Current BSA coverage of lesions.
- Claims or medical records demonstrating use of previous therapies.

For all coverage requests:

- If request is for every 4-week dosing, documentation of patient weight.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by, or in consultation with, a dermatologist.

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY RESTRICTIONS

- Induction dosing:
  - Enter a quantity authorization allowing 320 mg once every 4 weeks for the first 16 weeks of therapy.
- Maintenance dosing:
  - Patient weight < 120 kg: refer to formulary.
  - Patient weight ≥ 120 kg: OK to enter a quantity authorization allowing 320 mg every 4 weeks **if** patient has tried and failed every 8-week dosing.

OPERATION NOTES AND OTHER INFORMATION

Approve by HSN.

BONSITY® (TERIPARATIDE), FORTEO® (TERIPARATIDE), TYMLOS® (ABALOPARATIDE)

Updated May 31, 2023

Length of Authorization:	12 months, Maximum of 728 Day Supply (2 years) per lifetime
Initiative:	PAR: Forteo & Tymlos (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- Abaloparatide (Tymlos):
  - For the treatment of postmenopausal women or men with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.
- Teriparatide (Bonsity/Forteo):
  - For the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.
  - Indicated to increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.
  - For the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

FDA-RECOMMENDED DOSE

- Teriparatide: 20 mcg subcutaneously once a day.
  - Use of teriparatide for more than 2 years during a patient's lifetime should only be considered if a patient remains at or has returned to having a high risk for fracture.
- Abaloparatide: 80 mcg subcutaneously once daily.
  - Cumulative use of abaloparatide for more than 2 years during a patient's lifetime is not recommended.

HOW SUPPLIED

- Abaloparatide (Tymlos): 3120 mcg/1.56 mL (2000 mcg/mL) in a single-patient-use prefilled pen. The prefilled pen delivers 30 doses of abaloparatide, each containing 80 mcg.
- Teriparatide (Forteo): Multi-dose prefilled delivery device (pen) for subcutaneous injection containing 28 daily doses of 20 mcg. Each pen contains 2.4 mL.
- Teriparatide (Bonsity): Multi-dose prefilled delivery device (pen) for subcutaneous injection containing 28 daily doses of 20 mcg. Each pen contains 2.48 mL.

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member must have a diagnosis of osteoporosis as evidenced by one of the following clinical scenarios:
  - Hip (femoral neck or total hip), lumbar spine, and/or forearm (one-third) radius T-score of -2.5; **OR**
  - T-score between −1.0 and −2.5 with a 10-year probability ≥ 3% for hip fracture or ≥ 20% for major osteoporotic fracture; **OR**
  - Presence of fragility fractures in the absence of other metabolic bone disorders; **AND**
- The member must not have ANY of the following:
  - Paget's disease
  - Unexplained elevations of alkaline phosphatase
  - Open epiphyses
  - Prior external beam or implant radiation therapy involving the skeleton; **AND**
- The member must be at a high risk of fracture as evidenced by one of the following:
  - History of an osteoporotic fracture
  - Parental history of hip fracture
  - Low BMI
  - Rheumatoid arthritis
  - Alcohol intake (3 or more drinks per day)
  - Current smoking
  - Exposed to ≥5 mg/day of prednisolone for ≥3 months (or equivalent doses of other glucocorticoids); **AND**
- The member must meet one of the following:
  - The member is a postmenopausal female with osteoporosis; **OR**
  - The member is a male with osteoporosis; **OR**
  - The member has osteoporosis associated with sustained glucocorticoid therapy (**teriparatide** requests only); **AND**
- If brand Forteo 600 mcg/2.4 mL pens (GSN: 064481) are being requested, the member must have tried and failed the teriparatide 620 mcg/2.48 mL pens first (GSN: 080271).

For Continuation Coverage Requests:

- The member has had a positive clinical response to therapy, as documented by the member's provider; **AND**
- One of the following:
  - Teriparatide or abaloparatide: The member has not exceeded a cumulative DS of 728 per claim records; **OR**
  - Teriparatide only: The prescriber attests that the patient remains at or has returned to having a high risk for fracture despite 24 months of cumulative use of parathyroid hormone analogs.

REQUIRED MEDICAL INFORMATION

For initial requests, baseline t-score as applicable.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

- Refer to formulary.
- Maximum authorization of 728 DS per lifetime. Reviewer must check claim history prior to issuing authorization. Renewal authorizations should be limited appropriately based on cumulative DS received thus far, as to not allow more than 728 DS total per member, unless criteria is met for coverage of teriparatide beyond 24 months as noted above.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

BOSULIF® (BOSUTINIB)

Updated: February 26, 2024

Length of Authorization:	Five years
Initiative:	PAR: Bosulif (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of adults and pediatric patients 1 year of age and older with newly diagnosed chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML).
- For the treatment of adults with CP, accelerated phase (AP), or blast phase (BP) Ph+ CML with resistance or intolerance to prior therapy.

FDA-RECOMMENDED DOSE

- Adults: 400 mg (newly diagnosed) or 500 mg (treatment experienced) orally once daily.
- Pediatrics: 300 mg/m^2 (newly diagnosed) or 400 mg/m^2 (treatment experienced) orally once daily.

HOW SUPPLIED

- Tablets: 100 mg, 400 mg, and 500 mg
- Capsules: 50 mg, 100 mg

UTILIZATION CRITERIA

For initial coverage requests:

- For CML:
  - The member must have a diagnosis of chronic myelogenous leukemia.
  - The member must be either Philadelphia chromosome-positive or BCR-ABL1 positive.
  - The member does not have any of the following BCR-ABL1 mutations: T315I, V299L, G250E, or F317.
- For all:
  - The member must have a diagnosis of relapsed or refractory Ph+ all.
  - The member does not have any of the following BCR-ABL1 mutations: T315I, V299L, G250E, or F317.
- For myeloid/lymphoid neoplasms with eosinophilia:
  - The member must have a diagnosis of a myeloid/lymphoid neoplasms with eosinophilia; **AND**
  - The member's tumor must have an ABL1 rearrangement.

For continuation coverage requests:

- The member must continue to receive benefit as attested to by their specialist provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

1 year of age and older

REVIEWER REQUIREMENTS

N/A

PRESCRIBER RESTRICTIONS

Prescribed by an oncologist or hematologist

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OTHER INFORMATION

Approve by HICL.

BRAFTOVI® (ENCORAFENIB)

Updated: April 12, 2023

Length of Authorization: 5 years
Initiative: PAR: Braftovi & Mektovi (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For use in combination with binimetinib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation.
- For use in combination with cetuximab, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation.

FDA-RECOMMENDED STARTING DOSE

- Metastatic Melanoma: 450 mg orally once daily in combination with binimetinib.
- Colorectal Cancer: 300 mg orally once daily in combination with cetuximab.

HOW SUPPLIED

75 mg capsules available in cartons containing two 90-count bottles or two 60-count bottles.

COVERAGE CRITERIA

For Initial Coverage Requests:

- **For melanoma:**
  - The member has a confirmed diagnosis of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation; **AND**
  - The member has not previously been treated with a BRAF or MEK inhibitor (e.g., dabrafenib, trametinib, vemurafenib, cobimetinib).
- **For colorectal cancer:**
  - The member must have a diagnosis of V600E mutation positive metastatic colorectal cancer (CRC); **AND**
  - The member must be requesting encorafenib for use concomitantly with cetuximab or panitumumab.

For Continuation Coverage Requests:

- The member has had a positive response to therapy, as attested to by the member's oncology provider.

REQUIRED MEDICAL INFORMATION

BRAF V600E or V600K mutation status

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY/PARTIAL FILL RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

BREXAFEMME® (IBREXAFUNGERP)

Updated: February 13, 2024

Length of Authorization: 3 months for VVC. 6 months for RVVC.
Initiative: PAR: BREXAFEMME (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of vulvovaginal candidiasis (VVC) or reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC) in adult and postmenarchal pediatric females

FDA-RECOMMENDED DOSE

- **VVC**: One regimen consists of four 150 mg tablets administered as two 300 mg doses spaced 12 hours apart.
- **RVVC**: 300 mg (two 150 mg tablets) every 12 hours for one day for a total daily dosage of 600 mg (four 150 mg tablets) monthly for 6 months.

HOW SUPPLIED

150 mg tablets in 4-count blister packs.

COVERAGE CRITERIA

- **All Coverage Requests:**
  - For **VVC**:
    - The member has a confirmed diagnosis of VVC; **AND**
    - The member meets one of the following scenarios:
    - The member's VVC is confirmed to be resistant to azole-antifungals (e.g., fluconazole, terconazole); **OR**
    - The member has a documented allergy to azole-antifungals; **OR**
    - The member has tried and failed, or has contraindications to, **both** of the following:
      - Fluconazole
      - Terconazole
- For **RVVC**:
  - The member has a confirmed diagnosis of RVVC with three or more acute VVC episodes within the previous 12 months, **AND**
  - The member meets one of the following scenarios:
    - The member's VVC is confirmed to be resistant to fluconazole; **OR**
    - The member has tried and failed, or has contraindications to, a complete 6-month course of fluconazole for the prevention and treatment of RVVC.

REQUIRED MEDICAL INFORMATION

Documentation of antifungal culture sensitivities, if applicable.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

Must be reviewed by a licensed pharmacist or physician.

QUANTITY RESTRICTIONS

- **VVC**: Coverage is limited to 4 tablets per authorization (see formulary QL)
- **RVVC**: Authorize a total of 24 tablets per authorization

COVERAGE DURATION

- **VVC**: 3 months
- **RVVC**: 6 months

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

Approve by GSN.

BRONCHITOL® (MANNITOL)

Updated: November 3, 2023

Length of Authorization: 12 months
Initiative: PAR: Bronchitol (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the add-on maintenance therapy to improve pulmonary function in adult patients 18 years of age and older with cystic fibrosis.

FDA-RECOMMENDED DOSE

400 mg (ten 40 mg capsules) twice daily via inhaler.

HOW SUPPLIED

40 mg capsules for inhalation in 10, 140, or 560 count blister packs.

UTILIZATION CRITERIA

For Initial Coverage:

- The member has a diagnosis of cystic fibrosis; **AND**
- The member has passed the Bronchitol Tolerance Test; **AND**
- The member is not concurrently using hypertonic saline therapy; **AND**
- The member has tried and failed a combination of hypertonic saline and dornase alfa.

For Continuation of Coverage:

- The member has had a positive clinical response to therapy, as documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a pulmonologist or cystic fibrosis specialist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

BRUKINSA® (ZANUBRUTINIB)

Updated: May 4, 2023

Length of Authorization: 5 years
Initiative: PAR: Brukinsa (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.
- For the treatment of adult patients with Waldenström's macroglobulinemia (WM).
- For the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.
- For the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

FDA-RECOMMENDED DOSE

160 mg taken orally twice daily, or 320 mg taken orally once daily until disease progression or unacceptable toxicity.

HOW SUPPLIED

80 mg capsules (120 count bottles)

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **For MCL:**
  - The member has a diagnosis of Mantle Cell Lymphoma (MCL); **AND**
  - The member has tried and failed at least one prior therapy for this diagnosis.
- **For WM:**
  - The member has a diagnosis of Waldenström's macroglobulinemia (WM).
- **For MZL:**
  - The member has a diagnosis of Marginal Zone Lymphoma (MZL); **AND**
  - The member has tried and failed at least one anti-CD20-based regimen.
- **For CLL/SLL**
  - The member has a diagnosis of Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Leukemia (SLL)

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies, as applicable.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years.

QUANTITY RESTRICTIONS

Refer to formulary

OTHER INFORMATION

Approve by GSN.

BUDESONIDE ER 9 MG TABLET (UCERIS®)

Updated: August 2, 2023

Length of Authorization:	12 months
Initiative:	PAR: Uceris ER (IE 2462/NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the induction of remission in patients with active, mild to moderate ulcerative colitis.

FDA-RECOMMENDED DOSE

9 mg taken orally once daily in the morning for up to 8 weeks.

HOW SUPPLIED

9 mg tablets in 30-count bottles.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

The member has a diagnosis of distal inflammatory bowel disease (IBD).

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a gastroenterologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN..

BYLVAY™ (ODEVIXIBAT)

Updated: July 25, 2023

Length of Authorization:
Initiative: Par: Bylvay (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of pruritis in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC).
- For the treatment of cholestatic pruritus in patients 12 months of age and older with Alagille Syndrome (ALGS).

FDA-RECOMMENDED DOSE

- PFIC:40 mcg/kg once daily in the morning with a meal. If there is no improvement in pruritis after 3 months, the dose may be increased in 40 mcg/kg increments up to 120 mcg/kg. The max total daily dose is 6 mg.
- ALGS: 120 mcg/kg once daily in the morning with a meal.

HOW SUPPLIED

- 200 mcg and 600 mcg oral pellets in bottles of 30
- 400 mcg and 1200 mcg oral capsules in bottles of 30

COVERAGE CRITERIA

For Initial Coverage Requests:

For PFIC requests:

- The member has a confirmed diagnosis of PFIC; **AND**
- The member must not have PFIC type 2 with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3).

For ALGS requests:

- The member has a genetically confirmed diagnosis of Alagille syndrome.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- Weight (kg), measured within the previous 60 days.
- PFIC status with confirmation of genetic testing ruling out ABCB11 variants.

AGE RESTRICTIONS

3 months of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an ALGS or PFIC specialist.

REVIEWER REQUIREMENTS

Must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY RESTRICTIONS

Coverage is limited to the member's current weight; a quantity override will need to be entered for the length of the clinical PA as follows:

- 7.4 kg and below: 600 mcg/day
- 7.5 to 12.4 kg: 1200 mcg/day
- 12.5 to 17.4 kg: 1800 mcg/day
- 17.5 to 25.4 kg: 2400 mcg/day
- 25.5 to 35.4 kg: 3600 mcg/day
- 35.5 to 45.4 kg: 4800mcg/day
- 45.5 to 55.4 kg: 6000 mcg/day
- 55.5 kg and above: 7200 mcg/day

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN (approve the appropriate GSN correlated to the requested dosing).

CABLIVI® (CAPLACIZUMAB-YHDP)

Updated: May 10, 2023

Length of Authorization:	Initial approval: 30 days minus the number of days dosed in the hospital after the most recent plasma exchange completion Continuation: 28 days maximum
Initiative:	PAR: Cablivi (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with [therapeutic] plasma exchange [TPE] and immunosuppressive therapy.

FDA-RECOMMENDED STARTING DOSE

- Day 1 (Beginning of TPE Period): 11 mg IV bolus at least 15 minutes prior to TPE followed by 11 mg SQ after completion of TPE on day 1
- Day 2 until end of daily TPE Period: 11 mg SQ once daily following TPE
- After TPE Period: 11 mg SQ once daily, continuing for 30 days following the last daily TPE (treatment extension of additional 28 days possible depending on individual response)

HOW SUPPLIED

11 mg unit dose vial in a carton containing one sterile water filled syringe, one sterile vial adapter, one sterile hypodermic needle, and two alcohol swabs

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member has a documented diagnosis of aTTP; **AND**
- The member must have completed one round of TPE with evidence of recovered platelets within the prior 7 days; **AND**
- The member must have documentation of provider intent to continue concomitant immunosuppressive therapy

For Continuation Coverage Requests:

- The member must have experienced a drop in platelets below 150,000/microliter while on caplacizumab (indicative of relapse); **AND**
- The member must have recent ADAMTS13 activity levels less than 10%

REQUIRED MEDICAL INFORMATION

- Date of last plasma exchange
- Number of caplacizumab doses received since last plasma exchange
- For Continuation Requests: Current ADAMTS13 level (no more than 7 days old)

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a hematologist or oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

- Initial approval: 30 days minus the number of days dosed in the hospital after the most recent plasma exchange completion.
- Continuation: 28 days maximum

QUANTITY RESTRICTIONS

Refer to formulary

CABOMETYX® (CABOZANTINIB)

Updated: April 26, 2023

Length of Authorization:	5 years
Initiative:	PAR: Cabometyx (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of patients with advanced renal cell carcinoma (RCC).
- For the treatment of patients with advanced RCC, as a first-line treatment in combination with nivolumab.
- For the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.
- For the treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible.

FDA-RECOMMENDED DOSE

- RCC: 60 mg once daily; 40 mg once daily when in combination with nivolumab.
- HCC: 60 mg once daily.
- DTC: 60 mg once daily if BSA ≥ 1.2 m^2; 40 mg once daily if BSA < 1.2 m^2.

HOW SUPPLIED

20, 40, and 60 mg tablets in bottles of 30-count bottles.

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

For RCC

- The member has a diagnosis of renal cell carcinoma (RCC).

For NSCLC:

- The member has a diagnosis of non-small cell lung cancer (NSCLC) with RET gene rearrangement.

For HCC:

- The member has a diagnosis of hepatocellular carcinoma (HCC); **AND**
- The member has been previously treated with sorafenib.

For DTC:

- The member has a diagnosis of locally advanced or metastatic differentiated thyroid cancer (DTC); **AND**
- The member's cancer has progressed following VEGFR-targeted therapy; **AND**
- The member is radioactive iodine-refractory or ineligible.

For Endometrial Carcinoma:

- The member has a diagnosis of endometrial carcinoma; **AND**
- The member's cancer is recurrent, metastatic, or classified as high risk; **AND**
- The member has had at least one previous line of therapy for their condition.

For Gastrointestinal Stromal Tumors (GIST):

- The member has a diagnosis of GIST; **AND**
- The member has unresectable, recurrent, or metastatic disease; **AND**
- The member has tried and failed, or is contraindicated to, both imatinib and sunitinib.

For Bone Cancer:

- The member has a diagnosis of either osteosarcoma or Ewing sarcoma; **AND**
- The member has had at least one previous line of therapy for their condition.

For Kidney Cancer:

- The member has a diagnosis of relapsed or stage IV kidney cancer.

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

For NSCLC: RET gene rearrangement results.

AGE RESTRICTIONS

- DTC: 12 years of age and older
- All others: N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

CALQUENCE® (ACALABRUTINIB)

Updated: May 1, 2023

Length of Authorization: 5 years
Initiative: PAR: Calquence (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.
- For the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

FDA-RECOMMENDED DOSE

Dosed 100 mg orally every twelve hours.

HOW SUPPLIED

100 mg tablets in 60-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **Lymphoplasmacytic Lymphoma:**
  - The member plans on using this medication as a single agent alternative therapy; **AND**
  - The member failed primary therapy due to persistent symptoms, disease progression, or relapse)
- **CLL or SLL:**
  - The member has a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL); **AND**
  - The member is not ibrutinib refractory with a BTK C481S mutation
- **B-Cell Lymphoma:**
  - The member has been diagnosed with Marginal Zone Lymphoma of the Stomach, Marginal Zone Lymphoma of Non-gastric Sites (non-cutaneous), Nodal Marginal Zone Lymphoma, Splenic Marginal Zone Lymphoma, or Mantle Cell Lymphoma; **AND**
  - The member will use the agent as a second-line or subsequent therapy**; AND**
  - The member plans on using this medication as a single agent and is not ibrutinib-refractory with BTK C481S mutations (only for mantel cell lymphoma)

For Continuation Coverage Requests:

- The member must have confirmed response to treatment, as documented by the member's prescribing specialist.

REQUIRED MEDICAL INFORMATION

Documentation of BTK C481S mutation status

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

- Approve by HICL.
- Please contact the plan if there are any clinical questions regarding place in therapy or approvable indications.

CAMBIA® (DICLOFENAC POTASSIUM)

Updated: July 31, 2023

Length of Authorization:	12 months
Initiative:	PAR: Cambia (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the acute treatment of migraine attacks with or without aura in adults (18 years of age or older).

FDA-RECOMMENDED DOSE

One packet (50 mg) for the acute treatment of migraine.

HOW SUPPLIED

50 mg oral powder packet as a single packet or 9-count carton.

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has diagnosis of migraine; **AND**
- The member has tried and failed two or more generic triptan products unless otherwise contraindicated to the class. *

*Class contraindications may include a history of coronary artery disease, stroke, TIA, peripheral vascular disease, ischemic bowel disease, cardiac arrhythmias, and uncontrolled blood pressure.

FOR CONTINUATION COVERAGE REQUESTS

The member has had a beneficial response to therapy as attested to by the prescribing provider

REQUIRED MEDICAL INFORMATION

- Claims or medical records demonstrating use of previous therapies.
- Chart notes or medical records demonstrating reason for contraindication, as applicable.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to quantity limits on the formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN

CAMZYOS® (MAVACAMTEN)

Updated: November 2, 2023

Length of Authorization:	• Initial: 6 months • Continuation: 12 months
Initiative:	PAR: Camzyos (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.

FDA-RECOMMENDED DOSE

The recommended starting dose is 5 mg once daily. Allowable subsequent doses with titration are 2.5, 5, 10, or 15 mg once daily.

HOW SUPPLIED

2.5 mg, 5 mg, 10 mg, and 15 mg capsules in 30-count bottles.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS:

- The member has a diagnosis of symptomatic obstructive HCM established by **all** of the following:
  - Unexplained left ventricular hypertrophy with maximal left ventricular wall thickness of ≥ 15 mm (or ≥ 13 mm if familial hypertrophic cardiomyopathy)
  - Peak left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg
  - NYHA class II–III symptoms; **AND**
- The member has a left ventricular ejection fraction (LVEF) ≥ 55%; **AND**
- The member will be monitored with regular echocardiograms; **AND**
- The member is not taking a moderate/strong CYP2C19 inhibitor/inducer, strong CYP3A4 inhibitor, or moderate/strong CYP3A4 inducer; **AND**
- The member has tried and failed, or has a contraindication to **all** of the following:
  - A beta-blocker
  - A calcium-channel blocker
  - Disopyramide; **AND**
- The member has been evaluated for eligibility for septal ablation or septal myectomy.

FOR CONTINUATION COVERAGE REQUESTS:

- The member has experienced improvement in symptoms, peak oxygen consumption (pVO2), or peak LVOT gradient; **AND**
- The member has a left ventricular ejection fraction (LVEF) ≥55%; **AND**
- The member has been and will continue to be monitored with regular echocardiograms; **AND**
- The member is not taking a moderate/strong CYP2C19 inhibitor/inducer, strong CYP3A4 inhibitor, or moderate/strong CYP3A4 inducer.

REQUIRED MEDICAL INFORMATION

- Initial: Medical Records or chart notes documenting maximal left ventricular wall thickness, LVOT, NYHA class, LVEF, and previous medication trials with outcomes.
- Continuation: Medical Records or chart notes documenting LVEF.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a cardiologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 6 months
- Continuation: 12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by HSN.

CAYSTON® (AZTREONAM)

Updated: November 3, 2023

Length of Authorization: 12 months
Initiative: PAR: Cayston (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

To improve respiratory symptoms in cystic fibrosis (CF) patients with Pseudomonas aeruginosa. Safety and effectiveness have not been established in pediatric patients below the age of 7 years, patients with FEV1 < 25% or > 75% predicted, or patients colonized with Burkholderia cepacia.

FDA-RECOMMENDED DOSE

One single-use vial (75 mg of aztreonam) reconstituted with 1 mL of sterile diluent, administered 3 times a day via Altera® Nebulizer System for a 28-day course, followed by 28 days off.

HOW SUPPLIED

28-day kit of 84 sterile vials and 88 ampules of sterile diluent.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of CF with confirmed Pseudomonas aeruginosa infection; **AND**
- The member has documentation of FEV1 between 25% and 75% of predicted volume; **AND**
- The member is not colonized with Burkholderia cepacia per provider attestation; **AND**
- The member is not currently receiving inhaled tobramycin products.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy as attested to by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

For Initial Review:

- Concurrent medications; **AND**
- Documentation of Pseudomonas aeruginosa infection; **AND**
- Current FEV1.

AGE RESTRICTIONS

7 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a pulmonologist or Cystic Fibrosis specialist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

CERDELGA® (ELIGLUSTATE TARTRATE)

Updated: May 10, 2023

Length of Authorization:	Five years
Initiative:	PAR: Cerdelga (IE 2462 / NCPDP 75 – GSN), (IE 2641 / NCPDP 76 – GSN), (IE 15110 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

For the long-term treatment of adult patients with Gaucher disease type 1 (GD1) who are CYP2D6 extensive metabolizers (Ems), intermediate metabolizers (Ims), or poor metabolizers (PMs) as detected by an FDA-cleared test.

FDA-RECOMMENDED DOSE

- Two tablets per day for CYP2D6 Ems and Ims.
- One tablet per day for CYP PMs.

HOW SUPPLIED

84 mg capsules in 14-count and 56-count cartons.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member must have a diagnosis of Gaucher disease type 1 (GD1); **AND**
- The member must be CYP2D6 EM, IM, or PM, as detected by an FDA-cleared test.

For Continuation Coverage Requests:

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

CYP2D6 status results.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

Five years

QUANTITY RESTRICTIONS

- Formulary quantity restriction can be overridden to allow an MDD 2 for the duration of the clinical approval if the member is a CYP2D6 Ems and Ims.
- Defer to formulary restriction for CYP PMs.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

CERITINIB (ZYKADIA)

Updated: February 1, 2024

Length of Authorization: 5 years
Initiative: PAR: Zykadia (IE 2462/NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test

FDA-RECOMMENDED DOSE

450 mg orally once daily.

HOW SUPPLIED

150 mg capsules in 70-count and 84-count bottles.

UTILIZATION CRITERIA

For initial coverage requests:

- NSCLC requests:
  - The member has a diagnosis of NSCLC; **AND**
  - The member has one of the following as evidenced by testing results:
    - ALK rearrangement-positive disease.
    - ROS1 rearrangement-positive disease.
- Histiocytic Neoplasm requests:
  - The member has a diagnosis of Erdheim-Chester Disease; **AND**
  - The member has ALK rearrangement-positive disease as evidenced by testing results.
- Soft Tissue Sarcoma/Uterine Sarcoma requests:
  - The member has a diagnosis of an inflammatory myofibroblastic tumor (IMT); **AND**
  - The member has ALK rearrangement-positive disease as evidenced by testing results.
- T-Cell Lymphoma requests:
  - The member has relapsed/refractory anaplastic large cell lymphoma; **AND**
  - The member has ALK rearrangement-positive disease as evidenced by testing results

For continuation coverage requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Testing confirming applicable rearrangement/mutation status.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist.

REVIEWER REQUIREMENTS

Must be reviewed by a pharmacist or physician.

COVERAGE DURATION

5 years.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

CGRP INHIBITORS: AIMOVIG® (ERENUMAB), AJOVY® (FREMANEZUMAB), EMGALITY® (GALCANEZUMAB), NURTEC ODT® (RIMEGEPANT), UBRELVY® (UBROGEPANT), QULIPTA® (ATOGEPANT), ZAVEGEPANT (ZAVZPRET)

Updated: January 1, 2024

Length of Authorization:	See below
Initiative:	PAR: CGRP Inhibitors (IE 2462/NCPDP 75 – HICL) PAR: Emgality (IE 2462/NCPDP 75 – GSN) PAR: Ubrelvy (IE 2462/NCPDP 75 – HICL) PAR: Nurtec ODT (IE 2462/NCPDP 75 – GSN) PAR: Nurtec ODT Prevention Quantity (IE 2462/NCPDP 75 – GSN), (IE 15110 /NCPDP 76 – GSN), (IE 7001/NCPDP 76 – GSN), (IE 2641/NCPDP 75 – GSN) PAR: Loading Dose (IE 15110, 2641, 7001/NCPDP 76 – GSN)

POLICY AND PRODUCT INFORMATION

- Products in this class are indicated for one or more of the following:
  - Preventive treatment of migraines in adults
  - Treatment of episodic cluster headaches in adults (galcanezumab only)
  - Treatment of acute migraine with or without aura in adults (Rimegepant, ubrogepant, and zavegepant only)
- For migraine prevention: coverage for a calcitonin gene-related peptide (CGRP) inhibitor requires an on-label clinical diagnosis and therapeutic trial and failure of at least two (2) Level A or Level B prophylactic migraine agents.
- For acute treatment of migraine: coverage for a CGRP inhibitor requires an on-label clinical diagnosis, therapeutic trial, and failure of at least two generic triptan products, unless otherwise contraindicated.

HOW SUPPLIED

- Erenumab (Aimovig®): 70 mg/mL and 140 mg/mL single-dose prefilled syringe or pen
- Fremanezumab (Ajovy®): 225 mg/1.5 mL single-dose prefilled syringe
- Galcanezumab (Emgality®): 100 mg/mL single-dose prefilled syringe, 120 mg/mL single-dose prefilled syringe or pen
- Rimegepant (Nurtec ODT®): 75 mg orally disintegrating tablets in 8-count blister packs.
- Ubrogepant (Ubrelvy®): 50 mg and 100 mg tablets in 6, 8, 10, 12, and 30-count packets.
- Atogepant (Qulipta): 10 mg, 30 mg, and 60 mg tablets in 30-count bottles.
- Zavegepant (Zavzpret): 10 mg single use nasal sprays in 6-count package.

FDA-APPROVED INDICATION(S) AND RECOMMENDED DOSING

Drug	Migraine Prevention	Acute Migraine	Episodic Cluster Headache
Atogepant (Qulipta)	10 mg, 30 mg, or 60 mg taken orally once daily.	N/A	N/A
Erenumab (Aimovig)	70 mg or 140 mg injected subcutaneously once monthly	N/A	N/A
Fremanezumab (Ajovy) **Request for 675 mg every 3 months should not be approved. Only 225 mg monthly dosing allowed.**	225 mg injected subcutaneously once monthly or 675 mg injected once every 3 months, administered as three consecutive subcutaneous injections of 225 mg each	N/A	N/A
Galcanezumab (Emgality)	240 mg loading dose in the first month (administered as two consecutive subcutaneous injections of 120 mg each), followed by 120 mg injected once monthly thereafter	N/A	300 mg (administered as three consecutive subcutaneous injections of 100 mg each) at the onset of the cluster period, and then monthly until the end of the cluster period
Rimegepant (Nurtec ODT)	75 mg taken orally every other day.	75 mg as needed for acute episodes. Not to be used for more than 18 migraines per month.	N/A
Ubrogepant (Ubrelvy)	N/A	50 mg to 100 mg orally once daily, as needed. A second dose may be taken at least 2 hours after the initial dose, for a maximum daily dose of 200 mg. Not to be used for more than 8 migraines per month.	N/A
Zavegepant (Zavzpret)	n/a	10mg given as a single spray in one nostril, maximum of one per day. Not to be used for more than 8 migraines per month	

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS:

For the preventive treatment of migraines:

- The requested product is one of erenumab (Aimovig®), fremanezumab (Ajovy®), or galcanezumab (Emgality®) 120 mg; **AND**
  - The member has a diagnosis of episodic or chronic migraines; **AND**
  - The member will not be using the requested agent concomitantly with other CGRP inhibitors for prophylaxis; **AND**
  - The member has tried and failed two or more level A or level B prophylactic migraine treatments listed in "Table 1" below, unless otherwise contraindicated; **OR**
- The requested product is rimegepant (Nurtec® ODT) or atogepant (Qulipta); **AND**
  - The member has a diagnosis of episodic or chronic migraines; **AND**
  - The member will not be using the requested agent concomitantly with other CGRP inhibitors for prophylaxis; **AND**
  - The member has tried and failed two or more level A or level B prophylactic migraine treatments listed in "Table 1" below, unless otherwise contraindicated.

Table 1: level A or level B prophylactic migraine treatments	
Level A	**Level B**
• Valproic Acid/Divalproex Sodium • Topiramate • Propranolol • Timolol • Metoprolol • OnabotulinumtoxinA (Botox)	• Amitriptyline • Venlafaxine • Nadolol • Atenolol

For the treatment of episodic cluster headaches:

- The requested product is galcanezumab (Emgality®) 300 mg; **AND**
  - The member has a diagnosis of episodic cluster headaches; **AND**
  - The member has tried and failed one, or is contraindicated to all, of the following for prophylaxis of episodic cluster headache:
    - Verapamil
    - Lithium
    - Topiramate
- **Triptan: class contraindications may include a history of coronary artery disease, stroke, TIA, peripheral vascular disease, ischemic bowel disease, cardiac arrhythmias, and uncontrolled blood pressure.*

For the acute treatment of migraines:

- The requested product is rimegepant (Nurtec® ODT) or ubrogepant (Ubrelvy®), or zavegepant (Zayzpret); **AND**
  - The member has a diagnosis of migraine; **AND**
  - The member has tried and failed two or more generic triptan products, unless otherwise contraindicated to the class*; **AND**
  - For zavegepant (Zavzpret), the member has tried and failed or has a contraindication to all of the following:
    - rimegepant (Nurtec ODT)
    - ubrogepant (Ubrelvy)
    - lasmiditan (Reyvow)
- *Triptan: class contraindications may include a history of coronary artery disease, stroke, TIA, peripheral vascular disease, ischemic bowel disease, cardiac arrhythmias, and uncontrolled blood pressure.

FOR CONTINUATION OF COVERAGE REQUESTS:

For the preventive treatment of migraines:

- The member meets one of the following clinical scenarios attributable solely to the introduction of the CGRP inhibitor:
  - The member had a reduction of two or more migraine days per month when compared to baseline migraine days as attested to by the prescribing provider; **OR**
  - The member has had clinical improvement in migraine severity, as attested to by the prescribing provider

For the treatment of episodic cluster headaches:

- The member meets one of the following clinical scenarios attributable solely to the introduction of the CGRP inhibitor:
  - The member has had a reduction in frequency of five or more cluster headache attacks per week when compared to baseline headache attacks per week as attested to by the prescribing provider; **OR**
  - The member has had clinical improvement in headache severity, as attested to by the prescribing provider

For the acute treatment of migraines:

- The member has had a beneficial response to therapy as attested to by the prescribing provider

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

- For preventive treatment of migraines or episodic cluster headache (Aimovig® [erenumab], Ajovy® [fremanezumab], Emgality® [galcanezumab], Nurtec ODT® [rimegepant], Atogepant (Qulipta):
  - Initial: 3 months.
  - Continuation: 12 months.
- For treatment of acute migraine (Nurtec ODT® [rimegepant], Ubrelvy® [ubrogepant], Zayzpret [zavegepant]):
  - 12 months.

QUANTITY RESTRICTIONS

Drug Name	Initial Coverage Authorization	Continuation Coverage Authorization
Erenumab (Aimovig)	Refer to formulary.	Refer to formulary.
Fremanezumab (Ajovy)	Refer to formulary. **Plan does not allow Ajovy dosed 675 mg every 3 months.**	Refer to formulary.
Galcanezumab (Emgality)	• **For migraine prevention:** – **First**: Approve 120 mg pens or syringes for 1 month (fill count =1) by GSN, allowing for 240 mg per 30 days. – **Second**: Approve 120 mg pens or syringes for 2 months by GSN • **For episodic cluster headache:** – Approve a quantity exception by GSN allowing 3 syringes per 30 days	• **For migraine prevention:** Refer to formulary. • **For episodic cluster headache:** Approve a quantity exception by GSN allowing 3 syringes per 30 days.
Rimegepant (Nurtec ODT)	• **For migraine prevention:** – Approve by GSN, allowing for 16 tablets per 30 days. • **For acute migraine:** – Refer to formulary.	• **For migraine prevention:** – Approve by GSN, allowing for 16 tablets per 30 days. • **For acute migraine:** – Refer to formulary.
Atogepant (Qulipta)	Refer to formulary.	Refer to formulary.
Ubrogepant (Ubrelvy)	Refer to formulary.	Refer to formulary.
Zavegepant (Zavzpret)	Refer to formulary.	Refer to formulary.

INTERNAL NOTES:

- Aimovig®, Ajovy®, Nurtec ODT® for acute migraine, and Ubrelvy®: Refer to formulary. May not override formulary limits under any condition. Please reach out to account management with questions.
- Nurtec ODT® for migraine prevention: allow up to 16 tablets per 32 days.
- Nurtec ODT for acute treatment of migraine: allow up to 8 tablets per 32 days.
- Loading dose for Emgality® 120 mg/mL:
  - For migraine prevention: Enter second PA with a metric quantity and days' supply of #2/30 x 1 month for loading dose.
  - Use initiative PAR: Loading Dose
  - Select CTI reason code: 2nd O/R for Existing PA Approved. No approval letter is sent with second PA.

OPERATIONAL NOTES AND OTHER INFORMATION

- Concomitant use of CGRP prophylactic agents is not allowed (only one approval can be active at a time). Once approval for the current requested agent is finalized, term the previous agent's approval.
- Approve clinical authorization by HSN.
- Approve quantity exceptions by GSN as described above.
- Emgality 100 mg syringe quantity exceptions are not approvable for a migraine indication (only for cluster headaches).
- **Internal note**: Medication trials listed in a letter of medical necessity signed by the provider are acceptable.

CHANTIX® (VARENICLINE)

Updated: July 27, 2023

Length of Authorization: 3 months
Initiative: PAR: Chantix (IE 2462 / NCPDP 75 – HICL), (IE 7001 / NCPDP 76 – HICL)

FDA-APPROVED INDICATION(S)

For use as an aid to smoking cessation treatment.

FDA-RECOMMENDED DOSE

- 1 mg twice daily following a 1-week titration as follows:
  - Days 1 – 3: 0.5 mg once daily
  - Days 4 – 7: 0.5 mg twice daily
  - Day 8 – end of treatment: 1 mg twice daily

HOW SUPPLIED

- Packs:
  - Starting 4-week card: 0.5 mg × 11 tablets and 1 mg × 42 tablets
  - Continuing 4-week card: 1 mg × 56 tablets
  - Starting month box: 0.5 mg × 11 tablets and 1 mg × 42 tablets
  - Continuing month box: 1 mg × 56 tablets
- Bottles of 0.5 mg or 1 mg (56 tablets)

UTILIZATION CRITERIA

For all Coverage Requests:

- The member has successfully quit smoking as confirmed by either a urine cotinine or carbon monoxide diagnostic test; **AND**
- The member has not received 24 weeks of treatment of varenicline in the past 12 months.

REQUIRED MEDICAL INFORMATION

Lab results confirming smoking cessation.

AGE RESTRICTIONS

16 years of age and older.

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

N/A

COVERAGE DURATION

3 months.

QUANTITY RESTRICTIONS

Refer to formulary; approval is limited to a total of 168 additional tablets.

OPERATIONAL NOTES/OTHER INFORMATION

- PA only required for members who require longer than 12 weeks of initial therapy.
- PA is only approvable once per member per 12-month period.

CHOLBAM® (CHOLIC ACID)

Updated: July 27, 2023

Length of Authorization:	Three months
Initiative:	PAR: Cholbam (IE 2462 / NCPDP 75 – GSN), (IE 2641 / NCPDP 76 – GSN), (IE 15110 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of bile acid synthesis disorders due to single enzyme defects (SEDs).
- For adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption.

FDA-RECOMMENDED DOSE

10 to 15 mg/kg administered orally once daily, or in two divided doses.

HOW SUPPLIED

50 mg and 250 mg capsules in 90-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of a bile acid synthesis disorders due to single enzyme defects (SEDs) or peroxisomal disorder (PD); **AND**
- The member has manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption secondary to bile acid synthesis disorders.

For Continuation Coverage Requests:

- The member must have experienced improvements in liver function, as defined by one of the following criteria:
  - ALT or AST values reduced to < 50 U/L or baseline levels reduced by 80%
  - Total bilirubin values reduced to < 1 mg/dL
  - No evidence of cholestasis on liver biopsy

REQUIRED MEDICAL INFORMATION

- Current member weight (kg)
- Confirmation of diagnosis with genetic testing.
- For renewals, current liver function tests (ALT, AST, total bilirubin)

AGE RESTRICTIONS

3 weeks and older.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a pharmacist or physician.

PRESCRIBER RESTRICTIONS

N/A

COVERAGE DURATION

Three months.

QUANTITY RESTRICTIONS

- Maximum daily dose must be verified by member weight. Should not surpass 15 mg/kg once daily.
- Internal Note: Enter PA with a metric quantity and days' supply sufficient for member's weight, not to exceed 15 mg/kg once daily.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

CIBINQO® (ABROCITINIB)

Updated: April 1, 2024

Length of Authorization:	12 months
Initiative:	PAR: Cibinqo (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.

FDA-RECOMMENDED STARTING DOSE

- 100 mg orally once daily.
  - If an adequate response is not achieved after 12 weeks, consider 200 mg once daily.

HOW SUPPLIED

50 mg, 100 mg, and 200 mg tablets in 30-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of moderate to severe atopic dermatitis; **AND**
- The member has one of the following:
  - A minimum body surface area (BSA) involvement of at least 10%; **OR**
  - Eczema Area and Severity Index (EASI) score of at least 16; **OR**
  - Physician Global Assessment (PGA) score of at least 3; **AND**
- The member meets **one** of the following clinical scenarios:
  - The member has greater than 50% of their BSA affected; **OR**
  - The member has had a previous trial of at least one therapy from at least two of the following preferred therapy categories, without adequate response:
    - Topical calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
    - Medium or high potency topical corticosteroids
    - Topical PDE-4 inhibitors (e.g., crisaborole); **AND**
- The member has had a previous trial and failure of at least **one** of the following:
  - Adbry; **OR**
  - Dupixent; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

For Continuation Coverage Requests:

- The member has had a positive clinical response to therapy, as documented by the member's specialist provider; **AND**
- The member's liver enzymes are below three times the upper limit of normal (per lab specified range); **AND**
- The member's lymphocyte count is greater than 500 cells/mm^3; **AND**
- The member's absolute neutrophil count (ANC) is greater than 500 cells/mm^3; **AND**
- The member's hemoglobin level is greater than 8 g/dL; AND

- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib); **AND**
- The member has experienced or maintained one of the following:
  - A reduction in BSA involvement of a least 20% from baseline; **OR**
  - A decrease in EASI score of at least 50% from baseline; **OR**
  - A PGA score of 0 or 1.

REQUIRED MEDICAL INFORMATION

For continuation: Lymphocyte counts, liver enzymes (AST, ALT), neutrophil counts (ANC), and hemoglobin levels, documented within the six months preceding the coverage request.

AGE RESTRICTIONS

12 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by a dermatologist or an allergist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve by GSN.
- Initial requests can only be approved for 100 mg dose.
- If the request is for more than 100 mg once daily, the member must have received at least 12 weeks of continuous therapy without adequate response (80% or higher MPR).

CIMZIA® (CERTOLIZUMAB PEGOL)

Updated: December 18, 2023

Length of Authorization:	12 months
Initiative:	PAR: Cimzia (IE 2462 / NCPDP 75 – HICL) PAR: Loading Dose (IE 15110, 2641, 7001 / NCPDP 76 – HICL)

FDA-APPROVED INDICATION(S)

- Moderately to severely active Crohn's disease (CD) who have had an inadequate response to conventional therapy.
- Moderately to severely active rheumatoid arthritis (RA).
- Active psoriatic arthritis (PsA).
- Active ankylosing spondylitis (AS).
- Moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.
- Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

FDA-RECOMMENDED DOSE

- CD: 400 mg (given as two subcutaneous injections of 200 mg) initially and at weeks 2 and 4, followed by 400 mg every four weeks.
- RA, PsA, AS, nr-axSpA: 400 mg (given as two subcutaneous injections of 200 mg) initially, and at weeks 2 and 4. Then, 200 mg every other week (400 mg every 4 weeks can be considered).
- PsO: 400 mg (given as 2 subcutaneous injections of 200 mg) every other week.
  - For Body weight ≤ 90 kg: 400 mg (given as 2 subcutaneous injections of 200 mg) initially and at weeks 2 and 4, followed by 200 mg every other week can be considered.

HOW SUPPLIED

- 200 mg vial of subcutaneous powder for solution (1 pack = 2 vials).
- 200 mg/1 mL pre-filled syringe (1 pack = 2 syringes and 3 pack = 6 syringes).

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- For all indications:
  - The member does not have congestive heart failure; **AND**
  - The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)
- For CD:
  - The member has a diagnosis of moderate to severely active Crohn's disease; **AND**
  - The member has had a previous trial of or contraindication to at least one of the following without adequate response:
    - Thiopurines (i.e., 6-mercaptopurine or azathioprine),
    - Corticosteroids
    - Methotrexate; **OR**
    - The member has tried and failed one or more previous biologic therapies (e.g., risankizumab, infliximab, certolizumab, vedolizumab, golimumab, ustekinumab, or natalizumab).

- Member has had a previous trial of, or a contraindication to all, **both** of the following:
  - Adalimumab
  - Stelara

- For RA:
  - The member has a diagnosis of moderately to severely active rheumatoid arthritis; **AND**
  - The member has had a previous trial of or contraindication to at least **one** of the following:
    - Methotrexate
    - Leflunomide
    - Hydroxychloroquine
    - Sulfasalazine; **AND**
  - The member has had a previous trial of or contraindication to at least **two** of the following without adequate response:
    - Adalimumab
    - Enbrel
    - Xeljanz
- For PsA:
  - The member has a diagnosis of active psoriatic arthritis; **AND**
  - The member has had a previous trial of or contraindication to at least **one** of the following:
    - Methotrexate
    - Sulfasalazine
    - Cyclosporine
    - Leflunomide; **AND**
  - The member has a previous trial of or contraindication to at least **two** of the following without adequate response:
    - Adalimumab
    - Cosentyx
    - Enbrel
    - Tremfya
    - Stelara
    - Xeljanz

- For AS
  - The member has a diagnosis of active ankylosing spondylitis; **AND**
  - The member has had a previous trial of at least **one**, or contraindication to **all**, of the following:
    - Nonsteroidal anti-inflammatory drugs (NSAIDs)
    - Methotrexate
    - Sulfasalazine; **AND**
  - The member has had a previous trial of, or contraindication, to at least two of the following without adequate response:
    - Adalimumab
    - Enbrel
    - Xeljanz
    - Cosentyx
- For nr-axSpA:
  - The member has a diagnosis of active non-radiographic axial spondylarthritis; **AND**
  - The member has had a previous trial of at least **one**, or contraindication to **all**, of the following:
    - Nonsteroidal anti-inflammatory drugs (NSAIDs)
    - Methotrexate
    - Sulfasalazine
- For PsO:
  - The member has a diagnosis of moderate-to-severe plaque psoriasis; **AND**
  - The member has psoriatic lesions that involve greater than or equal to 10% of body surface area (BSA), or that affect the palms, soles, head, neck, or genital area, leading to disability/impact on quality of life; **AND**
  - The member has had a previous trial of or contraindication to **one** or more of the following:
    - PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B)
    - Topical corticosteroids
    - Calcipotriene
    - Acitretin
    - Methotrexate
    - Cyclosporine; **AND**
  - The member has had a previous trial of or contraindication to at least **two** of the following without adequate response:
    - Adalimumab
    - Cosentyx
    - Enbrel
    - Tremfya
    - Stelara

FOR CONTINUATION COVERAGE REQUESTS

- Member continues to have a beneficial clinical response to therapy, as assessed by the member's specialist provider; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

REQUIRED MEDICAL INFORMATION

For Initial Coverage Requests:

- For members treated for PsO, current BSA coverage of lesions.
- Claims or medical records demonstrating use of previous therapies

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

- For CD, must be prescribed by or in consultation with a Gastroenterologist.
- For RA, AS, nr-axSpA, must be prescribed by or in consultation with a Rheumatologist.
- For PsA, PsO, or PsA/PsO co-diagnosis, must be prescribed by or in consultation with either a Rheumatologist or a Dermatologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

- Cimzia loading dose:
  - Enter second PA with a metric quantity and days' supply of #6/28 DS x 1 month for loading dose.
  - Use initiative PAR: Loading Dose
  - Select CTI reason code: 2nd O/R for Existing PA Approved. No approval letter is sent with second PA.
- For continuation approval: refer to formulary quantity limit.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

Approve by HSN

COMETRIQ® (CABOZANTINIB)

Updated: April 26, 2023

Length of Authorization:	5 years
Initiative:	PAR: Cometriq (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC).

FDA-RECOMMENDED DOSE

140 mg once daily without food until disease progression or unacceptable toxicity.

HOW SUPPLIED

- 140 mg daily-dose carton containing four 140 mg daily-dose blister cards (each blister card contains seven 80-mg and twenty-one 20-mg capsules).
- 100 mg daily-dose containing four 100 mg daily-dose blister cards (each blister card contains seven 80-mg and seven 20-mg capsules).
- 60 mg daily-dose containing four 60 mg daily-dose blister cards (each blister card contains twenty-one 20-mg capsules).

COVERAGE CRITERIA

For Initial Coverage Requests:

- For MTC:
  - The member has a diagnosis of metastatic medullary thyroid cancer (MTC).
- For NSCLC:
  - The member has a diagnosis of non-small cell lung cancer (NSCLC); **AND**
  - The member has documentation of RET gene rearrangement positive disease.
- For DTC:
  - The member has a diagnosis of unresectable, persistent, or metastatic differentiated thyroid cancer; **AND**
  - The member's disease is not amenable to radioactive iodine therapy (RAI); **AND**
  - The member has tried and failed, or is contraindicated to, lenvatinib or sorafenib

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

For NSCLC: RET gene rearrangement confirmation in chart notes.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

COPAXONE® (GLATIRAMER ACETATE)

Updated: May 26, 2023

Length of Authorization:	5 years
Initiative:	PAR: Copaxone (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults.

FDA-RECOMMENDED DOSE

20 mg subcutaneously once daily or 40 mg subcutaneously three times per week at least 48 hours apart.

HOW SUPPLIED

20 mg and 40 mg per mL syringes in individual blister packages supplied in 30- and 12-count cartons, respectively.

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member must have tried and failed one of the following or have a contraindication to the following products if requested for a shared indication: Avonex®, Betaseron®, Gilenya®, fingolimod, glatiramer acetate, Glatopa®, Kesimpta®, Mayzent®, Plegridy®, or dimethyl fumarate.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary quantity limits

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

Approve by HICL.

COPIKTRA® (DUVELISIB)

Updated: April 28, 2023

Length of Authorization: 5 years
Initiative: PAR: Copiktra (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic leukemia (CLL/SLL) or follicular lymphoma (FL) who have had at least two prior therapies.

FDA-RECOMMENDED STARTING DOSE

25 mg orally twice daily.

HOW SUPPLIED

15 and 25 mg capsules in 56-count bottles and blister packs.

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of relapsed or refractory CLL, SLL, Splenic or Nodal Marginal Zone Lymphoma (MZL), MALT Lymphoma, T-cell lymphoma not otherwise specified (PTCL-NOS), enteropathy-associated T-cell lymphoma (EATL), monomorphic epitheliotropic intestinal T-cell lymphoma (MEITL), angioimmunoblastic T-cell lymphoma (AITL), nodal peripheral T-cell lymphoma with TFH phenotype (PTCL, TFH), follicular T-cell lymphoma (FTCL), anaplastic large cell lymphoma (ALCL), or FL; **AND**
- The member's disease has progressed after two or more prior therapies.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OTHER INFORMATION

Approve by HICL.

CORDRAN® TAPE (FLURANDRENOLIDE TAPE)

Updated: July 31, 2023

Length of Authorization: 12 months
Initiative: PAR: Dermatological Agents (IE 2462 / NCPDP 75 – HICL, IE 2193, 2194 / NCPDP 60 – HICL)

FDA-APPROVED INDICATION(S)

For relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, particularly dry, scaling, localized lesions

FDA-RECOMMENDED DOSE

Tape to covered area every 12 hours, as needed

HOW SUPPLIED

4 mcg/sq. cm tape in 24 x 3-inch and 80 x 3-inch rolls

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has tried and failed three or more alternative high-potency topical steroid products:
    - Amcinonide 0.1%
    - Betamethasone dipropionate 0.05%
    - Betamethasone valerate 0.12%, 0.1%
    - Clobetasol propionate 0.05%
    - Desoximetasone 0.25%, 0.05%
    - Fluocinonide 0.1%, 0.05%
    - Fluticasone propionate 0.005%
    - Halobetasol propionate 0.05%
    - Mometasone furoate 0.1%
    - Triamcinolone acetonide 0.5%

FOR CONTINUATION COVERAGE REQUESTS

The member continues to benefit from treatment, as attested to by the member's treating provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a dermatologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

CORLANOR® (IVABRADINE)

Updated: November 3, 2023

Length of Authorization: 24 months
Initiative: PAR: Corlanor (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- To reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤ 35%, who are in sinus rhythm with resting heart rate ≥ 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.
- For the treatment of stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients 6 months of age and older, who are in sinus rhythm with an elevated heart rate.

FDA-RECOMMENDED DOSE

- Adults: 5 mg twice daily with food (maximum dose of 7.5 mg twice daily).
- Pediatrics: 0.05 mg/kg twice daily with food (maximum dose of 0.2 mg/kg twice daily twice daily for patients 6 months to less than 1 year of age, and 0.3 mg/kg twice daily for patients 1 year of age and older, up to a total of 7.5 mg twice daily).

HOW SUPPLIED

- 5 mg and 7.5 mg tablets in 60-count bottles.
- 5 mg/5 mL solution in 5 mL ampules in 28-count cartons.

UTILIZATION CRITERIA

For Initial Coverage Requests:

Heart Failure

- The member has a diagnosis of heart failure with left ventricular ejection fraction (LVEF) less than or equal to 35%; **AND**
- The member must be currently on a stable drug regimen for heart failure, consisting of an ACE-inhibitor, ARB, or ARNI; **AND**
- The member is either on maximally tolerated doses of beta-blockers or has a contraindication to beta-blocker use; **AND**
- The member is in sinus rhythm with resting heart rate ≥ 70 beats per minute.

Inappropriate Sinus Tachycardia

- The member has a diagnosis of inappropriate sinus tachycardia with a resting heart rate> 100 beats per minute (mean heart rate >90 beats per minute over 24 hours) **AND**
- The member is either on maximally tolerated doses of beta-blockers or has a contraindication to beta-blocker use, **AND**
- The member has palpitations, presyncope, or both.

For Continuation Coverage Requests:

- The member remains stable on therapy, as attested to by the treating cardiologist.

REQUIRED MEDICAL INFORMATION

For Initial Coverage Requests:

- Chart notes or medical records documenting left ventricular ejection fraction (LVEF); **OR**
- Chart notes or medical records documenting inappropriate sinus tachycardia.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with, a cardiologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

24 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by HICL.

COSENTYX® (SECUKINUMAB)

Updated: March 21, 2024

Length of Authorization:	12 months
Initiative:	PAR: Cosentyx (IE 2462 / NCPDP 75 – NDC-11) PAR: Loading Dose (IE 15110, 2641, 7001 / NCPDP 76 – NDC-11)

FDA-APPROVED INDICATION(S)

- For the treatment of moderate to severe plaque psoriasis (PsO) in patients 6 years of age and older who are candidates for systemic therapy or phototherapy.
- For the treatment of active psoriatic arthritis (PsA) in patients 2 years of age and older.
- For the treatment of adult patients with active psoriatic arthritis (PsA).
- For the treatment of adult patients with active ankylosing spondylitis (AS).
- For the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.
- For the treatment of active enthesitis-related arthritis (ERA) in patients 4 years of age and older.
- For the treatment of adult patients with moderate to severe hidradenitis suppurativa (HS).

FDA-RECOMMENDED STARTING DOSE

- HS and PsO (adults): 300 mg subcutaneously at weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks.
- PsO (pediatric patients):
  - < 50 kg: 75 mg subcutaneously at weeks 0, 1, 2, 3, and 4 followed by 75 mg every 4 weeks.
  - ≥ 50 kg: 150 mg subcutaneously at weeks 0, 1, 2, 3, and 4 followed by 150 mg every 4 weeks.
- PsA or AS: 150 mg at weeks 0, 1, 2, 3, and 4, and every 4 weeks thereafter.
- Pediatric PsA and ERA:
  - ≥ 15 kg and < 50 kg: 75 mg at weeks 0, 1, 2, 3, and 4 followed by 75 mg every 4 weeks.
  - ≥ 50 kg: 150 mg at weeks 0, 1, 2, 3, and 4 followed by 150 mg every 4 weeks.

HOW SUPPLIED

- 150 mg/mL "Sensoready" pens and 75 mg/0.5 mL and 150 mg/mL single-use prefilled syringes
- 300 mg/2 mL "Unoready" pens in a 1-count box.
- **Note**: Secukinumab is available in 1-count and 2-count boxes of pens and syringes. The UM PDP will only allow a quantity of 1 for the 1-count boxes, and a quantity of 2 for the 2-count boxes. See below for additional information on coverage allowances.
- **150 mg 1-pack NDCs require plan approval for coverage.**

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- **For all indications:**
  - The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib).
- **For PsO:**
  - The member has a diagnosis of moderate-to-severe PsO; **AND**

- The member has psoriatic lesions that involve greater than or equal to 10% of body surface area (BSA) or that affect the palms, soles, head, neck, or genital area leading to disability/impact on quality of life; **AND**
- The member has had a previous trial of or contraindication to at least one of the following:
  - PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B)
  - Topical corticosteroids
  - Calcipotriene
  - Acitretin
  - Methotrexate
  - Cyclosporine

- **For PsA:**
  - The member has a diagnosis of active PsA; **AND**
  - The member has had a previous trial of or contraindication to at least one of the following:
    - Methotrexate
    - Sulfasalazine
    - Cyclosporine
    - Leflunomide
- **For ERA:**
  - The member has a diagnosis of active ERA; **AND**
  - The member has tried and failed, or has a contraindication to one or more NSAIDs, steroid products, or methotrexate.
- **For AS:**
  - The member has a diagnosis of moderate to severe AS; **AND**
- The member has had a previous trial of at least **one**, or contraindication to **all**, of the following:
  - Nonsteroidal anti-inflammatory drugs (NSAIDs)
  - Methotrexate
  - Sulfasalazine
- **For nr-axSpA:**
  - The member has a diagnosis of active non-radiographic axial spondylarthritis; **AND**
  - The member has had a previous trial of at least **one**, or contraindication to **all**, of the following:
    - Nonsteroidal anti-inflammatory drugs (NSAIDs)
    - Methotrexate
    - Sulfasalazine
- **For HS:**
  - The member's HS diagnosis severity is Hurley Stage II–III; **AND**
  - The member has failed to show significant improvement with systemic antibiotic therapy of at least 3 months in duration.

FOR CONTINUATION COVERAGE REQUESTS (ALL INDICATIONS)

- The member has had a positive clinical response to therapy, as documented by the member's specialist provider.
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib).

REQUIRED MEDICAL INFORMATION

For initial coverage requests:

- Claims or medical records demonstrating use of previous therapies.
- For members treated for PsO, current BSA coverage of lesions.
- For pediatric members treated for PsO, PsA, or ERA: current weight

AGE RESTRICTIONS

- 2 years of age and older for PsA
- 4 years of age and older for ERA
- 6 years of age and older for PsO
- 18 years of age and older for all other indications

PRESCRIBER RESTRICTIONS

- AS: must be prescribed by or in consultation with a rheumatologist.
- HS: Must be prescribed by, or in consultation with, a dermatologist.
- All other indications: must be prescribed by or in consultation with a rheumatologist or dermatologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

12 months

QUANTITY/PARTIAL-FILL RESTRICTIONS

- **150 mg 1-pack NDCs require plan approval for coverage.**
- Cosentyx loading dose for 2-dose packs:
  - Plaque psoriasis
    - Loading dose: Enter second PA with a metric quantity and days' supply of #8/28 for loading dose.
    - Maintenance dose 300 mg every 4 weeks: Coverage Limits allow quantity of 2 for 28 days.
    - Maintenance dose 150 mg every 4 weeks: Coverage Limits allow quantity of 2 for 56 days.
  - Plaque psoriasis (pediatric patients weighing < 50 kg)
    - Loading dose: Enter second PA with a metric quantity and day's supply of #2/28 for loading dose.
    - Maintenance dose 75 mg every 4 weeks: Coverage Limits allow quantity of 0.5 for 28 days.
  - Plaque psoriasis (pediatric patients weighing ≥ 50 kg)
    - Loading dose: Enter second PA with a metric quantity and day's supply of #4/28 days for loading dose.
    - Maintenance dose 150 mg every 4 weeks: Coverage Limits allow quantity of 2 for 56 days.
  - Psoriatic arthritis
    - Loading dose: Enter second PA with a metric quantity and days' supply of #4/28 for loading dose.
    - Maintenance dose of 300 mg every 4 weeks: Coverage Limits allow quantity of 2 for 28 days.
    - Maintenance dose of 150 mg every 4 weeks: Coverage Limits allow quantity of 2 for 56 days.
  - Ankylosing spondylitis and nr-axSpA
    - Loading dose: Enter second PA with a metric quantity and days' supply of #4/28 for loading dose.
    - Maintenance dose of 150 mg every 4 weeks: Coverage Limits allow quantity of 2 for 56 days.
  - Hidradenitis Suppurativa
    - Loading dose: Enter second PA with a metric quantity and days' supply of #8/28 for loading dose.
    - Maintenance dose of 300 mg every 4 weeks: Coverage Limits allow quantity of 2 for 28 days.
- Loading Dose
  - Enter second PA with a metric quantity and days' supply indicated above for loading dose.
  - Use initiative PAR: Loading Dose
  - Select CTI reason code: 2nd O/R for Existing PA Approved. No approval letter is sent with second PA.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

- Approve by NDC
- **1-pack NDCs require plan approval for coverage.**

COTELLIC® (COBIMETINIB)

Updated: April 27, 2023

Length of Authorization: 12 months
Initiative: PAR: Cotellic (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib.
- For the treatment of adult patients with histiocytic neoplasms as a single agent.

FDA-RECOMMENDED DOSE

60 mg (three 20 mg tablets) orally taken once daily for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity

HOW SUPPLIED

20 mg film-coated tablets available in 63-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member meets one of the following clinical scenarios:
  - The member has confirmed BRAF V600E or V600 K mutation; **AND**
  - Cobimetinib will be used in combination with vemurafenib, **AND**
  - The member has a confirmed diagnosis of one of the following:
    - Melanoma
    - CNS Cancer; **OR**
  - The member has a diagnosis of one of the following:
    - Langerhans Cell Histiocytosis (LCH)
    - Erdheim-Chester Disease (ECD)
    - Rosai-Dorfman Disease

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy as assessed and documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Confirmation of BRAF V600E or V600K mutation.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by a hematologist or an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

CRESEMBA® (ISAVUCONAZONIUM)

Updated: October 26, 2023

Length of Authorization:	For the treatment of invasive aspergillosis and invasive mucormycosis: 3 months For the prophylactic treatment of fungal infections in high-risk patients receiving a bone-marrow transfusion: 6 months
Initiative:	PAR: Cresemba (IE 2462 / NCPDP 75 – GSN) PAR: Loading Dose (IE 15110, 2641, 7001 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of invasive aspergillosis and invasive mucormycosis in adults.

FDA-RECOMMENDED DOSE

372 mg orally every eight hours for six doses, followed by 372 mg orally once daily

HOW SUPPLIED

- 74.5 mg capsules in 35-count carton (5-count blister packs).
- 186 mg capsules in 14-count carton (7-count blister packs)
- 372 mg lyophilized powder in single-dose vials

COVERAGE CRITERIA

For the Initial Coverage Requests:

- For the initial treatment of Invasive Aspergillosis:
  - The member has a diagnosis of invasive aspergillosis; **AND**
  - A fungal culture report has been obtained prior to initiation of antifungal therapy; **AND**
  - One or more of the following clinical scenarios are met:
    - The member has tried and failed, or has contraindication to, voriconazole.
    - The member's fungal culture report shows sensitivity to only isavuconazonium.
- For the initial treatment of Invasive Mucormycosis:
  - The member has a diagnosis of invasive mucormycosis; **AND**
  - A fungal culture report has been obtained prior to initiation of antifungal therapy; **AND**
  - One or more of the following clinical scenarios are met:
    - The member has tried and failed posaconazole or amphotericin B
    - The member is transitioning from amphotericin B (i.e., using isavuconazonium as a step-down therapy)
    - The member's fungal culture report shows sensitivity to only isavuconazonium.
- For the Prophylactic Treatment of Fungal Infections in Patients Receiving a Bone-Marrow Transfusion:
  - The member is receiving a bone-marrow transfusion; **AND**
  - The member is high-risk per specialist attestation; **AND**
  - The member has tried and failed, or has contraindication to, voriconazole

For Continuation Coverage Requests:

- For continued infection treatment:
  - The member continues to have a diagnosis of invasive aspergillosis or invasive mucormycosis; **AND**
  - The member's fungal culture report shows continued sensitivity to isavuconazonium; **AND**
  - The member's fill records show adherence to therapy over the last three months, with a medication possession ratio of at least 80% (calculated by day-supply dispensed over the sum of days in treatment period).
- For continued infection prophylaxis:
  - The member remains at high risk of infection due to prior bone marrow transfusion.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

12 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an infectious disease specialist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

- For the treatment of invasive aspergillosis and invasive mucormycosis: 3 months
- For the prophylactic treatment of fungal infections in high-risk patients receiving a bone-marrow transfusion: 6 months

QUANTITY RESTRICTIONS

- If requesting the loading dose, coverage should allow the following:
  - Approve maintenance dose deferring to formulary quantity limits
  - Approve loading dose:
    - If 74.5 mg capsules: QPD of 5.7 for 1 month (171 x 30 days)
    - If 186 mg capsules: QPD of 2.3 for 1 month (69 x 30 days)
    - Use initiative PAR: Loading Dose
    - Select CTI reason code: 2nd O/R for Existing PA Approved. No approval letter is sent with second PA.
- If the coverage request is only for the maintenance dose, coverage should defer to formulary quantity limits.

OPERATIONAL NOTES AND OTHER INFORMATION

- Coverage should be limited to the oral capsule formulation by GSN.
- Isavuconazonium for injection is not a covered plan benefit.

DARAPRIM® (PYRIMETHAMINE)

Updated: May 8, 2023

Length of Authorization:	Initial: 6 months Renewal: 1 year
Initiative:	PAR: Daraprim (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of toxoplasmosis when used conjointly with a sulfonamide.

FDA-RECOMMENDED DOSE

- The adult starting dose is 50 to 75 mg of the drug daily, together with 1 to 4 g daily of a sulfonamide of the sulfapyrimidine type (e.g., sulfadiazine). This dosage is ordinarily continued for 1 to 3 weeks, depending on the response of the patient and tolerance to therapy. The dosage may then be reduced to about one half that previously given for each drug and continued for an additional 4 to 5 weeks.
- The pediatric dosage is 1 mg/kg/day divided into 2 equal daily doses, together with the usual pediatric sulfonamide dosage; after 2 to 4 days this dose may be reduced to one half and continued for approximately 1 month.
- Concurrent administration of folinic acid (i.e., leucovorin) is strongly recommended in all patients.

HOW SUPPLIED.

25 mg tablets in 30-count and 100-count bottles.

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of toxoplasmosis; **AND**
- The member will be receiving concomitant therapy with a sulfonamide (e.g., sulfadiazine) or clindamycin; **AND**
- The member will be receiving concomitant therapy with leucovorin.

For Continuation Coverage Requests:

- The member is immunodeficient and would benefit from continued therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Documentation of diagnosis

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a specialist provider

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

- Initial: 6 months
- Continuation: 1 year

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

DAURISMO® (GLASDEGIB)

Updated: May 1, 2023

Length of Authorization: 12 months
Initiative: PAR: Daurismo (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of newly diagnosed acute myeloid leukemia (AML), in combination with low dose cytarabine in adult patients who are ≥ 75 years of age or who have comorbidities that preclude use of intensive induction chemotherapy.

FDA-RECOMMENDED STARTING DOSE

100 mg orally once daily continuously, with cytarabine 20 mg subcutaneously administered twice daily on days 1 through10 of each 28-day cycle.

HOW SUPPLIED

- 100 mg tablets in 30-count bottles.
- 25 mg tablets in 60-count bottles.

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of AML; **AND**
- The member meets one of the following clinical scenarios:
  - Scenario 1:
    - The requested medication is being used for a late relapse (≥ 12 months since induction); **AND**
    - The member had previous successful induction therapy; **AND**
    - The same successful induction therapy regimen used previously is going to be repeated; **OR**
  - Scenario 2:
    - The member is treatment-naïve; **AND**
    - The requested medication is to be used in combination with low-dose cytarabine; **AND**
    - The member is 75 years of age or older **OR** has comorbidities that preclude use of intensive induction chemotherapy; **AND**
    - The member has an inability to tolerate intensive chemotherapy.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approve by HICL.

DESCOVY® (EMTRICITABINE/TENOFOVIR ALAFENAMIDE)

Updated: May 26, 2023

Length of Authorization:	For PrEP: 24 months For HIV Treatment: Lifetime **(use 12/31/2036 as end date)**
Initiative:	PAR: Descovy (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg.
- For the treatment of HIV-1 infection in pediatric patients weighing at least 14 kg and less than 35 kg when in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor.
- For pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sexual acquisition in at-risk adults and adolescents weighing at least 35 kg, excluding individuals at risk from receptive vaginal sex.

FDA-RECOMMENDED DOSE

- HIV Treatment:
  - Adults: One tablet containing 200 mg FTC and 25 mg of TAF taken orally once daily.
  - Pediatrics:

25 kg to less than 35 kg	One tablet containing 200 mg FTC and 25 mg of TAF taken orally once daily
14 kg to less than 25 kg	One tablet containing 120 mg FTC and 15 mg TAF taken orally once daily

- PrEP:
  - Adults and Adolescents weighting more than 35 kg: One tablet containing 200 mg FTC and 25 mg of TAF taken orally once daily.

HOW SUPPLIED

- 200 mg – 25 mg tablets in 30-count bottles.
- 120 mg – 15 mg tablets in 30-count bottles.

UTILIZATION CRITERIA

For Requests for HIV Treatment:

- Member must have a diagnosis of HIV-1; **AND**
- Member must be using Descovy as a component of a complete treatment regimen.

For Initial and Continuation Requests for the PrEP Indication:

- Member must have a confirmed negative test for HIV-1 within the last 3 months; **AND**
- Member must be ineligible to receive tenofovir disoproxil fumarate due to one of the following clinical scenarios:
  - Member must have bone mineral density (BMD) issue as evidenced by T-score of -1 or lower; **OR**
  - Member must have creatinine clearance or eGFR less than 60 mL/min.

REQUIRED MEDICAL INFORMATION

For PrEP:

- Negative HIV lab result from within 3 months of request
- LDL result from within 12 months of request
- For Renal Clinical Scenario: CrCl or eGFR
- For BMD Clinical Scenario: T-score

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

N/A

COVERAGE DURATION (MONTHS)

- For PrEP: 24 months
- For HIV Treatment: Lifetime

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

- This PA policy is intended to prevent unnecessary use of emtricitabine/tenofovir alafenamide (Descovy) for PrEP when the plan's formulary alternative for PrEP therapy, emtricitabine/ tenofovir disoproxil fumarate (Truvada), is a viable option.
- If approved for PrEP, member cost share should be set to $0.*
- *Internal Note for PrEP:
  - If DENIED, follow normal denial procedures.
  - If APPROVED, follow normal approval procedures, AND follow additional steps below to instruct the Admin technician team to place the cost share override:
    - Once approved, duplicate the Contact Detail.
      - Select CTI: Override Inquiry → Guidelines → Information Given
      - Leave in: MAP: Supervisor queue
      - Assign to: "Copay Override"
      - Add Work Log Note: "Requires copay override in FirstRx℠ for PrEP"
      - Leave Contact Detail: In Progress
      - Save.
  - Pharmacists: Send a message to the admin technicians in the Microsoft Teams group chat "EMP/ HP Fax Work" that an approved PrEP request requiring a copay override in FirstRx℠ has been sent to the MAP: Supervisor Queue. If there has been no response after 2 days, follow up to ensure that the override has been completed.

DIACOMIT® (STIRIPENTOL)

Updated: May 14, 2023

Length of Authorization:	12 months
Initiative:	PAR: Diacomit (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of seizures associated with Dravet syndrome (DS) in patients who are taking clobazam and are 6 months of age and older and weighing 7 kg or more

FDA-RECOMMENDED DOSE

Age of Patient	Body Weight	Dosing Regimen (administered by mouth in equally divided doses)	Total Daily Dose
6 months to < 1 year	7 kg and above	25 mg/kg twice daily[a,b]	50 mg/kg/day
1 year and above	7 kg to less than 10 kg	25 mg/kg twice daily[b]	50 mg/kg/day
	10 kg and above	25 mg/kg twice daily or 16.67 mg/kg three times daily	50 mg/kg/day Maximum daily dose is 3000 mg

HOW SUPPLIED

- Capsules: 250 mg, 500 mg in 60-count bottles.
- Powder packets for oral suspension: 250 mg, 500 mg in 60-count cartons.

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member has seizures associated with clinically diagnosed DS; **AND**
- The member will be receiving concurrent clobazam; **AND**
- The member has inadequate seizure control despite optimized therapy with valproic acid and adjunctive clobazam; **AND**
- The member has previously tried and failed, or has contraindications to, add-on therapy with topiramate.

For Continuation Coverage Requests:

- The member continues to tolerate and have a beneficial response to treatment, as attested to by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by HSN.

DIBENZYLINE® (PHENOXYBENZAMINE)

Updated: November 2,, 2023

Length of Authorization:	6 months
Initiative:	PAR: DIBENZYLINE (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of pheochromocytoma, to control episodes of hypertension and sweating. If tachycardia is excessive, it may be necessary to use a beta-blocking agent concomitantly.

FDA-RECOMMENDED DOSE

Initially, 10 mg twice a day. Dosage should be increased every other day, usually to 20 to 40 mg two or three times a day, until an optimal dosage is obtained, as judged by blood pressure control.

HOW SUPPLIED

10 mg capsules in 100-count bottles

UTILIZATION CRITERIA

For All Coverage Requests:

- The member has a confirmed diagnosis of pheochromocytoma; **AND**
- The member has tried and failed all of the following alpha 1-selective receptor blockers, unless contraindicated:
  - Terazosin
  - Doxazosin
  - Prazosin

REQUIRED MEDICAL INFORMATION

- Chart notes or medical records documenting diagnosis
- Claims or medical records demonstrating use of previous therapies

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an endocrinologist or oncologist who specializes in the management of pheochromocytoma.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

6 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND ADDITIONAL INFORMATION

Approve by GSN

DIFICID® (FIDAXOMICIN)

Updated: May 25, 2023

Length of Authorization: 1 month	
Initiative: PAR: Dificid (IE 2462 / NCPDP 75 – GSN, NCPDP 76 – GSN)	

FDA-APPROVED INDICATION(S)

Indicated in adult and pediatric patients aged 6 months and older for the treatment of C. difficile-associated diarrhea (CDAD).

FDA-RECOMMENDED DOSE

- One 200 mg tablet orally twice daily for 10 days in adults and pediatric patients weighing at least 12.5 kg and able to swallow tablets.
- Pediatric granules for suspension dosage:

Body Weight	Dose Administered Twice Daily	Volume of 40 mg/mL Suspension to be Administered Orally Twice Daily
4 kg to less than 7 kg	80 mg	2 mL
7 kg to less than 9 kg	120 mg	3 mL
9 kg to less than 12.5 kg	160 mg	4 mL
12.5 kg and above	200 mg	5 mL

HOW SUPPLIED

- Tablets: 200 mg tablets in 20 count bottles
- Granules for oral suspension: 150 mL amber glass bottles of 9.53 g of granules that contain 5.45 g of fidaxomicin. After reconstitution, the total oral suspension volume is 136 mL (40 mg/mL).

UTILIZATION CRITERIA

For All Coverage Requests:

- The member must have a confirmed diagnosis of CDAD; **AND**
- The member must meet one of the following situations:
  - The member started therapy in the hospital and request is to complete the course; **OR**
  - The member has tried and failed on oral vancomycin in the last 30 days.

REQUIRED MEDICAL INFORMATION

Weight of patient for if pediatric use.

AGE RESTRICTIONS

6 months of age and older

PRESCRIBER RESTRICTIONS

- If therapy started at an inpatient level of care, there is no prescriber restriction.
- If therapy is started at an outpatient level of care, it must be prescribed by or in consultation with an infectious disease specialist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

1 month

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

DOPTELET® (AVATROMBOPAG)

Updated: May 11, 2023

Length of Authorization:	For Chronic Liver Disease with scheduled procedure: 30 day (one fill). For Chronic Immune Thrombocytopenia: Initial: 3 months, Renewal: 12 months
Initiative:	PAR: Doptelet: Chronic Liver Disease (IE 2462 / NCPDP 75 – GSN, IE 15110 / NCPDP 76 – GSN) PAR: Doptelet: Other (IE 2462 / NCPDP 75 – GSN. IE 2641, 15110 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure
- For the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

FDA-RECOMMENDED STARTING DOSE

- Chronic Liver Disease w/ scheduled procedure:
  - Dosed per platelet count: 60 mg (3 tablets) for platelets less than $40x10^9$/L or 40 mg (2 tablets) for platelet counts of $40\text{-}50x10^9$/L, taken once daily for five consecutive days. The final dose should be taken 5–8 days prior to surgery.
- Chronic Immune Thrombocytopenia:
  - Starting dose of 20 mg by mouth once daily.
  - Refer to the package insert for dose adjustments after at least two weeks on initial dose (based on platelet count).

HOW SUPPLIED

20 mg tablets in 10 and 15-count blister cards. Also available as a carton of two 15 count blister cards.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

For Chronic Liver Disease with schedule procedure:

- The member has a confirmed diagnosis of chronic liver disease; **AND**
- The member has an initial platelet count less than $50x10^9$/L; **AND**
- The member has a planned invasive, high risk, procedure to be performed 10-13 days after initiation date of avatrombopag; **AND**
- The member is not receiving, or plans to receive, other TPO-Ras (i.e., lusutrombopag, romiplostim, eltrombopag).

For Chronic Immune Thrombocytopenia (ITP):

- The member has a confirmed diagnosis of chronic immune thrombocytopenia; **AND**
- The member has an initial platelet count less than 30,000/ µL; **AND**
- The member is not receiving, or plans to receive, other TPO-Ras (i.e., romiplostim, eltrombopag); **AND**
- The member has previously failed any of the following treatments for chronic immune thrombocytopenia:
  - Four weeks of standard prednisone therapy or high dose dexamethasone (HDD); **OR**
  - Immunoglobulins; **OR**
  - Splenectomy

For Continuation Coverage Requests:

- For Chronic Immune Thrombocytopenia (ITP):
  - The member has had an increase in platelet count to ≥ 50,000/mm^3 or increase that is sufficient to avoid clinically important bleeding after at least 4 weeks of max dose.

REQUIRED MEDICAL INFORMATION

Current platelet count (lab draw dated within at least 6 months of the request).

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a hepatologist or hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- For Chronic Liver Disease with scheduled procedure: 30 day (one fill).
- For Chronic Immune Thrombocytopenia:
  - Initial: 3 months
  - Continuation: 12 months

QUANTITY RESTRICTIONS

- For Chronic Liver Disease with scheduled procedure:
  - Use PAR: Doptelet: Chronic Liver Disease
  - If platelets are less than $40x10^9$/L: Max quantity of 15 tablets per fill. Enter PA with a metric quantity and days' supply #15/5 DS (MDD 3).
  - If platelet counts are equal to or greater than $40x10^9$/L: Maximum quantity of 10 tablets per fill. Enter PA with a metric quantity and days' supply #10/5 DS.
- For Chronic Immune Thrombocytopenia:
  - Use PAR: Doptelet: Other
  - Enter PA with a metric quantity and days' supply #30/30 DS.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

DUPIXENT® (DUPILUMAB)

Updated: April 1, 2024

Length of Authorization:	6 months (initial); 12 months (continuation)
Initiative:	PAR: Dupixent (IE 2462 / NCPDP 75 – GSN) PAR: Loading Dose (IE 15110, 2641, 7001 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of patients 6 months of age and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
- As an add-on maintenance treatment in patients with moderate-to-severe asthma 6 years of age and older with an eosinophilic phenotype or with oral corticosteroid- (OCS) dependent asthma.
- As an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).
- For the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE).
- For the treatment of adult patients with prurigo nodularis (PN).

FDA-RECOMMENDED STARTING DOSE

- Atopic dermatitis (adults) and PN: An initial dose of 600 mg (two 300 mg injections), followed by 300 mg every other week.
- Atopic dermatitis (pediatric patients)
  - 15 kg to less than 30 kg: 600 mg (two 300 mg injections), followed by 300 mg every 4 weeks.
  - 30 kg to less than 60 kg: 400 mg (two 200 mg injections), followed by 200 mg every other week.
  - 60 kg or more: 600 mg (two 300 mg injections), followed by 300 mg every other week.
- Asthma: An initial dose of 400 mg or 600 mg followed by 200 mg or 300 mg every other week
- CRSwNP: 300 mg every other week
- EoE: 300 mg every week.

HOW SUPPLIED

- 100 mg/0.67 mL, 200 mg/1.14 mL and 300 mg/2 mL pre-filled syringes in 2-count packages
- 300 mg/2 mL and 200 mg/1.14 mL pens in 2-count packages

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

For All Indications:

- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

OCS Dependent Asthma:

- The member has a diagnosis of moderate-to-severe asthma; **AND**
- The member is currently utilizing daily OCS and has been receiving OCS for at least 4 weeks in addition to a high-dose ICS product, plus either a LABA or LAMA.

Atopic Dermatitis:

- The member has a diagnosis of moderate-to-severe atopic dermatitis; **AND**
- The requested dose is within FDA labeling for submitted weight; **AND**
- The member has one of the following:
  - A minimum body surface area (BSA) involvement of at least 10%, **OR**
  - Eczema Area and Severity Index (EASI) score of at least 16; **OR**
  - Physician Global Assessment (PGA) score of at least 3; **AND**
- The member meets **one** of the following clinical scenarios:
  - The member has a greater than 50% of their BSA impacted; **OR**
  - The member has had a previous trial of at least one therapy from two of the following preferred therapy categories without adequate response:
    - Topical Calcineurin Inhibitors (e.g., tacrolimus, pimecrolimus)
    - Medium- or high-potency topical corticosteroids
    - Topical PDE-4 Inhibitors (e.g., crisaborole)

Eosinophilic Asthma:

- The member has a diagnosis of moderate-to-severe asthma; **AND**
- The member is currently utilizing a high-dose inhaled corticosteroid (ICS) product plus either a long-acting beta-2 agonist (LABA) or a long-acting muscarinic antagonist (LAMA); **AND**
- The member has documentation of blood eosinophils greater than or equal to 150 cells/mcl, measured within the preceding six months **or** the member has been established on an alternative anti-IL-4/5 product (i.e., mepolizumab, reslizumab, or benralizumab).

CRSwNP:

- The member has a diagnosis of CRSwNP; **AND**
- The member will use dupilumab in combination with intranasal corticosteroids (unless unable to tolerate or contraindicated); **AND**
- The member has tried and failed **one** of the following:
  - Intranasal corticosteroids; **OR**
  - Surgical intervention.

EoE:

- The member has a diagnosis of EoE; **AND**
- The member weighs ≥ 40 kg; **AND**
- The member has tried and failed dietary avoidance/modifications; **AND**
- The member has tried and failed, or has a contraindication to, budesonide oral viscous suspension or fluticasone propionate aerosol inhalation.

PN:

- The member has a diagnosis of prurigo nodularis (PN); **AND**
- The member has ≥ 20 nodular lesions; **AND**
- The member has tried and failed, or is contraindicated to, at least one generic high-potency topical corticosteroid; **AND**
- The member has tried and failed two or more, or is contraindicated to all, generic topical corticosteroid products (**Note**: high potency topical corticosteroid from above counts towards this requirement); **AND**
- The member has tried and failed a non-steroid PN treatment (e.g., methotrexate, cyclosporine, phototherapy, topical pimecrolimus, topical tacrolimus).

FOR CONTINUATION COVERAGE REQUESTS

For All Indications:

- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

For Atopic Dermatitis:

- The member has had a positive clinical response to therapy, as documented by the member's specialist provider; **AND**
- The requested dose is within FDA labeling for submitted weight; **AND**
- The member has experienced or maintained one of the following:
  - A reduction in BSA involvement of a least 20% from baseline
  - A decrease in EASI score of at least 50% from baseline
  - A PGA score of 0 or 1

For Eosinophilic Asthma:

- The member has experienced a decrease in the frequency of exacerbations and improvement in symptoms, as attested to by the member's specialist provider.

For OCS-dependent Asthma:

- The member has decreased their dose of OCS by at least 50%; **OR**
- The member has decreased their dose of OCS by any amount and the member has experienced a decrease in the frequency of exacerbations and improvement in symptoms, as attested to by the member's specialist provider.

For CRSwNP, EOE, and PN

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- For members treated for atopic dermatitis: current BSA coverage, EASI score, or PGA score.
- For pediatric members (under 18 years of age) treated for atopic dermatitis: current weight.
- For members treated for eosinophilic asthma: documentation of an eosinophil count (cells/mcL) with date.
- For members treated for EoE: chart notes or medical records demonstrating diagnosis and current weight.
- For members treated for PN: Chart notes or medical records demonstrating diagnosis and number of nodular lesions
- For all indications: treatment plan with all previous and concurrent therapies.

AGE RESTRICTIONS

- Atopic Dermatitis: 6 months of age and older
- Asthma: 6 years of age and older
- CRSwNP and PN: 18 years of age and older
- EoE: 12 years of age and older.

PRESCRIBER RESTRICTIONS

- For **eosinophilic asthma, OCS-dependent asthma, and CRSwNP**: Must be prescribed by an allergist, immunologist, pulmonologist, or an ear, nose, and throat (ENT) specialist.
- **For EoE:** Must be prescribed by or in consultation with an allergist, immunologist, pulmonologist, gastroenterologist, or an Ear, Nose, and Throat (ENT) specialist.
- For **Atopic Dermatitis or PN**: Must be prescribed by or in consultation with a dermatologist or allergist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

6 months (initial); 12 months (continuation)

QUANTITY RESTRICTIONS

- **Asthma:**
  - For initial requests, enter the approval as follows:
    - For members 12 years of age and older: Approve one fill with an MDD of 0.286 (override formulary quantity limit).
    - For all ages, approve the clinical PA for six months.
    - **Internal note:** Loading dose: approve an initial dose of 400 mg or 600 mg, followed by 200 mg or 300 mg every other week.
      - For the 300 mg/2 mL syringe or pen, enter a second PA with a metric quantity and days' supply of #8/28 DS for loading dose x 1 month.
      - For the 200 mg/1.14 mL syringe or pen, enter a second PA with a metric quantity and days' supply of #4.564/28 DS for loading dose x 1 month.
  - For continuation requests, approve for 12 months and refer to the formulary quantity limits.
- **Atopic Dermatitis and PN**
  - For initial requests, enter the approval with an additional quantity override as follows:
    - Approve for one month with the following quantity limits based on weight/age:

Body Weight	Initial Dose	Quantity Limit on PA
15 to less than 30 kg	600 mg (two 300 mg injections)	MDD 0.286
30 to less than 60 kg	400 mg (two 200 mg injections)	MDD 0.163
60 kg or more (or age 18 +)	600 mg (two 300 mg injections)	MDD 0.286

Internal note: Atopic Dermatitis loading dose instructions

- 60 kg or more (or > 18 years of age+):
  - Loading dose: Approve an initial dose of 600 mg (two 300 mg/2 mL syringes).
  - Enter second PA with a metric quantity and days' supply of #8/28 DS for loading dose x 1 month.
- 30 kg to less than 60 kg
  - Loading dose: Approve an initial dose of 400 mg (two 200 mg injections).
  - Enter second PA with a metric quantity and days' supply of #4.564/28 DS for loading dose x 1 month.
- 15 kg to less than 30 kg
  - Loading dose: Approve an initial dose of 600 mg (two 300 mg injections).
  - Enter second PA with a metric quantity and days' supply of #6/28 DS for loading dose x 1 month.
  - For continuation requests, approve for 12 months and refer to the formulary quantity limit.
- **CRSwNP:**
  - Refer to formulary quantity limits.
- **EoE:**
  - Approve 300 mg weekly.
- **Loading Doses:**
  - Use PAR: Loading dose
  - Select CTI reason code: 2nd **O/R** for Existing PA Approved. No approval letter is sent with second PA.

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve the appropriate GSN for the member dose/weight, use the GSN of the requested delivery device (i.e., pen vs. syringe).
- If the pharmacy calls requesting syringes instead of pens (with the same strength), or vice versa, update the quantity approval and the clinical approval, as applicable, to the requested GSN.

EGATEN® (TRICLABENDAZOLE)

Updated May 30, 2023

Length of Authorization:	60 days
Initiative:	PAR: Egaten (IE 2462 / NCPDP 75 – GSN, IE 15110 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of fascioliasis in patients 6 years of age and older

FDA-RECOMMENDED DOSE

- Two doses of 10 mg/kg given 12 hours apart (total of 20 mg/kg)
- Tablets may be divided in half; if dosage cannot be adjusted exactly, round dose upwards.

HOW SUPPLIED

250 mg tablets in blister packs of 4 tablets

UTILIZATION CRITERIA

For All Coverage Requests:

- The member has a diagnosis of fascioliasis

REQUIRED MEDICAL INFORMATION

Current member weight (kg).

AGE RESTRICTIONS

6 years of age or older

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

60 days

QUANTITY RESTRICTIONS

Approve quantity sufficient for a single day supply per the recommended dose (20 mg/kg), calculated based on provided weight, and rounding upwards to nearest package multiple (blister pack of 4 tablets cannot be split).

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

ELMIRON® (PENTOSAN POLYSULFATE SODIUM)

Updated: July 27, 2023

Length of Authorization:	Initial: 6 months; Continuation: 24 months
Initiative:	PAR: Elmiron (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the relief of bladder pain or discomfort associated with interstitial cystitis

FDA-RECOMMENDED STARTING DOSE

The recommended dose is 300 mg/day taken as one 100 mg capsule orally three times daily

HOW SUPPLIED

100 mg capsules in 100-count bottles.

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member must have a diagnosis of interstitial cystitis; **AND**
- The member must have been counseled on the risk of the potential risk for macular damage and vision-related injuries with pentosan polysulfate treatment; **AND**
- The member must have tried and failed or have a contraindication to, two of the following for pain relief
  - Tricyclic antidepressant (e.g., amitriptyline, nortriptyline)
  - Cimetidine
  - Hydroxyzine

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

16 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a urologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

- Initial: 6 months
- Continuation: 24 months

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

EMPAVELI™ (PEGCETACOPLAN)

Updated: April 2, 2024

Length of Authorization:	Initial: 6 months; Continuation: 12 months
Initiative:	PAR: EMPAVELI (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

FDA-RECOMMENDED DOSE

1,080 mg by subcutaneous infusion twice weekly via a commercially available infusion pump with a reservoir of at least 20 mL

HOW SUPPLIED

- 1,080 mg/20 mL (54 mg/mL) solution in 20 mL single-dose vials
- Pump and Infusion supplies supplied by manufacturer through Apellis Assist program

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by flow cytometry; **AND**
- The member has a hemoglobin < 10.5 g/dL within the last 60 days; **AND**
- The member has had at least 1 transfusion in the last year; **AND**
- The member will not concomitantly use with iptacopan (Fabhalta), eculizumab (Soliris) or ravulizumab (Ultomiris).

For Continuation Coverage Requests:

- The member will not concomitantly use with iptacopan (Fabhalta), eculizumab (Soliris) or ravulizumab (Ultomiris).
- The member has experienced a clinical response as shown by **one** of the following:
  - Stabilization of hemoglobin levels; **OR**
  - Reduction in number of transfusions required; **OR**
  - Normalization or decrease of LDH levels.

REQUIRED MEDICAL INFORMATION

- **Initial**: Hemoglobin levels, diagnosis documentation, transfusion numbers.
- **Continuation**: Hemoglobin levels, transfusion numbers, or LDH levels, as applicable.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a hematologist or nephrologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- **Initial**: 6 months.
- **Continuation**: 12 months.
- **See Quantity Restrictions** for quantity override duration.

QUANTITY RESTRICTIONS

- Refer to formulary for standard dose requests.
- A quantity limit override for requests of 1,080 mg infused every three days is permissible if the member has documentation of LDH levels greater than 2 times the upper limit of normal. Approve this quantity override for 3 months at a time.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

EMSAM® (SELEGILINE)

Updated June 29, 2023

Length of Authorization:	24 months
Initiative:	PAR: Emsam (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adults with major depressive disorder (MDD).

FDA-RECOMMENDED DOSE

6 mg per 24 hours. Selegiline has been systematically evaluated and shown to be effective in a dose range of 6 mg per 24 hours to 12 mg per 24 hours. However, the trials were not designed to assess if higher doses are more effective than the lowest effective dose of 6 mg per 24 hours.

HOW SUPPLIED

6 mg per 24 hours (20 mg per 20 cm^2), 9 mg per 24 hours (30 mg per 30 cm^2) and 12 mg per 24 hours (40 mg per 40 cm^2) transdermal systems (TDS).

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member must have a diagnosis of Major Depressive Disorder (MDD); **AND**
- The member must have tried and failed at least two antidepressants from different classes (e.g., SSRIs, TCAs, tetracyclics, SNRIs, modified cyclics, MAOIs).
- If the request is for 9 mg or 12 mg patches the following must be true:
  - The prescriber must be a psychiatrist; **AND**
  - The prescriber must attest that they are aware of the cardiovascular safety risk following ingestion of tyramine-rich foods.

For Continuation Coverage Requests:

- The member has had a positive clinical response to therapy, as documented by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

24 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

EMVERM® (MEBENDAZOLE)

Updated May 22, 2023

Length of Authorization:	Three months
Initiative:	PAR: Emverm (IE 2462 / NCPDP 75 – GSN, NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of patients two years of age and older with gastrointestinal infections caused by Ancylostoma duodenale (hookworm), Ascaris lumbricoides (roundworm), Enterobius vermicularis (pinworm), Necator americanus (hookworm), and Trichuris trichiura (whipworm)

FDA-RECOMMENDED DOSE

- Pinworm: One 100 mg tablet (total quantity of one)
- Hookworm, Roundworm, Whipworm: One 100 mg tablet twice daily for three days (total quantity of six)

HOW SUPPLIED

100 mg chewable tablets in 1-count blister packs

UTILIZATION CRITERIA

For All Coverage Requests:

- The member must be diagnosed with an intestinal worm of known morphology

REQUIRED MEDICAL INFORMATION

The type of intestinal worm (pinworm, hookworm, roundworm, whipworm) occupying member

AGE RESTRICTIONS

2 years of age and older.

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

Three months

QUANTITY RESTRICTIONS

- For pinworm: Limited to a quantity of one per fill. Enter PA with a metric quantity and days' supply of #1/fill.
- For hookworm, roundworm, and whipworm: Limited to a quantity of six per fill. Enter PA with metric quantity and days' supply of #6/fill.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

ENBREL® (ETANERCEPT)

Updated December 18 , 2023

Length of Authorization:	12 months
Initiative:	PAR: Enbrel (IE 2462 / NCPDP 75 – HICL) PAR: Loading Dose (IE 15110, 2641, 7001 / NCPDP 76 – HICL)

FDA-APPROVED INDICATION(S)

- For reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA)
- For reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients 2 years of age and older
- For reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (PsA)
- For reducing signs and symptoms in patients with active ankylosing spondylitis (AS)
- For the treatment of patients 4 years of age or older with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy

FDA-RECOMMENDED DOSE

- For RA, AS, and PsA: 50 mg once weekly
- For Adult PsO: 50 mg twice weekly for three months, following by 50 mg once weekly
- For Pediatric PsO, Pediatric PsA, or JIA:
  - ≥ 138 lb: 50 mg weekly
  - < 135 lb: 0.8 mg/kg weekly

HOW SUPPLIED

- 50 mg/mL as a single-dose prefilled syringe, SureClick autoinjector, and “Enbrel Mini” prefilled cartridge for use with the “AutoTouch” reusable autoinjector
- 25 mg/0.5 mL as a single-dose prefilled syringe
- 25 mg multiple dose vials for subcutaneous injection

UTILIZATION CRITERIA

FOR INITIAL REVIEW

- For all conditions:
  - The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)
- For Moderate-to-Severely Active RA:
  - The member has a diagnosis of moderate-to-severely active rheumatoid arthritis (RA); **AND**
  - The member has had a previous trial of or contraindication to at least one of the following:
    - Methotrexate
    - Leflunomide
    - Hydroxychloroquine
    - Sulfasalazine

- For Moderate-to-Severely Active PsA:
  - The member has a diagnosis of active psoriatic arthritis; **AND**
  - The member has had a previous trial of, or contraindication to, at least one of the following:
    - Methotrexate
    - Sulfasalazine
    - Cyclosporine
    - Leflunomide
- For Moderate-to-Severely Active Polyarticular JIA:
  - The member has a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (JIA); **AND**
  - The member has had a previous trial of or contraindication to at least one of the following:
    - Methotrexate
    - Leflunomide
    - Hydroxychloroquine
    - Sulfasalazine
- • For AS:
  - The member has a diagnosis of ankylosing spondylitis (AS); **AND**
  - The member has had a previous trial of at least **one**, or contraindication to **all**, of the following:
    - Nonsteroidal anti-inflammatory drugs (NSAIDs)
    - Methotrexate
    - Sulfasalazine
- For Plaque Psoriasis (PsO):
  - The member has a diagnosis of moderate-to-severe plaque psoriasis (PsO); **AND**
  - The member has psoriatic lesions that involve greater than or equal to 10% of body surface area (BSA), or that affect the palms, soles, head, neck, or genital area, leading to disability/impact on quality of life; **AND**
  - The member has had a previous trial of or contraindication to at least one of the following:
    - PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B)
    - Topical corticosteroids
    - Calcipotriene
    - Acitretin
    - Methotrexate
    - Cyclosporine

FOR CONTINUATION AND RENEWALS

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

REQUIRED MEDICAL INFORMATION

- Claims or medical records demonstrating use of previous therapies.
- For members treated for PsO: current BSA coverage of lesions.
- For Pediatric PsO, Pediatric PsA, or JIA diagnoses: current weight.

AGE RESTRICTIONS

- RA, PsA, AS: 18 years of age and older.

- JIA: 2 years of age and older.
- PsO: 4 years of age and older.

PRESCRIBER RESTRICTIONS

- RA, AS, JIA: Must be prescribed by or in consultation with a rheumatologist.
- PsA, PsO, or PsO with PsA: must be prescribed by or in consultation with a dermatologist or rheumatologist.

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

- For RA, JIA, AS, PsA, and Pediatric PsO:
  - Refer to formulary.
- For PsO:
  - Initial: approve a quantity override to permit 8 per 28 days (50 mg twice weekly) for the first three months.
  - Continuation: Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HSN

ENSPRYNG™ (SATRALIZUMAB)

Updated May 8, 2023

Length of Authorization:	12 months
Initiative:	PAR: Enspryng PAR: Loading Dose (IE 15110, 2641, 7001 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

FDA-RECOMMENDED DOSE

120 mg subcutaneously at weeks 0, 2, and 4, followed by a maintenance dosage of 120 mg every 4 weeks.

HOW SUPPLIED

Cartons of one single-dose 120 mg/mL prefilled syringe.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member must have the specific diagnosis of NMOSD; **AND**
- The member must be anti-aquaporin-4 (AQP4) antibody positive as confirmed with submitted test results.

FOR CONTINUATION COVERAGE REQUESTS

- The member has had a positive clinical response to therapy, as documented by the member's neurology provider.

REQUIRED MEDICAL INFORMATION

AQP4 positive test results.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by a neurologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY/PARTIAL-FILL RESTRICTIONS

- Loading dose: quantity limit override must be entered to allow an MDD 0.08 for the first fill.
  - Use initiative PAR: Loading Dose
  - Select CTI reason code: 2nd O/R for Existing PA Approved. No approval letter is sent with second PA.
- Maintenance dose: Refer to formulary.

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by GSN.

ENVARSUS XR® (TACROLIMUS EXTENDED-RELEASE TABLETS)

Updated August 21, 2023

Length of Authorization:	Five years
Initiative:	PAR: Envarsus XR (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the prophylaxis of organ rejection in kidney transplant patients in combination with other immunosuppressants.
- For the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations, in combination with other immunosuppressants.

FDA-RECOMMENDED DOSE

Dosed to tacrolimus trough concentration (ranges of 4 to 11 ng/mL). Refer to package insert for detailed dosing recommendations.

HOW SUPPLIED

0.75 mg, 1 mg, and 4 mg extended-release tablets in 30-count and 100-count bottles.

COVERAGE CRITERIA

For Coverage Requests:

- The member has tried one or more generic tacrolimus products; **AND**
- The member has failed to maintain stable tacrolimus trough concentrations on the generic product, as documented in the member's medical history.

REQUIRED MEDICAL INFORMATION

Medical history supportive of inability to maintain stable tacrolimus trough concentrations.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

Five years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

- Coverage requires documentation of failure to maintain consistent tacrolimus levels sufficient to maintain adequate immunosuppression for prophylaxis of organ rejection. Patient convenience and shortages of generic tacrolimus products are not covered indications.
- If the pharmacy or provider claims an inability to obtain generic tacrolimus products as the reason for the coverage request, please contact the plan for awareness and instruction on how to proceed with the review.
- Approve by HSN

EOHILIA® (BUDESONIDE ORAL SUSPENSION)

Updated: March 28, 2024

Length of Authorization:	12 weeks
Initiative:	PAR: Eohilia (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For 12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis (EoE).

FDA-RECOMMENDED DOSE

2 mg orally twice daily for 12 weeks.

HOW SUPPLIED

2 mg or 10 mL viscous suspension single-dose packs in 60-count carton.

COVERAGE CRITERIA

For Coverage Requests:

- The member has a documented diagnosis of EoE; **AND**
- The member has tried and failed dietary modifications; **AND**
- The member has tried and failed, or is contraindicated to, prepared budesonide oral suspension using nebulizer inhalation product.

For continuation coverage requests:

- The member must continue to receive benefit as attested to by their specialist provider.

REQUIRED MEDICAL INFORMATION

- Chart notes or medical records confirming diagnosis.
- Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

11 years of age and older.

PRESCRIBER RESTRICTIONS

Prescribed by, or in consultation with, an allergist or gastroenterologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 weeks

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

Approve by GSN

EPCLUSA® (VELPATASVIR AND SOFOSBUVIR)

Updated October 26, 2023

Length of Authorization:	If 24-week utilization criteria met: 24 weeks All others: 12 weeks
Initiative:	PAR: Epclusa (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult and pediatric patients 3 years and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection, with or without compensated cirrhosis, or with decompensated cirrhosis in combination with ribavirin

FDA-RECOMMENDED DOSE

- Adult dose: one 400 mg/100 mg tablet once daily.
- Pediatric dosing:

Body Weight (kg)	Velpatasvir/Sofosbuvir Dose
≥ 30 kg	400/100 mg once daily
17–30 kg	200/50 mg once daily
< 17 kg	150 mg/37.5 mg once daily

- Treatment duration: 12 weeks (guideline pathway to 24 weeks w/ decompensated cirrhosis ineligible for ribavirin)

HOW SUPPLIED

- Oral tablets available in 400/100 mg and 200/50 mg strengths supplied in 28-count bottles.
- Oral pellets available in 200/50 mg and 150/37.5 mg packets supplied in 28-count cartons (for pediatric patients).

UTILIZATION CRITERIA

For all coverage requests:

- The member has a diagnosis of HCV, with HCV RNA drawn and measured within the previous 6 months; **AND**
- The member has been evaluated to be absent of current alcohol or other substance abuse issues and has been advised/cautioned on such activities.
- Additional criteria if requesting 24 weeks of therapy:
  - The member is ribavirin ineligible; **AND**
  - The member has decompensated cirrhosis.

REQUIRED MEDICAL INFORMATION

HCV RNA viral load with date, cirrhosis status (if requesting 24 weeks).

AGE RESTRICTIONS

3 years of age or older

PRESCRIBER RESTRICTIONS

Must be prescribed by a gastroenterologist, hepatologist, or infectious disease specialist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION (MONTHS)

- If 24-week utilization criteria met: 24 weeks.
- All others: 12 weeks

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve by GSN.

EPIDIOLEX® (CANNABIDIOL)

Updated May 11, 2023

Length of Authorization:	3 months (initial); 12 months (continuation)
Initiative:	PAR: Epidiolex (IE 2462 / NCPDP 75 – HICL, IE 15110, 2641 / NCPDP 76)

FDA-APPROVED INDICATION(S)

For the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or tuberous sclerosis complex (TSC) in patients one year of age and older

FDA-RECOMMENDED DOSE

- Starting dose: 2.5 mg/kg by mouth twice daily
- Titration: 2.5 mg/kg twice daily each week (do not increase dose more frequently than every other day)
- Recommended dose:
  - LGS or DS: 5 mg/kg twice daily (max 10 mg/kg twice daily)
  - TSC: 12.5 mg/kg twice daily

HOW SUPPLIED

100 mg/mL (100 mL and 60 mL bottles) of cannabidiol, supplied in a child-resistant amber glass bottle. Supplied with two 5 mL oral syringes and a bottle adaptor.

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member has a confirmed diagnosis of Lennox-Gastaut Syndrome (LGS), Dravet Syndrome (DS), tuberous sclerosis complex (TSC); or treatment-resistant epilepsy; **AND**
- The member has tried and failed one or more antiepileptic drugs; **AND**
- The member will use cannabidiol as add-on therapy with one or more antiepileptic drugs; **AND**
- The member has obtained serum transaminases (ALT and AST) and total bilirubin levels prior to starting treatment.

For Continuation Requests:

- The member continues to tolerate and have a beneficial response to treatment, as attested to by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Member weight (kg)

AGE RESTRICTIONS

One year of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 3 months
- Continuation: 12 months

QUANTITY RESTRICTIONS

- Approve with quantity restriction calculated using the FDA-approved max dose per indication and the member's current weight + 10 kg. Round up to allow the nearest 100 mL multiple.

OPERATIONAL AND OTHER INFORMATION

Enter approval by HSN.

ERGOTAMINE DERIVATIVES (DIHYDROERGOTAMINE MESYLATE, ERGOTAMINE TARTRATE, AND ERGOTAMINE TARTRATE/CAFFEINE)

Updated: July 27, 2023

Length of Authorization: 12 months
Initiative: PAR: Ergotamines (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

See package inserts

FDA-RECOMMENDED DOSE

See package inserts

HOW SUPPLIED

See package inserts

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of vascular headache (e.g., migraine, migraine variants or so-called "histaminic cephalalgia"); **AND**
- The member has tried and failed two or more generic triptan products; **AND**
- The member must be receiving a level "A" or "B" prophylactic agent or a prophylactic CGRP inhibitor for the prevention of migraines, unless otherwise contraindicated.

Level A	Level B
• Valproic Acid/Divalproex Sodium • Topiramate • Propranolol • Timolol • Metoprolol • OnabotulinumtoxinA (Botox)	• Amitriptyline • Venlafaxine • Nadolol • Atenolol

FOR CONTINUATION COVERAGE REQUESTS

- The member has had a beneficial response to therapy as attested to by the prescribing provider; **AND**
- The member must be receiving a level "A" or "B" prophylactic agent or a prophylactic CGRP inhibitor for the prevention of migraines, unless otherwise contraindicated.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

- This criteria applies to the following HSNs: 000155, 001868, 001869.
- Approve by requested HSN.

ERIVEDGE® (VISMODEGIB)

Updated January 4, 2024

Length of Authorization:	5 years
Initiative:	PAR: Erivedge (IE 2462/NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery, or who are not candidates for surgery, and who are not candidates for radiation.

FDA-RECOMMENDED DOSE

150 mg taken orally once daily.

HOW SUPPLIED

150 mg capsules in 28-count bottles.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- For Skin Cancer:
  - The member has a diagnosis of metastatic or diffuse basal cell carcinoma (BCC); **OR**
  - The member has a diagnosis of locally advanced basal cell carcinoma; **AND**
  - One of the following is true for the member:
    - The member's cancer has recurred following surgery; **OR**
    - The member is not a candidate for surgery or radiation.
- For CNS Cancer:
  - The member has a diagnosis of medulloblastoma; **AND**
  - The member has experienced recurrence following prior systemic therapy; **AND**
  - The member will be using vismodegib as monotherapy.

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies as applicable to place in therapy

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by GSN.

ERLEADA® (APALUTAMIDE)

Updated February 13, 2024

Length of Authorization:	12 months
Initiative:	PAR: Erleada (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of patients with non-metastatic castration-resistant prostate cancer (NM-CRPC)
- For the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC)

FDA-RECOMMENDED STARTING DOSE

240 mg orally once daily; dosed concurrently with a gonadotropin-releasing hormone (GnRH) analog, or without in patients with a bilateral orchiectomy

HOW SUPPLIED

- 60 mg tablets in 120 count bottles
- 240 mg tablets in 30 count bottles

COVERAGE CRITERIA

For initial coverage requests:

- The member has a diagnosis of mCSPC or NM-CRPC; **AND**
- The member's treatment plan must not include concurrent use with alternative second-generation anti-androgens (e.g., abiraterone acetate); **AND**
- The member has undergone bilateral orchiectomy **or** will concurrently receive a GnRH analog

For continuation coverage requests:

- Confirmation that the member continues to have a beneficial response to therapy as assessed and documented by the member's specialist provider

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

ESBRIET® (PIRFENIDONE)

Updated November 17, 2023

Length of Authorization:	12 months
Initiative:	PAR: Esbriet (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of idiopathic pulmonary fibrosis (IPF)

FDA-RECOMMENDED DOSE

- Days 1 through 7: 267 mg three times daily (801 mg/day)
- Days 8 through 14: 534 mg three times daily (1602 mg/day)
- Days 15 onward: 801 mg three times daily (2403 mg/day)

HOW SUPPLIED

- 267 mg tablets and 267 mg capsules in 270-count bottles
- 801 mg tablets in 90-count bottles
- 534 mg tablets in generic only (not covered)

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a documented, confirmed diagnosis of IPF; **AND**
- The member does not have severe hepatic impairment (Child Pugh C); **AND**

For Continuation Coverage Requests:

- The member has experienced a positive clinical response as attested to by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Initial Requests: Documentation of diagnosis in medical records

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a pulmonologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve by HSN
- Pirfenidone 534 mg tablet (available only as the generic form) is not a covered product and should not be made payable by any authorization entered as a result of this PA.

ETRASIMOD (VELSIPITY)

Updated March 1, 2024

Length of Authorization:	12 months
Initiative:	PAR: Velsipity (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of moderately to severely active ulcerative colitis in adults.

FDA-RECOMMENDED DOSE

2 mg orally once daily

HOW SUPPLIED

2 mg tablets in 30-count bottles.

UTILIZATION CRITERIA

For initial coverage requests:

- The member has a diagnosis of moderate to severely active Ulcerative Colitis; **AND**
- The member has had a previous trial of, or contraindication to, at least one of the following:
  - Thiopurines (i.e., 6-mercaptopurine or azathioprine)
  - Corticosteroids; **OR**
- The member has tried and failed one or more previous biologic therapies (e.g., infliximab, certolizumab, vedolizumab, golimumab, ustekinumab, or natalizumab); **OR**
  - The member has had a previous trial of, or contraindication to, at least two of the following preferred agents:
    - Adalimumab
    - Stelara
    - Xeljanz; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib), or other potent immunosuppressives (e.g., azathioprine, cyclosporine).

For continuation coverage requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib), or other potent immunosuppressives (e.g., azathioprine, cyclosporine).

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by, or in consultation with, a gastroenterologist.

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

EUCRISA® (CRISABOROLE 2% OINTMENT)

Updated May 31, 2023

Length of Authorization: 2 years	
Initiative: PAR: Dermatological Agents (IE 31121 / NCPDP 608 – GSN)	

FDA-APPROVED INDICATION(S)

For topical treatment of mild to moderate atopic dermatitis in patients 3 months of age and older

FDA-RECOMMENDED DOSE

- Apply a thin layer twice daily to affected areas.
- Once clinical effect is achieved, consider reducing application to once daily.

HOW SUPPLIED

60 g and 100 g tubes

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of atopic dermatitis (eczema); **AND**
- The member has tried and failed, or is contraindicated to, at least one generic high-potency topical corticosteroid; **AND**
- The member has tried and failed two or more, or is contraindicated to all, generic topical corticosteroid products.
  - **Note:** High-potency topical corticosteroid from above counts towards this requirement.

FOR CONTINUATION COVERAGE REQUESTS

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

3 months of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a dermatologist or allergist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

2 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

EVRYSDI™ (RISDIPLAM)

Updated September 7, 2023

Length of Authorization: 12 months	
Initiative: PAR: Evrysdi (IE 2462 / NCPDP 75 – GSN; IE 2641, 15110 / NCPDP 60 – GSN)	

FDA-APPROVED INDICATION(S)

For the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

FDA-RECOMMENDED DOSE

Taken once daily. Recommended dosage is determined by age and body weight. Refer to table below.

Age and Body Weight	Recommended Daily Dosage
Less than 2 months of age	0.15 mg/kg
2 months to < 2 years of age	0.2 mg/kg
2 years of age and older weighing < 20 kg	0.25 mg/kg
2 years of age and older weighing ≥ 20 kg	5 mg

HOW SUPPLIED

60 mg/80 mL amber glass bottle containing powder for constitution

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a documented diagnosis of type 1, 2, or 3 SMA confirmed by genetic testing; **AND**
- The member has not been previously treated with nusinersen or onasemnogene abeparvovec-xioi; **AND**
- The member must not be fully ventilator dependent.

For Continuation Coverage Requests:

- The member has as improvement in motor function relative to the course of natural disease, as attested to by a member's neurologist or neuromuscular specialist.

REQUIRED MEDICAL INFORMATION

SMA classification.

AGE RESTRICTIONS

Ages 0 through 25 years

PRESCRIBER RESTRICTIONS

Must be prescribed by a neurologist or neuromuscular specialist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

EXKIVITY™ (MOBOCERTINIB)

Updated April 25, 2023

Length of Authorization:	5 years
Initiative:	PAR: Exkivity (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy

FDA-RECOMMENDED DOSE

160 mg (4 capsules) once daily

HOW SUPPLIED

40 mg capsules in 90 and 120-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of locally advanced or metastatic NSCLC; **AND**
- The member has an EGFR exon 20 insertion mutation as confirmed by an FDA-approved test.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's oncologist.

REQUIRED MEDICAL INFORMATION

FDA-approved test confirming presence of EGFR exon 20 insertion mutation

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

Approve by GSN

FABHALTA™ (IPTACOPAN)

Updated: April 1, 2024

Length of Authorization:	Initial: 6 months Continuation: 12 months
Initiative:	PAR: Fabhalta (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

FDA-RECOMMENDED DOSE

200 mg orally twice daily.

HOW SUPPLIED

200 mg capsules in 60-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by flow cytometry; **AND**
- The member has a hemoglobin < 10 g/dL within the last 60 days; **AND**
- The member has had at least 1 transfusion in the last year; **AND**
- The member will not concomitantly use with pegcetacoplan (Empaveli), eculizumab (Soliris), or ravulizumab (Ultomiris).

For Continuation Coverage Requests:

- The member is not concomitantly using with pegcetacoplan (Empaveli), eculizumab (Soliris), or ravulizumab (Ultomiris); **AND**
- The member has experienced a clinical response as shown by one of the following:
  - Stabilization of hemoglobin levels; **OR**
  - Reduction in number of transfusions required

REQUIRED MEDICAL INFORMATION

- **Initial**: Hemoglobin levels, diagnosis documentation, transfusion numbers.
- **Continuation**: Hemoglobin levels, transfusion numbers as applicable.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a hematologist or nephrologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- **Initial**: 6 months
- **Continuation**: 12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

Approve by GSN

FASENRA® (BENRALIZUMAB)

Updated August 3, 2023

Length of Authorization:	12 months
Initiative:	PAR: Fasenra (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

FDA-RECOMMENDED DOSE

30 mg subcutaneously every 4 weeks for the first 3 doses, followed by once every 8 weeks thereafter.

HOW SUPPLIED

30 mg/mL solution in a single-dose prefilled syringe (for administration by a healthcare provider) or autoinjector (for self-administration).

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a confirmed diagnosis of severe asthma; **AND**
- The member is currently utilizing a high-dose inhaled corticosteroid (ICS) product plus either a long-acting beta-2 agonist (LABA) or long-acting muscarinic antagonist (LAMA); **AND**
- The member has documentation of blood eosinophils greater than or equal to 150 cells/mcL measured within the preceding six weeks, **or** the member has been established on an alternative anti-IL-4/5 product (e.g., mepolizumab, reslizumab, dupilumab); **AND**
- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

FOR CONTINUATION COVERAGE REQUESTS

- The member has experienced a decrease in the frequency of exacerbations and improvement in symptoms, as attested to by the member's specialist provider; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

REQUIRED MEDICAL INFORMATION

Documentation of blood eosinophil count (cells/mcL) with date.

AGE RESTRICTIONS

12 years of age or older

PRESCRIBER RESTRICTIONS

Must be prescribed by an asthma specialist, allergist, or pulmonologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

OTHER INFORMATION

Members transitioning from medical benefit to the pharmacy benefit should be treated as a continuation of therapy requests.

FECAL MICROBIOTA SPORES, LIVE-BRPK (VOWST)

Updated July 25, 2024

Length of Authorization:	12 months
Initiative:	PAR: Vowst (IE 2462 / NCPDP 75 — GSN)

FDA-APPROVED INDICATION(S)

Indicated to "prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI."

FDA-RECOMMENDED DOSAGE

Four capsules by mouth once daily for three consecutive days.

HOW SUPPLIED

Capsules in 12-count bottles.

UTILIZATION CRITERIA

For initial coverage requests:

- The member has a diagnosis of recurrent CDI as evidenced by the following:
  - Positive stool test for C. difficile within the past 60 days; **AND**
  - ≥ 3 episodes of CDI within 12 months; **AND**
- The member will be using following resolution of most recent CDI episode for the prevention of recurrence (i.e., not for treatment); **AND**
- The member has failed two or more of the following alternative therapies for prevention of recurrent CDI:
  - Zinplava
  - Rebyota
  - FMT

REQUIRED MEDICAL INFORMATION

Confirmatory stool test results, chart notes documenting 3 episodes of CDI in most recent 12 months, and treatment plan (including resolution of antibiotic therapy prior to initiation of Vowst).

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an Infectious Disease or Gastroenterology specialist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

- Approve by GSN.
- Note the formulary quantity limit. The is only approvable once per 365 days.

FINTEPLA® (FENFLURAMINE)

Updated September 20, 2023

Length of Authorization: 12 months
Initiative: PAR: Fintepla (IE 2462 / NCPDP 75; IE 15110 / NCPDP 76 – GSN)

FDA-APPROVED INDICATIONS

For the treatment of seizures associated with Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older

FDA-RECOMMENDED DOSE

- Initial: 0.1 mg/kg twice daily; may increase based on response and tolerability after 7 days to 0.2 mg/kg twice daily; and increased even further after another 7 days to 0.35 mg/kg twice daily (0.2 mg/kg twice daily if taking concomitant stiripentol and clobazam).
- Maximum dose: 26 mg/day, 17 mg/day with concomitant stiripentol and clobazam.

HOW SUPPLIED

Oral solution: 2.2 mg/mL (30 mL or 360 mL bottle)

COVERAGE CRITERIA

INITIAL COVERAGE REQUESTS

- The member has seizures associated with clinically diagnosed Dravet syndrome or Lennox-Gastaut syndrome; **AND**
- The member has inadequate seizure control despite optimized therapy with at least two other anticonvulsant medications; **AND**
- The member has a normal echocardiogram (i.e., no valvular heart disease or pulmonary arterial hypertension).

CONTINUATION COVERAGE REQUESTS

The member continues to tolerate and have a beneficial response to treatment, as attested to by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- The member's current weight (kg)
- Claims or medical records demonstrating use of previous therapies

AGE RESTRICTIONS

2 years of age or older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

- Approvable quantity must be limited to the FDA-approved weight-based dosing per treatment plan with concurrent medications. Plan approval is required if the member requires more than one 360 mL bottle to fill up to a 30-day supply.
- When calculating restriction for pediatric patients, add 10 kg to the member's current weight to allow for growth during their approval cycle.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

FIRAZYR® (ICATIBANT)

Updated May 26, 2023

Length of Authorization:	60 days
Initiative:	PAR: Firazyr (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

FDA-RECOMMENDED DOSE

- 30 mg administered by subcutaneous (SC) injection
- No more than 3 doses may be administered in any 24-hour period

HOW SUPPLIED

30 mg single-use, prefilled syringe

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member must have confirmatory diagnosis of HAE due to C1 inhibitor deficiency (HAE-1 or HAE-2), including confirmation of low C4 levels and low functional C1 inhibitor (C1-INH) activity; **AND**
- The member is not using therapy in combination with other approved treatments for acute HAE attacks (e.g., recombinant C1-INH, ecallantide); **AND**
- The prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from acute attack therapy with icatibant; **AND**
- The prescriber attests that the member is not concurrently taking any medications that may exacerbate HAE (e.g., ACE inhibitors, estrogens).

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy as assessed and documented by the member's specialist provider; **AND**
- The quantity on hand for the member is not greater than two syringes.

REQUIRED MEDICAL INFORMATION

For initial reviews, confirmatory diagnosis of HAE, including C1-INH and C4 levels with date drawn.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an immunologist, allergist, or hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

60 days

QUANTITY RESTRICTIONS

- Refer to formulary.
- Limit to one fill per approval.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

FIRDAPSE® AND RUZURGI (AMIFAMPRIDINE)

Updated: August 2, 2023

Length of Authorization: 12 months	
Initiative: PAR: Amifampridine (IE 2462 / NCPDP 75 – GSN; IE 15110, 2641 / NCPDP 76 – GSN)	

FDA-APPROVED INDICATION(S)

- For the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults and pediatric patients 6 years of age or older.

FDA-RECOMMENDED DOSE

- 15 mg to 80 mg daily in three to four divided doses, not to exceed 20 mg per dose.

HOW SUPPLIED

- 10 mg functionally-scored tablets in 10-count blister packs, and 60-count and 240-count bottles.

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a confirmed diagnosis of LEMS, **AND**
  - The member has clinical symptoms of muscle weakness, autonomic dysfunction, and decreased tendon reflexes, **AND**
  - The member's diagnosis is confirmed via Repetitive Nerve Stimulation (RNS) testing showing a reproducible post-exercise increase in compound muscle compared with pre-exercise baseline value, or via voltage-gated calcium channel (VGCC) antibody testing.

FOR CONTINUATION COVERAGE REQUESTS

- The member continues to tolerate and have a beneficial response to treatment, as attested to by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- Documentation of test results confirming the diagnosis of LEMS
- Member weight

AGE RESTRICTIONS

6 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist or oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS AND ADDITIONAL INFORMATION

Approve by HSN.

FLUOXETINE TABLETS

Updated: November 29, 2023

Length of Authorization:	5 years
Initiative:	PAR: Fluoxetine Tablets (IE 2462 / NCPDP 75, IE 2194 / NCPDP 60 – GSN) EXC: Non-Formulary Product (IE 50076 / NCPDP 70 – GSN, IE 50084 / NCPDP 78 – GSN)

POLICY OVERVIEW

The University of Michigan Prescription Drug Plan covers fluoxetine capsules without any extra criteria. Fluoxetine tablets require prior authorization using this criteria set for coverage determinations due to high relative cost and clinical similarity to the capsules.

FDA-APPROVED INDICATION(S)

For the treatment of Major Depressive Disorder, obsessions, and compulsions in patients with obsessive compulsive disorder, binge-eating and vomiting behaviors in patients with moderate to severe Bulimia Nervosa, and panic disorder, with or without agoraphobia

FDA-RECOMMENDED DOSE

20 mg to 80 mg orally once daily

HOW SUPPLIED

10 mg, 20 mg, and 60 mg tablets

COVERAGE CRITERIA

For all tablet-formulation coverage reviews:

- The member is unable to tolerate the capsule formulations of fluoxetine, as attested to by the member's provider; **OR**
- The member is currently established on a 5 mg-incremental dose (e.g., 15 mg once daily), accomplished by splitting one 10 mg tablet into two 5 mg half tablets, and modification to the currently established 5 mg-incremental dose may result in serious behavioral risks, such as harm to oneself or others, as attested to by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

Coverage of 10 mg fluoxetine tablets, up to a quantity of three tablets per day, does not require prior authorization for members 18 years of age and younger

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

- Refer to formulary quantity limits.
- If approved for incremental dosing, approval for fluoxetine 10 mg tablets should be entered at the GSN level with a maximum daily dose of 0.5 tablets per day.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

FOTIVDA® (TIVOZANIB)

Updated March 24, 2023

Length of Authorization:	5 years
Initiative:	PAR: Fotivda (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

The treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies.

FDA RECOMMENDED DOSE

1.34 mg orally once daily for 21 days followed by 7 days off treatment.

HOW SUPPLIED

1.34 mg or 0.89 mg capsules (bottles of 21).

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of relapsed/refractory RCC; **AND**
- The member has received at least two prior systemic therapies.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies as applicable to place in therapy.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by GSN.

FUROSCIX® (FUROSEMIDE SUBCUTANEOUS ON-BODY KIT)

Updated: February 1, 2024

Length of Authorization:	1 month
Initiative:	PAR: Furoscix (IE 2462/NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of congestion due to fluid overload in adult patients with New York Heart Association (NYHA) Class II and Class III chronic heart failure.

FDA-RECOMMENDED DOSE

The single-use, On-Body Infusor with prefilled cartridge is pre-programmed to deliver 30 mg of furosemide over the first hour followed by 12.5 mg per hour for the subsequent 4 hours (i.e., 80 mg per infusion).

HOW SUPPLIED

Carton containing one 80 mg/10 mL prefilled cartridge co-packaged with one On-Body Infusor

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of New York Heart Association (NYHA) Class II and Class III chronic heart failure with congestion due to fluid overload; **AND**
- The member is on background loop therapy.

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of background loop therapy.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a cardiologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

1 month

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

FRUZAQLA (FRUQUINTINIB) FUROSCIX® (FUROSEMIDE SUBCUTANEOUS ON-BODY KIT)

Updated: January 29, 2024

Length of Authorization:	5 years
Initiative:	PAR: Fruzaqla (IE 2462/NCPDP 75 – HSN)

FDA-APPROVED INDICATION(S)

The treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy.

FDA-RECOMMENDED DOSE

5 mg orally once daily for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity. First dose reduction: 4 mg orally once daily. Second dose reduction is 3 mg orally once daily. Permanently discontinue in patients unable to tolerate 3 mg orally once daily.

HOW SUPPLIED

5 mg and 1 mg capsules in 21-count bottle.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS:

- The member has a diagnosis of advanced or metastatic colorectal cancer; **AND**
- The member has been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy.

FOR CONTINUATION COVERAGE REQUESTS:

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approvals should be entered at the HSN level.

GALAFOLD™ (MIGALASTAT)

Updated: August 18, 2023

Length of Authorization:	12 months
Initiative:	PAR: Galafold (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data

FDA-RECOMMENDED DOSE

123 mg (one capsule) orally once every other day

HOW SUPPLIED

123 mg capsules in 14-count wallet packs

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a confirmed diagnosis of Fabry disease with documentation of a GLA variant with migalastat susceptibility (refer to list of variants in the product's package insert); **AND**
- Member is NOT receiving, or plans to receive, concurrent enzyme replacement therapy (e.g., Fabrazyme).

FOR CONTINUATION COVERAGE REQUESTS

- The member has a documented response, as attested to by the member's specialist provider(s); **AND**
- The member is NOT receiving, or plans to receive, concurrent enzyme replacement therapy (i.e., Fabrazyme).

REQUIRED MEDICAL INFORMATION

Chart notes or medical records demonstrating GLA variant with migalastat susceptibility.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a physician who specializes in medical genetics and/or Fabry Disease

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

12 months

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES

N/A

GAVRETO™ (PRALSETINIB)

Updated May 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Gavreto (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients with metastatic rearranged during transfection (RET)-fusion positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test.
- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy.
- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)

FDA-RECOMMENDED STARTING DOSE

400 mg orally once daily.

HOW SUPPLIED

100 mg capsules in 60-count and 90, and 120-count bottles.

UTILIZATION CRITERIA

For initial coverage requests:

- **Thyroid Carcinoma:**
  - The member has a documented diagnosis of papillary **or** follicular **or** Hurthle Cell carcinoma; **AND**
  - The member has unresectable locoregional recurrent, persistent, or metastatic disease not amenable to radioactive iodine; **AND**
  - The member's disease is RET-fusion mutation positive.
- **Medullary Carcinoma:**
  - The member has a documented diagnosis of medullary carcinoma that is RET mutation-positive.
- **Anaplastic Carcinoma:**
  - The member has a documented diagnosis of anaplastic carcinoma that is RET mutation-positive; **AND**
  - Used as a single agent for one of the following:
    - Neoadjuvant therapy for borderline resectable stage IVA or IVB (locoregional) disease
    - First or second-line therapy for stage IVC (metastatic) disease
- **Non-Small Cell Lung Cancer (NSCLC):**
  - The member has a documented diagnosis of NSCLC that is RET mutation-positive.

For continuation coverage requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's oncologist.

REQUIRED MEDICAL INFORMATION

RET-fusion test results.

AGE RESTRICTIONS

12 years of age or older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary quantity limits.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

GILOTRIF® (AFATINIB)

Updated February 13, 2024

Length of Authorization:	5 years
Initiative:	PAR: Gilotrif (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test
- For the treatment of patients with metastatic squamous NSCLC progressing after platinum-based chemotherapy

FDA-RECOMMENDED DOSE

40 mg orally, once daily

HOW SUPPLIED

20 mg, 30 mg, and 40 mg tablets in 30-count bottles.

UTILIZATION CRITERIA

For initial coverage review:

- Member must have a diagnosis of NSCLC; **AND**
- The member meets one of the following clinical scenarios:
  - The member must have a documented EGFR mutation susceptible to afatinib. Acceptable mutations include:
    - Exon 19 deletion/insertion
    - Exon 18 (G719X)
    - Exon 20 (S768I)
    - Exon 21 (L858R)
    - Exon 21 (L861Q); **OR**
  - The member has metastatic squamous NSCLC progressing after platinum-based chemotherapy.

For continuation coverage requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- Documentation of EGFR mutation status as applicable.
- Claims or medical records demonstrating use of previous therapies (as applicable).

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years.

QUANTITY RESTRICTIONS

Follow formulary quantity limits

OPERATIONAL NOTES AND OTHER INFORMATION

Enter approval by HICL.

GLP-1 AGONISTS (TYPE II DIABETES): TRULICITY® (DULAGLUTIDE); VICTOZA® (LIRAGLUTIDE); BYETTA®, BYDUREON BCISE® (EXENATIDE); OZEMPIC®, RYBELSUS® (SEMAGLUTIDE), MOUNJARO™ (TIRZEPATIDE)

Updated: January 1, 2024

Length of Authorization:	5 years
Initiative:	PAR: GLP-1 Agonists: GSN (IE 2462 / NCPDP 75) (IE 31121 / NCPDP 608)– UOMGLP1DL) (list-level initiative for Victoza, Ozempic, Rybelsus, and Mounjaro) PAR: GLP-1 Agonists: HSN (IE 2462 / NCPDP 75 – HICL) (for Trulicity, Byetta, Bydureon)

POLICY AND PRODUCT INFORMATION

- GLP-1 agonists indicated for the management of type II diabetes mellitus in adults are covered for adults with type II diabetes mellitus.
- An electronic step may bypass PA criteria for preferred GLP-1 agents:
  - The electronic step requires a diagnosis of type II diabetes.
- If the electronic step criteria is not met, then use criteria below.
  - **Note**: GLP-1 agonists indicated to manage obesity are not included in this guideline. Reference 'Weight Loss' for products indicated for weight loss (i.e., liraglutide and semaglutide).

FDA-APPROVED INDICATION(S)

Dulaglutide, liraglutide, exenatide, exenatide microspheres, semaglutide, and tirzepatide are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

FDA-RECOMMENDED DOSE

Various—refer to package inserts.

HOW SUPPLIED

Various—refer to package inserts.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

The member has a documented diagnosis of type II diabetes mellitus.

FOR CONTINUATION COVERAGE REQUESTS

The member continues to benefit from treatment with the GLP-1 agonist, as attested to by the member's treating provider.

REQUIRED MEDICAL INFORMATION

- Documentation of diagnosis

AGE RESTRICTIONS

- Refer to formulary.

PRESCRIBER RESTRICTIONS

N/A

REVIEWER RESTRICTIONS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

Five years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

- All products should be entered at the HSN level to allow for different strengths and dosage forms except for Liraglutide (Victoza) and semaglutide (Ozempic, Rybelsus), which should be entered by GSN if needed.
- The member's use of drug samples does not meet the criteria for having been established on therapy and does not count towards tried and failed medications.
- Continuation requests that were approved by a previous or secondary insurer, or for members who are new to the current plan, should be reviewed as initial requests.
- Coverage of concurrent use of multiple GLP-1/GIP inhibitors is not permitted. Once approval for the current requested agent is finalized, term previous agent's approval.
- STP: GLP-1 Agonists (IE 31121 / NCPDP 608 - HICL) still active but not in general use
- STP: Rybelsus (IE 31121 / NCPDP 608 – GSN) still active but not in general use

GROWTH HORMONE (SOMATROPIN, SOMATROGON, SOMAPACITAN, AND LONAPEGSOMATROPIN)

Updated: April 1, 2024

Length of Authorization:	12 months
Initiative:	PAR: Growth Hormone Preferred (List Level: UOMGHPDL – Omnitrope, Genotropin) PAR: Growth Hormone Non-Preferred (List Level: UOMGHNPDL)

POLICY AND PRODUCT INFORMATION

This policy applies to formulary somatropin products, somapacitan, somatrogon, and lonapegsomatropin. For all members, Omnitrope,Genotropin, and Genotropin Miniquick are the preferred growth hormone products.

FDA-APPROVED INDICATION(S)

See package insert.

FDA-RECOMMENDED DOSE

See package insert.

HOW SUPPLIED

See package insert.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- For all members, Omnitrope, Genotropin, and Genotropin Miniquick are the preferred growth hormone products. All requests for other non-preferred products must trial and fail Omnitrope **or** Genotropin/Genotropin Miniquick.
- Pediatric patients (< 18 years of age):
- Member must have epiphyses open, as confirmed by wrist film or other evaluation and **one** of the following diagnoses:
  - Member must have a diagnosis of chronic renal failure and growth retardation; **OR**
  - Member must have a diagnosis of short stature homeobox gene (SHOX) deficiency; **OR**
  - Member must have a diagnosis of Turner Syndrome, Noonan Syndrome, or Prader-Willi Syndrome; **OR**
  - Member must have diagnosis of idiopathic short stature and meet the following criteria:
    - The patient has a height less than or equal to -2.25 standard deviations (SD) below the corresponding mean height for age and sex; **AND**
    - The patient has been evaluated for and does not have a diagnosis of constitutional delay of growth and puberty (CDGP); **AND**
    - One of the following:
      - The patient has a predicted adult height that is below the normal range; **AND**
      - **One** of the following:
        - The patient's sex is male and predicted adult height is less than 63 inches; **OR**
        - The patient's sex is female and predicted adult height is less than 59 inches; **OR**
        - The patient is more than 2 SD below their mid-parental target height; **OR**
    - Member must have a diagnosis of small for gestational age (SGA) and meet the following criteria:
    - The patient is 2 years of age or older; **AND**

        - The patient has a documented birth weight and/or birth length that is 2 or more standard deviations (SD) below the mean for gestational age; **AND**
        - At 24 months of age, the patient failed to manifest catch-up growth evidenced by a height that remains 2 or more standard deviations (SD) below the mean for age and sex; **OR**
    - Member must have a diagnosis of growth hormone (GH) deficiency and meet the following criteria:
        - Documented failure of at least one GH stimulation test (defined as a peak growth hormone level of less than 10mcg/L after GH stimulation by insulin, arginine, clonidine, glucagon, or levodopa); **AND**
        - One of the following:
            - Height is > 2 standard deviations below the mean for age and sex; **OR**
            - Growth velocity is subnormal; **OR**
            - Bone age is delayed
- Adult patients (18 years of age and older):
    - Member must have a diagnosis of HIV and an unintentional weight loss of 10% over 12 months or a BMI < 18.5; **OR**
    - Member must have a diagnosis of documented GH deficiency and have failed two GH stimulation tests; **OR**
    - Member must have a diagnosis of Short Bowel Syndrome; **AND**
        - Member is currently receiving specialized nutrition support directed by a healthcare professional (Total Parenteral Nutrition (TPN), Peripheral Parenteral Nutrition (PPN), or high-complex carbohydrate, low-fat diet) and maintaining appropriate daily caloric intake requirements.For Continuation Coverage Requests
- Pediatric patients (< 18 years of age):
    - Confirmation that the member continues to have a beneficial response to therapy as assessed and documented by the member's specialist provider; **AND**
    - Growth velocity is 2 cm/year or more.
- Adult patients (18 years of age and older):
    - Confirmation that the member continues to have a beneficial response to therapy as assessed and documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- For initial reviews, current height, weight, and lab results confirming diagnosis, as applicable
- For continuation requests: current height and weight.

AGE RESTRICTIONS

- Somatropin or Somapacitan: 2 years of age and older
- Somatrogon: 3–17 years of age.
- Lonapegsomatropin: 1–17 years of age.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an endocrinologist or pediatric nephrologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

N/A

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve by List Level
  - PAR: Growth Hormone Preferred (List Level: UOMGHPDL – Omnitrope, Genotropin)
  - PAR: Growth Hormone Non-Preferred (List Level: UOMGHNPDL)

HAEGARDA® (HUMAN C1 – ESTERASE INHIBITOR)

Updated May 25, 2023

Length of Authorization:	6 month (initial), 12 month (continuation)
Initiative:	PAR: Haegarda (IE 2462 / NCPDP 75 – GSN; IE 2641, 15110 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

For the routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in patients 6 years of age and older.

FDA-RECOMMENDED DOSE

60 International Units (IU) per kg body weight by subcutaneous (S.C.) injection twice weekly (every 3 or 4 days)

HOW SUPPLIED

2000 and 3000 IU vials of lyophilized powder for reconstitution

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member must have confirmatory diagnosis of HAE due to C1 inhibitor deficiency (HAE-1 or HAE-2), including confirmation of low C4 levels and low functional C1 inhibitor (C1-INH) activity; **AND**
- The member is not receiving concurrent prophylactic medications for HAE (i.e., lanadelumab, berotralstat); **AND**
- The prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy; **AND**
- The prescriber attests that the member is not concurrently taking any medications that may exacerbate HAE (e.g., ACE inhibitors, estrogens).

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy as assessed and documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- For all requests: Current body weight
- For initial requests: confirmatory diagnosis of HAE, including C1-INH and C4 levels with date drawn.

AGE RESTRICTIONS

6 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an immunologist, allergist, or hematologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Approvals should be limited to 60 IU/kg per 3 days.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

HARVONI® (LEDIPASVIR AND SOFOSBUVIR)

Updated October 23, 2023

Length of Authorization:	Treatment-Naïve members without cirrhosis, and HCV RNA less than 6 million IU/mL: 8 weeks All others: 12 weeks
Initiative:	PAR: Harvoni (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of chronic hepatitis C virus (HCV) in adults and pediatric patients 3 years of age and older:
  - Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis
  - Genotype 1 infection with decompensated cirrhosis, in combination with ribavirin
  - Genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin

FDA-RECOMMENDED DOSE

- One ledipasvir 90 mg/sofosbuvir 400 mg tablet daily for adults.
- For pediatric patients 3 years of age and older:

Body Weight (kg)	Dosing	Daily Dose
≥ 35	One 90 mg/400 mg tablet or Two 45 mg/200 mg tablets or Two 45 mg/200 mg packets	90 mg/400 mg once daily
17 to < 35	One 45 mg/200 mg tablet or One 45 mg/200 mg packet	45 mg/200 mg once daily
< 17	One 33.75 mg/150 mg packet	33.75 mg/150 mg once daily

- Treatment Duration
  - 8 weeks: treatment naïve genotype 1 without cirrhosis, and HCV RNA less than 6 million IU/mL
  - 24 weeks: treatment experienced genotype 1 with compensated cirrhosis (Child-Pugh A)
    - 12 weeks can be considered with ribavirin.
  - 12 weeks: all other eligible populations

HOW SUPPLIED

- Tablets: ledipasvir 90 mg/ sofosbuvir 400 mg tablets and ledipasvir 45 mg/ sofosbuvir 200mg tablets are supplied in 28-count bottles.
- Oral pellets: ledipasvir 45 mg/ sofosbuvir 200 mg pellets and ledipasvir 33.75 mg/ sofosbuvir 150 mg pellets are supplied in cartons, each containing 28 packets.

UTILIZATION CRITERIA

All Coverage Requests:

- Member has a diagnosis of HCV Genotype 1, 4, 5, or 6, with HCV RNA drawn and measured within the previous 6 months; **AND**
- Member has been evaluated to be absent of current alcohol or other substance abuse issues, and has been advised/cautioned on such activities; **AND**
- Member does not have documentation of decompensated cirrhosis (Child-Pugh B, C).
- Additional criteria for pellet packs
  - The member is 10 years of age or younger; **OR**
  - The member has a documented difficulty in swallowing or dysphagia or requires tube feeding.

REQUIRED MEDICAL INFORMATION

- HCV RNA viral load with date
- HCV Genotype
- Previous treatment history
- Child-Pugh Score

AGE RESTRICTIONS

Member must be 3 years of age or older

PRESCRIBER RESTRICTIONS

Must be prescribed by a gastroenterologist, hepatologist, or infectious disease specialist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION (MONTHS)

- Treatment-naïve members without cirrhosis, and HCV RNA less than 6 million IU/mL: 8 weeks
- All others: 12 weeks

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve by GSN.
- Coverage in the setting of decompensated cirrhosis is disallowed due more cost effective, guideline recommended options at place in therapy (e.g., sofosbuvir/velpatasvir).

HEMATOPOIETIC AGENTS (EPOETIN ALFA, DARBEPOETIN, EPOETIN BETA)

Updated May 11, 2023

Length of Authorization:	3 months
Initiative:	PAR: Hematopoietic Agents (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

Various, refer to specific package inserts

FDA-RECOMMENDED STARTING DOSE

Various, refer to specific package inserts

HOW SUPPLIED

- Darbepoetin (Aranesp):
  - Vials of 25 mcg/mL, 40 mcg/mL, 60 mcg/mL, 100 mcg/mL, 200 mcg/mL, 300 mcg/mL
  - Syringes of 10 mcg/0.4 mL, 25 mcg/0.42 mL, 40 mcg/0.4 mL, 60 mcg/0.3 mL, 100 mcg/0.5 mL, 150 mcg/0.3 mL, 200 mcg/0.4 mL, 300 mcg/0.6 mL, 500 mcg/1 mL
- Epoetin alfa (Epogen, Procrit, Retacrit):
  - Vials of 2,000 units/mL, 3,000 units/mL, 4,000 units/mL, 10,000 units/mL, 20,000 units/mL, 40,000 units/mL
- Epoetin beta (Mircera):
  - Syringes of 30 mcg/0.3 mL, 50 mcg/0.3 mL, 75 mcg/0.3 mL, 100 mcg/0.3 mL, 120 mcg/0.3 mL, 150 mcg/0.3 mL, 200 mcg/0.3 mL, 250 mcg/0.3 mL, 360 mcg/0.6 mL

UTILIZATION CRITERIA

For All Coverage Requests:

- The member has a diagnosis of anemia; **AND**
- The member must have a pre-treatment Hgb less than or equal to 10 g/dL, documented within the previous 30 days of the next anticipated dose; **OR**
- The member must have an on-treatment Hgb less than or equal to 12 g/dL, documented within the previous 30 days of the next anticipated dose; **AND**
- Retacrit and Aranesp are the preferred products. All requests for other non-preferred products must trial and fail Retacrit and Aranesp if requested for a shared indication.

REQUIRED MEDICAL INFORMATION

Complete blood count with differential, with date

AGE RESTRICTIONS

None

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist, hematologist, or nephrologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

3 months

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

HEMLIBRA® (EMICIZUMAB)

Updated May 10, 2023

Length of Authorization: 12 months	
Initiative: PAR: Hemlibra (IE 2462 / NCPDP 75 – HICL; IE 2641, 15110 / NCPDP 76 – GSN)	

FDA-APPROVED INDICATION(S)

For routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors.

FDA-RECOMMENDED DOSE

- 3 mg/kg subcutaneously once weekly for the first four weeks, followed by a maintenance dose of:
  - 1.5 mg/kg weekly; **OR**
  - 3 mg/kg every two weeks; **OR**
  - 6 mg/kg every four weeks

HOW SUPPLIED

30 mg/1 mL, 60 mg/0.4 mL, 105 mg/0.7 mL, and 150 mg/1 mL single-dose vials

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of hemophilia A (congenital factor VIII deficiency); **AND**
- The member is not planning to receive concurrent bypassing agent (i.e., aPCC, Feiba).

For Continuation Coverage Requests:

- The member has had a positive response to therapy, as documented by the member's specialty provider; **AND**
- The member is not planning to receive concurrent bypassing agent (i.e., aPCC, Feiba).

REQUIRED MEDICAL INFORMATION

- Treatment history
- Member weight (kg).

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by a hematologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Approval is limited to 28-day supply with a maximum dose of 3 mg/kg per week in the first four weeks, followed by a maximum of 1.5 mg/kg per week thereafter. When calculating restriction, add 10 kg to the member's current weight to allow for growth during their approval cycle.

- Enter a PA (days 1–28) with a metric quantity and days' supply sufficient for 3 mg/kg per week x 28 days, THEN
- Enter a PA (days 29–365) with a metric quantity and days' supply sufficient for 1.5 mg/kg per week thereafter.

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by HICL.

HUMIRA® (ADALIMUMAB) AND BIOSIMILARS

Updated December 18, 2023

Length of Authorization:	For members with Ulcerative Colitis, the initial coverage will be for 3 months, followed by 12 months for continuation For all other indications, 12 months
Initiative:	PAR: Adalimumab (list level) PAR: Adalimumab: HC Quantity Limit (list level) PAR Adalimumab: LC Quantity Limit (list level) PAR: Humira (IE 2462 / NCPDP 75 – HICL; IE 2193 / NCPDP 60 – HICL) PAR: Humira Quantity Limit (IE 15110, 2641, 7001 / NCPDP 76 – HICL)

FDA-APPROVED INDICATION(S)

- For reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active Rheumatoid Arthritis (RA)
- For reducing signs and symptoms of moderately to severely active polyarticular Juvenile Idiopathic Arthritis (JIA) in pediatric patients 2 years of age and older
- For reducing signs and symptoms, inhibiting the progression of structural damage, and improving commensurately physical function in adult patients with active Psoriatic Arthritis (PsA)
- For reducing signs and symptoms in adult patients with active Ankylosing Spondylitis (AS)
- For reducing signs and symptoms and inducing and maintaining clinical remission in adult and pediatric patients, 6 years of age and older, with moderately to severely active Crohn's Disease (CD) who have had an inadequate response to conventional therapy
- For inducing and sustaining clinical remission in adult and pediatric patients with moderately to severely active ulcerative colitis (UC).
- For the treatment of adult patients with moderate to severe chronic plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate
- For the treatment of moderate to severe hidradenitis suppurativa (HS) in patients 12 years of age and older
- For the treatment of non-infectious intermediate, posterior and pan-uveitis in adults and pediatric patients 2 years of age and older

FDA-RECOMMENDED DOSE

- Table 1: approved adalimumab regimens per indication

Adult Indications	Induction (Days 0–28)	Maintenance (Days 29+)
RA, PsA, and AS	N/A	40 mg QOW; may increase to 40 mg QW or 80 mg QOW in RA
Adult CD, UC	160 mg day 1, 80 mg day 15	40 mg QOW
PsO, Uveitis	80 mg day 1, 40 mg day 8	40 mg QOW
HS	160 mg day 1, 80 mg day 15	40 mg QW or 80 mg QOW

- QW: once weekly
- QOW: once every other week

Pediatric Indications	Induction (Days 0–28)	Maintenance (Days 29+)
JIA, Uveitis (≥ age 2)	N/A	22–33 lbs.: 10 mg QOW 33–66 lbs.: 20 mg QOW > 66 lbs.: 40 mg QOW
CD (≥ age 6)	37–88 lbs.: 80 mg day 1, 40 mg day 15	37–88 lbs.: 20 mg QOW

Pediatric Indications	Induction (Days 0–28)	Maintenance (Days 29+)
	≥ 88 lbs.: adult CD dosing	≥ 88 lbs.: 40 mg QOW
UC (≥ 5 years)	44–88 lbs.: 80 mg day 1, 40 mg day 8, 15 ≥ 88 lbs.: 160 mg day 1, 80 mg day 8, 15	44–88 lbs.: 40 mg QOW or 20 mg QW ≥ 88 lbs.: 80 mg QOW or 40 mg QW
HS (≥ age 12)	66–132 lbs.: 80 mg day 1, 40 mg day 8 ≥ 132 lbs.: adult HS dosing	66–132 lbs.: 40 mg QOW ≥ 132 lbs.: Adult HS dosing

- QW: once weekly
- QOW: once every other week

HOW SUPPLIED

Refer to package inserts

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REVIEWS (NOTE QUANTITY RESTRICTIONS PER INDICATION)

- **For all Conditions:**
  - For all requests exceeding the FDA-approved maintenance dose, the member must have documentation of persistent symptomatology or lack of remission after three or more months of the initial maintenance regimen; **AND**
  - The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib).
- **Moderate to Severe Rheumatoid Arthritis (RA) and Juvenile Idiopathic Arthritis (JIA):**
  - The member has a diagnosis of moderate to severe Rheumatoid Arthritis or Juvenile Idiopathic Arthritis; **AND**
  - The member has had a previous trial of or contraindication to at least one of the following:
    - Methotrexate
    - Leflunomide
    - Hydroxychloroquine
    - Sulfasalazine
- **Psoriatic Arthritis (PsA):**
  - The member has a diagnosis of active psoriatic arthritis; **AND**
  - The member has had a previous trial of, or contraindication to, at least one of the following:
    - Methotrexate
    - Sulfasalazine
    - Cyclosporine
    - Leflunomide
- **Ankylosing Spondylitis (AS):**
  - The member has a diagnosis of Ankylosing Spondylitis; **AND**
  - The member has had a previous trial of at least **one**, or contraindication to **all**, of the following:
    - Nonsteroidal anti-inflammatory drugs (NSAIDs)
    - Methotrexate
    - Sulfasalazine

- **Plaque Psoriasis (PsO):**
  - The member has a diagnosis of moderate-to-severe PsO; **AND**
  - The member has psoriatic lesions that involve greater than or equal to 10% of body surface area (BSA), or that affect the palms, soles, head, neck, or genitalia area, leading to disability/impact on quality of life; **AND**
  - The member has had a previous trial of or contraindication to at least one of the following:
    - PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B)
    - Topical corticosteroids
    - Calcipotriene
    - Acitretin
    - Methotrexate
    - Cyclosporine
- **Crohn's Disease (CD):**
  - Member has a diagnosis of moderately to severely active CD; **AND**
  - The member has had a previous trial of or contraindication to at least one of the following:
    - Thiopurines (i.e., 6-mercaptopurine or azathioprine)
    - Corticosteroids
    - Methotrexate; **OR**
  - The member has tried and failed one or more previous biologic therapies (e.g., risankizumab, infliximab, certolizumab, vedolizumab, golimumab, ustekinumab, or natalizumab).
- **Ulcerative Colitis (UC):**
  - The member has a diagnosis of moderate to severely active UC; **AND**
  - The member has had a previous trial of or contraindication to at least one of the following:
    - Thiopurines (e.g., 6-mercaptopurine or azathioprine)
    - Corticosteroids; **OR**
  - The member has tried and failed one or more previous biologic therapies (e.g., infliximab, certolizumab, vedolizumab, golimumab, ustekinumab, or natalizumab).
- **Hidradenitis Suppurativa:**
  - The member's hidradenitis suppurativa diagnosis severity is Hurley Stage II–III; **AND**
  - The member has failed to show significant improvement with systemic antibiotic therapy of at least 3 months in duration
- **Uveitis:**
  - The member has a diagnosis of uveitis; **AND**
  - The member does not have a diagnosis of isolated anterior uveitis.

FOR CONTINUATION COVERAGE REQUESTS

- For all indications: the member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)
- Review of therapy by the respective specialist confirms that the member continues to have a beneficial response to therapy at the member's current dose.
- For dose increases to 40 mg once-weekly: after three or more months of maintenance therapy at 40 mg every-other week, the member continues to have symptoms related to the indicated disease, or has inflammatory markers (i.e., elevated C-reactive protein) suggesting continued inflammation.
- For Ulcerative Colitis: member must have evidence of clinical remission by week 8 of adalimumab therapy.

REQUIRED MEDICAL INFORMATION

- Current weight (required only for members less than 18 years of age)
- For members treated for PsO: current BSA coverage of lesions.
- Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

- RA, PsA, AS, PsO: 18 years of age and older.
- JIA, Uveitis: 2 years of age and older.
- HS: 12 years of age and older.
- CD: 6 years of age and older.
- UC: 5 years of age and older.

PRESCRIBER RESTRICTIONS

- RA, JIA, AS: must be prescribed by or in consultation with a rheumatologist.
- HS: must be prescribed by or in consultation with a dermatologist.
- PsA, PsO or PsO with PsA: Must be prescribed by or in consultation with a dermatologist or rheumatologist.
- CD, UC: must be prescribed by or in consultation with a gastroenterologist.
- Uveitis: must be prescribed by or in consultation with an ophthalmologist or rheumatologist.

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

- For members with ulcerative colitis: three months (initial), 12 months (continuation)
- For all other indications: 12 months

QUANTITY/PARTIAL-FILL RESTRICTIONS

- For all increased maintenance requests, the member must have documentation of remaining symptoms or lack of remission per clinical markers after three or more months of the initial maintenance regimen, unless the member has previously been established on the higher dose and decreasing the dose would put the member at risk of relapse or flare
- Internal note:
  - For loading doses, maintenance doses, and increased maintenance doses above the formulary limit, enter second PA with metric quantity and days' supply to allow dosing listed in the below table.
    - For Humira: use initiative PAR: Humira Quantity Limit
    - For Biosimilars: create two different QL initiatives and place as approved
    - PAR: Adalimumab: HC Quantity Limit
    - PAR Adalimumab: LC Quantity Limit
    - For loading doses, select CTI reason code: 2nd O/R for Existing PA Approved. No approval letter is sent with loading dose PA.

HUMIRA — all strengths			
Indication	**Loading Dose, Initial Induction (New Starts Only); 28 days**	**Maintenance; 12 months***	**Increased Maintenance Request; 12 months**
RA, PsA, and AS	N/A	Qty. #2/28 days	Qty. #4/28 days
JIA	N/A	Qty. #2/28 days	N/A
Adult CD, UC	Qty. #6/28 days	Qty. #2/28 days	Qty. #4/28 days
Pediatric CD	< 88 lbs.: Qty. #3/28 days > 87 lbs.: Qty. #6/28 days	Qty. #2/28 days	Qty. #4/28 days
Pediatric UC	<88 lbs.: Qty. #4/28 days >87 lbs.: Qty. #8/28 days	Qty. #4/28 days	N/A
PsO, Uveitis	Qty. #4/28 days	Qty. #2/28 days	N/A
HS	Qty. #6/28 days	Qty. #4/28 days	N/A

- ***Members with Ulcerative Colitis and new to treatment are limited to an initial maintenance period of 3 months, followed by 12-months if continuation criteria are met**

BIOSIMILARS — 40 mg						
Indication	**Loading Dose, Initial Induction (New Starts Only); 28 days** **PA needed for LD Quantity†**		**Maintenance; 12 months*** **No PA for Quantity unless noted**		**Increased Maintenance Request; 12 months (i.e., weekly)** **PA needed for Quantity**	
	HC	LC	HC	LC	HC	LC
RA, PsA, and AS	N/A	N/A	#0.8/28 days	#1.6/28 days	#2/28 days	#4/28 days
JIA	N/A	N/A	#0.8/28 days	#1.6/28 days	N/A	N/A
Adult CD, UC	#2.4/28 days	#4.8/28 days	#0.8/28 days	#1.6/28 days	#2/28 days	#4/28 days
Pediatric CD	< 88 lbs.: #1.2/28 days	< 88 lbs.: #2.4/28 days	#0.8/28 days	#1.6/28 days	#2/28 days	#4/28 days
	> 87 lbs.: #2.4/28 days	> 87 lbs.: #4.8/28 days				
Pediatric UC	< 88 lbs.: #1.6/28 days > 87 lbs.: #3.2/28 days	<88 lbs.: #3.2/28 days > 87 lbs.: #6.4/28 days	#2/28 days *PA for qty needed*	#4/28 days *PA for qty needed*	N/A	N/A
PsO, Uveitis	#1.6/28 days	#3.2/28 days	#0.8/28 days	#1.6/28 days	N/A	N/A
HS	#2.4/28 days	#4.8/28 days	#2/28 days *PA for qty needed*	#4/28 days *PA for qty needed*	N/A	N/A

***HC = PAR: Adalimumab: HC Quantity Limit**

***LC = PAR: Adalimumab: LC Quantity Limit**

***Members with Ulcerative Colitis and new to treatment are limited to an initial maintenance period of 3 months, followed by 12-months if continuation criteria are met.**

†Override for appropriate quantity as either “each” or “mL” based on what the pharmacy is processing. If there is no rejected claim to reference, place the loading dose QL PA for “each”.

BIOSIMILARS – 80 mg (when a patient needs 2 injections of 40 mg)						
Indication	**Loading Dose, Initial Induction (New Starts Only); 28 days PA needed for LD Quantity†**		**Maintenance; 12 months* PA needed for Quantity**		**Increased Maintenance Request; 12 months (i.e., weekly) PA needed for Quantity**	
	HC	**LC**	**HC**	**LC**	**HC**	**LC**
RA, PsA, and AS	N/A	N/A	#2/28 days	#4/28 days	#4/28 days	#8/28 days
JIA	N/A	N/A	#2/28 days	#4/28 days	N/A	N/A
Adult CD, UC	#4.8/28 days	#9.6/28 days	#2/28 days	#4/28 days	#4/28 days	#8/28 days
Pediatric CD	< 88 lbs.: #2.4/28 days	< 88 lbs.: #4.8/28 days	#2/28 days	#4/28 days	#4/28 days	#8/28 days
	> 87 lbs.: #4.8/28 days	> 87 lbs.: #9.6/28 days				
Pediatric UC	< 88 lbs.: #3.2/28 days > 87 lbs.: #6.4/28 days	< 88 lbs.: #6.4/28 days > 87 lbs.: #12.8/28 days	#4/28 days	#8/28 days	N/A	N/A
PsO, Uveitis	#3.2/28 days	#6.4/28 days	#2/28 days	#4/28 days	N/A	N/A
HS	#4.8/28 days	#9.6/28 days	#4/28 days	#8/28 days	N/A	N/A

***HC = PAR: Adalimumab: HC Quantity Limit**

***LC = PAR: Adalimumab: LC Quantity Limit**

***Members with Ulcerative Colitis and new to treatment are limited to an initial maintenance period of 3 months, followed by 12-months if continuation criteria are met.**

†Override for appropriate quantity as either "each" or "mL" based on what the pharmacy is processing. If there is no rejected claim to reference, place the loading dose QL PA for "each".

OPERATIONAL NOTES/OTHER INFORMATION

- Unless clearly and specifically indicated to be for Brand Humira, all requests should be reviewed as a request for a biosimilar agent.
  - Change request to **Amjevita**, approve or deny using normal process. Prep the PA using GSN: 085225.
  - If needed, duplicate, and place any loading dose or quantity approvals using **milliliters for biosimilars**.
  - If approved, fax back message to provider: This PA approval will apply to all covered adalimumab biosimilars.
- For quantity limit requests for Amjevita or other biosimilars:
  - Create two different QL initiatives below and place as appropriate. These will be approved and closed as 2nd override for existing PA.
  - High concentration PA: PAR Adalimumab: HC Quantity Limit
    - For weekly dosing of 40 mg—lock in 2/28 days
    - For weekly dosing of 80 mg—lock in 4/28 days
  - Low concentration PA: PAR Adalimumab: LC Quantity Limit

    - For **weekly** dosing of 40 mg—lock in 4/28 days
    - For **weekly** dosing of 80 mg—lock in 8/28 days
- When approving, use canned fax back "Approval: QUANTITY LIMIT," and enter in the quantity and days' supply that was approved
- Approve by HICL.
- Approve only covered biosimilar HSN's with each approval.
- All Humira and other non-formulary or excluded brand requests are to be converted to the biosimilar initiative, unless they are non-formulary requests submitted for review against the non-formulary policy.

IBRANCE® (PALBOCICLIB)

Updated May 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Ibrance (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, advanced, or metastatic breast cancer in combination with the following:
  - An aromatase inhibitor as initial endocrine-based therapy; **OR**
  - Fulvestrant in patients with disease progression following endocrine therapy.

FDA-RECOMMENDED DOSE

125 mg once daily taken with food for 21 days followed by 7 days off treatment.

HOW SUPPLIED

125 mg, 100 mg, 75 mg tablets and capsules in 21-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- Breast cancer:
  - The member has a diagnosis of breast cancer; **AND**
  - The member has HR-positive, HER2-negative disease; **AND**
  - The member's condition is described as advanced or metastatic; **AND**
  - The member meets one of the following descriptions:
    - Postmenopausal female; **OR**
    - Premenopausal female treated with ovarian ablation or suppression; **OR**
    - Male undergoing concomitant suppression of testicular steroidogenesis; **AND**
  - The member takes the medication in combination with fulvestrant or an aromatase inhibitor.
- Well-differentiated or dedifferentiated liposarcoma (WD-DDLS):
  - The member has a diagnosis of unresectable WD-DDLS of the retroperitoneum.

For Continuation Coverage Requests:

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Genetic testing confirming HR-positive and HER2-negative status

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approve by HSN

ICLUSIG® (PONATINIB)

Updated May 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Iclusig (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients with chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior kinase inhibitors.
- For the treatment of adult patients with accelerated phase (AP) or blast phase (BP) CML or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom no other kinase inhibitors are indicated.
- For the treatment of adult patients with T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL).

FDA-RECOMMENDED DOSE

45 mg administered orally once daily

HOW SUPPLIED

- 10, 15, 30, and 45 mg capsules in 30-count bottles
- 15 mg capsules in 60-count bottles

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member meets one of the following clinical scenarios:
  - Scenario 1:
    - The member has a diagnosis of chronic, accelerated, or blast phase T3151-positive chronic myeloid leukemia (CML).
  - Scenario 2:
    - The member has a diagnosis of Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL).
  - Scenario 3:
    - The member has chronic phase myeloid/lymphoid neoplasms with eosinophilia; **AND**
    - The member has either FGFR1 or ABL1 rearrangements.
  - Scenario 4:
    - The member has a diagnosis of Chronic phase, CML; **AND**
    - The member has tried and failed at least two prior kinase inhibitors.
  - Scenario 5:
    - The member has a diagnosis of accelerated or blast phase CML; **AND**
    - No other tyrosine kinase inhibitors are indicated for their diagnosis.

For Continuation Coverage Requests:

- Member has had a positive clinical response to therapy, as documented by the member's oncologist provider.

REQUIRED MEDICAL INFORMATION

Documentation of mutation status as applicable for diagnosis

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist

REVIEWER REQUIREMENTS

Must be reviewed by a pharmacist

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by HICL.

IDHIFA® (ENASIDENIB)

Updated April 13, 2023

Length of Authorization:	5 years
Initiative:	PAR: Idhifa (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) who have a specific genetic Isocitrate dehydrogenase-2 (IDH2) mutation

FDA-RECOMMENDED DOSE

100 mg orally once daily

HOW SUPPLIED

50 mg and 100 mg tablets in 30-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of AML; **AND**
- The member has a documented IDH2 mutation as detected by an FDA-approved test.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Medical records or chart notes supporting IDH2 mutation status

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

IMBRUVICA® (IBRUTINIB)

Updated January 17, 2024

Length of Authorization:	5 years
Initiative:	PAR: Imbruvica (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) with or without 17p deletion
- For the treatment of adult patients with Waldenström's macroglobulinemia (WM)
- For the treatment of adult and pediatric patients ages 1 year and older with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.

FDA-RECOMMENDED DOSE

- CLL/SLL/WM: 420 mg orally once daily
- cGVHD:
  - 2 years of age and older: 420 mg orally once daily
  - 1 to less than 12 years of age: 240 mg/m^2 orally once daily (up to a dose of 420 mg)

HOW SUPPLIED

- 70 mg capsules in 28-count bottles
- 140 mg capsules in 90- and 120-count bottles
- 140 mg, 280 mg, 420 mg, tablets in folded blister cards each containing two 14-count blister strips
- 70 mg/mL suspension in 108 mL bottles

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of mantle cell lymphoma; **AND**
- The member meets one of the following clinical scenarios:
  - The member has received at least one prior line of therapy for their indication; **OR**
  - The member is using Ibrutinib in combination with rituximab as pretreatment for RHyperCVAD regimen optimization; **OR**
- The member has a diagnosis of one of the following:
  - Chronic lymphocytic leukemia; **OR**
  - Small lymphocytic lymphoma; **OR**
  - Waldenström's macroglobulinemia/Lymphoplasmacytic lymphoma; **OR**
- The member has a diagnosis of one of the following:
  - Histologic transformation to diffuse large B-cell lymphoma; **OR**
  - Post-transplant lymphoproliferative disorders; **OR**
  - Gastric MALT lymphoma; **OR**
  - Nongastric MALT lymphoma; **OR**
  - Diffuse large B-cell lymphoma (non-GCB DLBCL and non-candidate for transplant); **OR**
  - AIDS-related B-cell lymphoma; **OR**
  - High-grade B-cell lymphoma; **OR**

- Follicular lymphoma (grade 1–2); **OR**
- Hairy cell leukemia; **OR**
- Nodal or splenic marginal zone lymphoma (MZL); **AND**

- The member has received at least one prior line of therapy for their indication**; OR**
- The member has a diagnosis of primary CNS lymphoma; **AND**
- The member meets one of the following clinical scenarios:
  - The member has received at least one prior line of therapy for their indication; **OR**
  - The member is using as an induction therapy if patient is unsuitable or intolerant to high dose methotrexate; **OR**
- The member has a diagnosis of chronic graft versus host disease; **AND**
- The member has tried and failed at least one other systemic therapy for the indication.

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies as applicable to place in therapy

AGE RESTRICTIONS

- cGVHD: 1 year of age and older
- All other indications: 18 years of age and older

PRESCRIBER RESTRICTIONS

- For cGVHD: Must be prescribed by or in consultation with a transplant specialist, oncologist, or hematologist
- All other indications: Must be prescribed by or in consultation with an oncologist or hematologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by HSN

IMCIVREE™ (SETMELANOTIDE)

Updated: July 21, 2023

Length of Authorization:	Initial: 16 weeks Continuation: 12 months
Initiative:	PAR: Imcivree (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to:
  - Pro-opiomelanocortin (POMC), pro-protein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) gene deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance; **OR**
  - Bardet-Biedl syndrome (BBS).

FDA-RECOMMENDED DOSE

- Adults and pediatrics 12 years and older: initial dosing is 2 mg (0.2 mL) subcutaneously once daily for 2 weeks. May increase dose to 3 mg (0.3 mL) once daily if additional weight loss is desired and if tolerated.
- Pediatrics 6 to less than 12 years of age: initial dosing is 1 mg (0.1 mL) subcutaneously once daily for 2 weeks. May increase to 2 mg (0.2 mL) or 3 mg (0.3 mL) once daily if additional weight loss is desired and if tolerated.

HOW SUPPLIED

10 mg/mL solution in a 1 mL multidose vial.

UTILIZATION CRITERIA

For Initial Coverage Requests

- The member has a diagnosis of:
  - BBS; **OR**
  - POMC, PCSK1, or LEPR gene deficiency obesity, confirmed by genetic testing; **AND**
  - The member's genetic variant is interpreted as pathogenic, likely pathogenic, or of uncertain significance; **AND**
- The member has obesity defined as:
  - Adult patients: BMI ≥ 30 kg/m^2; **OR**
  - Pediatric patients: BMI ≥ 95th percentile using growth chart assessments

For Continuation Coverage Requests After First 16 Weeks of Treatment

- The member has not experienced any adverse effects from the medication; **AND**
  - The member has lost ≥ 5% of baseline body weight; **OR**
  - The member has lost ≥ 5% of baseline BMI.

For Continuation Coverage Requests After at Least 12 months of Treatment

- The member has at least maintained weight loss or reduction in BMI; **AND**
- The member has not experienced any adverse effects from the medication.

REQUIRED MEDICAL INFORMATION

- Initial Requests:
  - Documentation of BBS or POMC, PCSK1, or LEPR gene deficiency.
  - Baseline (pre-treatment) body weight or BMI.
- Continuation Requests:
  - Current body weight or BMI

AGE RESTRICTIONS

6 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an endocrinologist, a geneticist, or a physician who specializes in metabolic disorders

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 16 weeks
- Continuation: 12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

IMPAVIDO® (MILTEFOSINE)

Updated May 10, 2023

Length of Authorization:	60 days
Initiative:	PAR: Impavido (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of visceral *Leishmania donovani*, cutaneous *Leishmania braziliensis, guyanensis*, and *panamensis*; and mucosal *Leishmania panamensis* in adults and adolescents ≥ 12 years of age weighing ≥ 30 kg.

FDA-RECOMMENDED DOSE

- Patients 30 to 44 kg: 50 mg twice daily for 28 days
- Patients ≥ 45 kg: 50 mg three times daily for 28 days

HOW SUPPLIED

50 mg capsules on 14-count blister cards

UTILIZATION CRITERIA

For All Coverage Requests:

- Member must have a confirmed diagnosis of one of the following:
  - Visceral Leishmania donovani
  - Cutaneous Leishmania braziliensis, guyanensis, or panamensis
  - Mucosal Leishmania panamensis
  - Amebic meningoencephalitis

REQUIRED MEDICAL INFORMATION

- Member weight (kg)
- Confirmation of leishmaniasis infection or amebic meningoencephalitis, including the subsequent Centers for Disease Control and Prevention (CDC) pathology report

AGE RESTRICTIONS

12 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an infectious disease specialist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

60 days

QUANTITY RESTRICTIONS

Max 28 days per treatment course

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

INBRIJA™ (LEVODOPA INHALATION POWDER)

Updated July 28, 2023

Length of Authorization:	12 months
Initiative:	PAR: Inbrija (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the intermittent treatment of "off" episodes in people with Parkinson's disease taking carbidopa/levodopa

FDA-RECOMMENDED DOSE

Two 42 mg capsules (84 mg) via oral inhalation up to five times daily as needed for symptomatic management of "off" period

HOW SUPPLIED

Capsules containing 42 mg dry powder in 60-count and 92-count blister packs

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of Parkinson's disease; **AND**
- The member is currently receiving a carbidopa/levodopa formulation; **AND**
- The member has tried and failed one or more of the following "off" period management strategies:
  - Add-on therapy with a dopamine agonist (i.e., pramipexole, ropinirole, rotigotine)
  - Add-on therapy with an MAO-B inhibitor (i.e., rasagiline, selegiline, safinamide)
  - Add-on therapy with a COMT inhibitor (i.e., entacapone, tolcapone)
  - Extended-release carbidopa/levodopa
  - Modifications or alterations to carbidopa/levodopa dose scheduling

FOR CONTINUATION COVERAGE REQUESTS

The member continues to require on-demand treatment for "off" periods and has a beneficial response to treatment, as attested to by the member's specialist provider

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age or older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

12 months

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

INCRELEX® (MECASERMIN)

Updated: October 25, , 2023

Length of Authorization:	12 months
Initiative:	PAR: Increlex (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of growth failure in pediatric patients 2 years of age and older with the following:
  - Severe primary insulin-Like Growth Factor (IGF-1) deficiency; **OR**
  - Growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.

FDA-RECOMMENDED DOSE

The recommended starting dose is 0.04 to 0.08 mg/kg (40 to 80 micrograms/kg) twice daily by subcutaneous injection. If well-tolerated for at least one week, the dose may be increased by 0.04 mg/kg per dose, to the maximum dose of 0.12 mg/kg given twice daily.

HOW SUPPLIED

10 mg/mL solution in 4 mL multi-dose vials.

COVERAGE CRITERIA

For Initial Coverage Requests:

- GH deletion with neutralizing antibodies:
  - The member has a growth hormone gene deletion and neutralizing antibodies to growth hormone; **AND**
  - The member's epiphyses are open as confirmed by provider evaluation; **AND**
  - The member has been evaluated for other causes of growth failure; **AND**
  - The member or caregiver has been educated on how to monitor blood glucose levels, received a glucometer and necessary testing supplies, and demonstrated knowledge of blood glucose monitoring and hypoglycemia management.
- IGF-1 deficiency:
  - The member has a diagnosis of severe primary IGF deficiency, as evidenced by all of the following:
    - Height standard deviation score of less than or equal to -3.0; **AND**
    - Basal IGF-1 standard deviation score of less than or equal to -3.0; **AND**
    - Normal or elevated growth hormone (GH); **AND**
  - The member's epiphyses are open as confirmed by provider evaluation; **AND**
  - The member has been evaluated for other causes of growth failure; **AND**
  - The member or caregiver has been educated on how to monitor blood glucose levels, received a glucometer and necessary testing supplies, and demonstrated knowledge of blood glucose monitoring and hypoglycemia management.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Chart note documentation of diagnosis parameters listed above.

AGE RESTRICTIONS

- 2 years of age minimum
- 18 years of age maximum

PRESCRIBER RESTRICTIONS

Must be prescribed by a pediatric endocrinologist or other growth disorder specialist

REVIEWER REQUIREMENTS

Requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION INSTRUCTIONS AND OTHER INFORMATION

- Approve by GSN.
- Not renewable for continuation past 18 years of age.

INDOMETHACIN SUPPOSITORY (INDOCIN)

Updated: July 25, 2023

Length of Authorization:	12 months
Initiative:	PAR: Indomethacin Suppository (IE 2464 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- Moderate to severe rheumatoid arthritis including acute flares of chronic disease.
- Moderate to severe ankylosing spondylitis.
- Moderate to severe osteoarthritis.
- Acute painful shoulder (bursitis and/or tendinitis).
- Acute gouty arthritis.

FDA-RECOMMENDED DOSE

Refer to FDA label.

HOW SUPPLIED

50 mg rectal suppository in 30-count box.

COVERAGE CRITERIA

For initial coverage requests:

- The member has an FDA-approved diagnosis; **AND**
- The member has tried and failed ALL formulary alternatives; **AND**
- If indication is for RA or AS, the member will be receiving concomitant disease modifying therapy.

For continuation coverage requests:

- The member has had a beneficial response to therapy as attested to by the prescribing provider; **AND**
- If indication is for RA or AS, the member will be receiving concomitant disease modifying therapy.

REQUIRED MEDICAL INFORMATION

Claims records or chart note documentation of trialed agents and concomitant therapy (if applicable)

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

INFERTILITY DRUGS (FOLLITROPIN BETA, FOLLITROPIN ALFA, MENOTROPINS, CHORIONIC GONADOTROPIN [HCG], GANIRELIX, CETRORELIX)

Updated: November 15, 2023

Length of Authorization:	2 years
Initiative:	PAR: Infertility Agents (IE 2462 / NCPDP 75 – HICL; IE 2192 / NCPDP 61 – HICL; IE 2194 / NCPDP 60 – HICL) STP: Infertility Agents (IE 31121 / NCPDP 608 – GSN) – see internal note below

POLICY AND PRODUCT INFORMATION

Coverage for injectable infertility medications requires a prior authorization for males of all ages and females 45 years of age and older.

UTILIZATION CRITERIA

For women aged 45 years and older:

- For follitropins (follitropin beta and alfa), menotropins, and hCG:
  - Infertility is not due to primary ovarian failure; **AND**
  - Treatment is used as part of an assisted reproductive technology (ART) program; **AND**
  - If request is for medication other than hCG, the treatment will be used in conjunction with hCG.
- For ganirelix, cetrorelix:
  - The member is undergoing controlled ovarian stimulation.

For males aged 4 years and older:

- The request is for chorionic gonadotropin (hCG); **AND**
- The member has a diagnosis of prepubertal cryptorchidism not caused by anatomic obstruction; **AND**
- The member does not have a diagnosis of precocious puberty.

For males aged 18 years and older:

- The request is for a follitropin (follitropin beta or alfa), menotropin, or hCG; **AND**
- The member has a diagnosis of infertility and hypogonadotropic hypogonadism; **AND**
- The member does not have a diagnosis of primary testicular failure.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

See “Utilization Criteria”

PRESCRIBER RESTRICTIONS

Must be prescribed by an endocrinologist or reproductive specialist.

REVIEWER REQUIREMENTS

All coverage requests must be review by a licensed pharmacist or physician.

COVERAGE DURATION

2 years

QUANTITY RESTRICTIONS

- Follitropin beta, follitron alfa: Max dose of 450 IU/day.
- Menotropins: Maximum dose of 225 IU/day.
- hCG: Max quantity of 36,000 USP units/30 days.
- Cetrorelix acetate, ganirelix acetate: Max dose of 0.25 mg/day.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve all requests by HSN.

Internal notes:

- Brand name medications included in this policy (for males of all ages and females 45 years of age and older) are Follistim® AQ, Gonal-F®, Gonal-F® RFF, Gonal-F® RFF REDI-JECT, Menopur®, Novarel®, Ovidrel®, Pregnyl®, and Cetrotide®.
- Apply the Step Therapy Clinical Policy for all requests with a ST requirement. **In addition**, apply the Infertility Clinical Policy for males of all ages and females 45 years of age and older.

INGREZZA® (VALBENAZINE)

Updated August 23, 2023

Length of Authorization:	Five years
Initiative:	PAR: Ingrezza (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of adults with:

- Tardive dyskinesia
- Chorea associated with Huntington's disease

FDA-RECOMMENDED DOSE

- Tardive dyskinesia: The initial dose is 40 mg once daily. After one week, increase the dose to the recommended dose of 80 mg once daily. Continuation of 40 mg once daily may be considered for some patients.
- Chorea associated with Huntington's disease: The initial dosage is 40 mg once daily. Increase the dose in 20 mg increments every two weeks to the recommended dosage of 80 mg once daily.

HOW SUPPLIED

- 40 mg, 60 mg, and 80 mg capsules in bottles of 30 capsules.
- 28-day initiation pack containing: 7 x 40 mg and 21 x 80 mg capsules.

COVERAGE CRITERIA

FOR ALL COVERAGE REQUESTS

- For tardive dyskinesia:
  - The member has a diagnosis of tardive dyskinesia; **AND**
  - The member must have experienced the tardive dyskinesia for longer than 3 months (chronic); **AND**
  - The member must have either failed or cannot tolerate withdrawal of dopamine antagonists; **AND**
  - The member must have been using antipsychotic medications or dopamine D2 antagonists for at least 3 months (or at least 1 month if patient is 60 years of age or older) as documented in the prescription claims history or chart notes; **AND**
  - The member must not be taking concurrent VMAT2 inhibitor
- For chorea associated with Huntington's disease:
  - The member has a diagnosis of chorea associated with Huntington's disease; **AND**
  - The member must not be taking concurrent VMAT2 inhibitor.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist, movement disorder specialist, or psychiatrist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

Five years

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS AND ADDITIONAL INFORMATION

Approve by HSN

INHALED CORTICOSTEROIDS

Updated February 20, 2024

Length of Authorization:	5 years
Initiative:	PAR: Inhaled corticosteroids: 2462 (IE 2462 / NCPDP 75 – HICL)

INHALED CORTICOSTEROID PRODUCTS

- Ciclesonide (Alvesco®)
- Mometasone furoate (Asmanex® HFA)
- Mometasone furoate (Asmanex® Twisthaler®)

FDA-APPROVED INDICATION(S)

For the maintenance treatment of asthma as prophylactic therapy in adult and adolescent patients 12 years of age and older (Alvesco®), 5 years of age and older (Asmanex® HFA), or 4 years of age and older (Asmanex® Twisthaler®).

FDA-RECOMMENDED DOSE

Various, refer to package inserts.

HOW SUPPLIED

Various, refer to package inserts.

UTILIZATION CRITERIA

Initial Coverage Requests

- For mometasone furoate (Asmanex HFA/Twisthaler):
  - The member has therapeutic failure of **two** preferred inhalers
    - Beclomethasone (QVAR)
    - Budesonide (Pulmicort Flexhaler)
    - Fluticasone furoate (Arnuity); **OR**
    - Fluticasone propionate (Flovent Diskus/HFA)
- For ciclesonide (Alvesco):
  - The member has therapeutic failure of **one** preferred inhaler
    - Beclomethasone (QVAR)
    - Budesonide (Pulmicort Flexhaler)
    - Fluticasone furoate (Arnuity); **OR**
    - Fluticasone propionate (Flovent Diskus/HFA)

Continuation Coverage Requests

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies or intolerance.

AGE RESTRICTIONS

- Alvesco® HFA: 12 years of age and older.
- Asmanex® HFA: 5 years of age and older.
- Asmanex® Twisthaler®: 4 years of age and older.

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by HSN.

INLYTA® (AXITINIB)

Updated January 17, 2024

Length of Authorization:	5 years
Initiative:	PAR: Inlyta (2462/75 HICL)

FDA-APPROVED INDICATION(S)

- In combination with avelumab for the first-line treatment of patients with advanced renal cell carcinoma (RCC).
- In combination with pembrolizumab for the first-line treatment of patients with advanced RCC.
- As a single agent for the treatment of advanced RCC after failure of one prior systemic therapy.

FDA-RECOMMENDED DOSE

Recommended starting dose: 5 mg twice daily

HOW SUPPLIED

1 mg and 5 mg tablets in 180-count and 60-count bottles, respectively.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of advanced RCC; **AND**
  - The member will be receiving axitinib as a single agent; **OR**
  - The member will be receiving axitinib in combination with pembrolizumab**; OR**
- The member has a diagnosis of alveolar soft part sarcoma (ASPS) and is also receiving pembrolizumab; **OR**
- The member has a diagnosis of thyroid carcinoma where clinical trials and other guideline indicated systemic therapies are unavailable or inappropriate (e.g., unresectable locoregional recurrent or persistent disease not amenable to radioactive iodine (RAI) therapy, or distant metastatic disease not amenable to RAI therapy).

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Medical records confirming diagnosis and prior therapy where appropriate

AGE RESTRICTIONS

None

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION
5 years
QUANTITY RESTRICTIONS
Refer to formulary
OPERATION NOTES AND OTHER INFORMATION
Approve by HSN

INQOVI® (DECITABINE AND CEDAZURIDINE)

Updated April 28, 2023

Length of Authorization:	5 years
Initiative:	PAR: Inqovi (IE 2462/NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

FDA-RECOMMENDED DOSE

One tablet (containing 35 mg decitabine and 100 mg cedazuridine) orally once daily on days 1 through 5 of each 28-day cycle for a minimum of 4 cycles.

HOW SUPPLIED

35–100 mg tablets; supplied as 5 tablets in one blister card

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member must have a diagnosis of MDS or CMML; **AND**
- The member must have an International Prognostic Scoring System (IPSS) score of 1 or higher.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Prescribed by an oncologist or hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary quantity limits.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

INREBIC® (FEDRATINIB)

Updated May 1, 2023

Length of Authorization:	Initial: 3 months Continuation: 6 months
Initiative:	PAR: Inrebic (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF)

FDA-RECOMMENDED DOSE

400 mg orally once daily

HOW SUPPLIED

100 mg capsules in 120-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member must have one of the following diagnoses:
  - Primary or secondary myelofibrosis; **OR**
  - Lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement.

For Continuation Coverage Requests:

- The member must have a documented decrease in symptoms versus baseline

REQUIRED MEDICAL INFORMATION

For Lymphoid, myeloid, or mixed lineage neoplasms: evidence of JAK2 rearrangement.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

- Initial: 3 months
- Continuation: 6 months

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

IRESSA® (GEFITINIB)

Updated May 1, 2023

Length of Authorization:	12 months
Initiative:	PAR: Iressa (IE 2462/NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test

FDA-RECOMMENDED DOSE

250 mg orally once daily

HOW SUPPLIED

250 mg capsules in a 30-count bottle

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of recurrent, advanced, or metastatic NSCLC; **AND**
- The member has documentation of exon 19 deletions or exon 21 substitution mutations as detected by an FDA-approved test**; AND**
- The member plans on using this medication as a single agent.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Documentation of eGFR mutation status

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

ISTURISA® (OSILODROSTAT)

Updated: November 14, 2023

Length of Authorization:	1 year
Initiative:	PAR: Isturisa (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

FDA-RECOMMENDED DOSE

- Initial Titration: 2 mg orally twice daily to start; increase by 1 to 2 mg twice daily (no more frequently than every 2 weeks) based on rate of cortisol changes, tolerability, and symptom improvement.
- Maximum dose: 30 mg orally twice daily.

HOW SUPPLIED

1 mg, 5 mg, and 10 mg tablets in 20- and 60-count blister packs.

UTILIZATION CRITERIA

For Initial Coverage:

- The member has a confirmed diagnosis of Cushing's disease*; **AND**
- The member has tried and failed, or is inappropriate for, pituitary surgery; **AND**
- The member has tried and failed at least one other — or is contraindicated to all — guideline-recommended second-line treatment options for the treatment of Cushing's disease (i.e., ketoconazole, mitotane, etomidate, cabergoline, and pasireotide).

**Requires confirmation of disease vs. syndrome. Cushing's syndrome is not a covered diagnosis.*

For Continuation of Coverage:

- The member must have documentation of clinical benefit as attested to by the member's endocrinology provider.

REQUIRED MEDICAL INFORMATION

- Medical records or chart notes supporting diagnosis; **AND**
- Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an endocrinologist

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

1 year

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

DEFERASIROX (JADENU®, EXJADE®)

Updated October 05, 2023

Length of Authorization:	3 months
Initiative:	PAR: Jadenu (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of chronic iron overload due to chronic blood transfusions in patients 2 years of age and older
- For the treatment of chronic iron overload due to non-transfusion dependent thalassemia (NTDT) syndromes with a liver iron concentration (LIC) of at least 5 mg/g of dry weight and a serum ferritin level greater than 300 mcg/L in patients 10 years of age and older

FDA-RECOMMENDED DOSE

- **For Transfusion Iron Overload:**
  - Jadenu: 14 mg/kg once daily (initial), up to 28 mg/kg once daily.
  - Exjade: 20 mg/kg once daily (initial), up to 40 mg/kg once daily.
- **For Iron Overload in Non-Transfusion-Dependent Thalassemia Syndromes:**
  - Jadenu: 7 mg/kg once daily (initial), up to 14 mg/kg once daily.
  - Exjade: 10 mg/kg once daily (initial), up to 20 mg/kg once daily.

HOW SUPPLIED

Various, refer to package insert

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- For all conditions:
  - The member does not have a high-risk myelodysplastic syndrome; **AND**
  - The member has platelet counts greater than 50 x 109/L; **AND**
  - The member does not have serum creatinine greater than two times the age-appropriate upper limit of normal or creatinine clearance less than 40 mL/min.
- For chronic iron overload due to blood transfusions:
  - The member must have documentation of serum ferritin level ≥ 1000 mcg/L within last 60 days
- For chronic iron overload due to non-transfusion dependent thalassemia (NTDT) syndromes:
  - The member must have documentation of a serum ferritin level greater than 300 mcg/L

FOR CONTINUATION COVERAGE REQUESTS

- The member must have documentation that serum ferritin, serum creatinine, creatinine clearance, serum transaminases, and bilirubin have been monitored monthly; **AND**
- The member continues to have a beneficial response to therapy as assessed and documented by the member's specialist provider

REQUIRED MEDICAL INFORMATION

- Initial requests: Platelet counts, serum creatinine, creatinine clearance, and body weight.
- Continuation requests: Serum ferritin, creatinine, transaminases, bilirubin, and body weight.

AGE RESTRICTIONS

2 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an oncologist or hematologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

3 months

QUANTITY/PARTIAL-FILL RESTRICTIONS

N/A

OPERATIONAL NOTES AND OTHER INFORMATION

- Approval is limited to the tablet formulations only.
- Quantity approvals must fall under the maximum dosage limits recommended by the FDA, as determined by patient weight at the time of the request.

JAKAFI® (RUXOLITINIB)

Updated May 1, 2023

Length of Authorization:	6 months
Initiative:	PAR: Jakafi (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis
- For the treatment of adult patients with polycythemia vera who have had an inadequate response to, or are intolerant of hydroxyurea
- For the treatment of steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years of age and older
- For the treatment of chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

FDA-RECOMMENDED DOSE

5, 15, or 20 mg twice daily based on disease state, platelet count, renal function, and hepatic function

HOW SUPPLIED

5, 10, 15, 20, 25 mg tablets in 60-count bottles

UTILIZATION CRITERIA

FOR ALL INDICATIONS

For Initial Coverage Requests:

- Member is not concurrently using a tyrosine kinase inhibitor or immunomodulatory agents (e.g., lenalidomide, thalidomide, pomalidomide)
- Member has been assessed for signs and symptoms of infection prior to therapy initiation

For Continuation Coverage Requests:

- Member is not concurrently using a tyrosine kinase inhibitor or immunomodulatory agents (e.g., lenalidomide, thalidomide, pomalidomide)

FOR THE TREATMENT OF CAR T-CELL RELATED TOXICITIES:

- The member has G4 cytokine release syndrome; **AND**
- The member is refractory to high-dose corticosteroids and anti-IL-6 therapy

FOR THE TREATMENT OF MYELOFIBROSIS (MF)

For Initial Review:

- Member must be clinically diagnosed with primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis; **AND**
- Ruxolitinib is planned to be used as monotherapy.

For Continuation:

- Member must have a documented 35% reduction in spleen volume as measured by CT or MRI (or 50% reduction in palpable spleen length); **OR**
- Member must have a documented decrease in symptoms versus baseline.

FOR THE TREATMENT OF POLYCYTHEMIA VERA

For Initial Review:

- The member has a diagnosis of polycythemia vera; **AND**
- The member has documentation of an inadequate response to, or intolerance of, hydroxyurea

For Continuation:

- Member must have a documented 35% reduction in spleen volume as measured by CT or MRI (or 50% reduction in palpable spleen length); **OR**
- Member must have a documented decrease in symptoms versus baseline.

FOR THE TREATMENT OF PEDIATRIC ACUTE LYMPHOBLASTIC LEUKEMIA:

- The member has Pediatric Acute Lymphoblastic Leukemia; **AND**
- The member uses the medication in one of the following ways:
  - Induction or consolidation therapy: component of Total Therapy XVII regimen + ruxolitinib for Ph-like B-ALL with mutations associated with JAK-STAT pathway activation
  - Consolidation therapy: component of COG AALL1521 regimen + ruxolitinib for Ph-like B-ALL and CRLF2+ or CRLF2- with JAK2 fusions, EPOR rearrangements, SH2B3 alterations, IL7R insertions and deletions

FOR THE TREATMENT OF ACUTE GRAFT-VERSUS-HOST DISEASE (GVHD)

For Initial Review

- Member must have acute GVHD

For Continuation:

- Member is in the process of tapering off therapy by one dose level approximately every 8 weeks; **OR**
- Member must have been assessed for the potential for tapering off ruxolitinib; **AND**
- Member must have a rationale, per provider attestation, to remain on a stable dose of ruxolitinib (i.e., not counting a tapering period).

FOR THE TREATMENT OF CHRONIC GRAFT-VERSUS-HOST DISEASE (GVHD)

For Initial Review

- Member must have chronic GVHD; **AND**
- The member must have tried and failed corticosteroid monotherapy; **AND**
- The member must be using ruxolitinib as additional therapy in conjunction with systemic corticosteroids unless continuation is clinically inappropriate.

For Continuation:

- The member continues to have beneficial response to therapy, as assessed by the member's provider; **AND**
- Member is not concurrently using a tyrosine kinase inhibitor or immunomodulatory agents (e.g., lenalidomide, thalidomide, pomalidomide).

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

- For MF or Polycythemia Vera: 18 years of age and older
- For GVHD: 12 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

6 months

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approve by HICL.

JAVYGTOR®, KUVAN® (SAPROPTERIN DIHYDROCHLORIDE)

Updated February 13, 2024

Length of Authorization:	3 months (initial), 5 years (continuation)
Initiative:	PAR: Kuvan (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

Indicated to reduce blood phenylalanine (Phe) levels in adult and pediatric patients one month of age and older with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU). Kuvan is to be used in conjunction with a Phe-restricted diet.

FDA-RECOMMENDED DOSE

- Initial: 10 to 20 mg/kg once daily. Adjust dose after 1 month based on blood phenylalanine levels.
- Maintenance range: 5 to 20 mg/kg once daily.

HOW SUPPLIED

- 150 mg tablets in 120-count bottles
- 100 mg and 500 mg powder packets in cartons of 30-unit dose packets

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of phenylketonuria (PKU); **AND**
- The member is on a phenylalanine restricted diet; **AND**
- The member's current treatment plan does not include pegvaliase-pqpz use.

FOR CONTINUATION COVERAGE REQUESTS

- The member continues to be on a phenylalanine restricted diet; **AND**
- The member's current treatment plan does not include pegvaliase-pqpz use; **AND**
- The member continues to have a beneficial response to therapy, as evidenced by blood Phe levels lower than baseline.

REQUIRED MEDICAL INFORMATION

- Initial: Pre-therapy phenylalanine levels
- Continuation: On-therapy phenylalanine levels from the last 6 months

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 3 months
- Continuation: 5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by HSN

JESDUVROQ® (DAPRODUSTAT)

Updated: December 22, 2023

Length of Authorization:	Initial: 6 months Continuation: 12 months
Initiative:	PAR: Jesduvroq 75/2462

FDA-APPROVED INDICATION(S)

For the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least four months.

FDA-RECOMMENDED DOSE

- Administer orally once daily, with or without food.
- Dosage modifications may be necessary due to hemoglobin level, liver function, and concomitant medications.
- Treatment should not be continued beyond 24 weeks of therapy if a clinically meaningful increase in Hb level is not achieved.

HOW SUPPLIED

1, 2, 4, 6, or 8 mg tablets in 30-count bottles or 100-count blister pack.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of anemia due to CKD, **AND**
- The member must have been receiving dialysis for ≥ 4 months, **AND**
- The member is hyporesponsive to erythropoietin stimulating agent (ESA) therapy, defined as:
  - The need for > 300 IU/kg per week of epoetin alfa; **OR,**
  - 1.5 mcg/kg per week of darbepoetin.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies as applicable to place in therapy.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

Initial: 6 months

Continuation: 12 months

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN

JULUCA® (DOLUTEGRAVIR/RILPIVIRINE)

Updated May 8, 2023

Length of Authorization:	5 years
Initiative:	PAR: Juluca (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the components of dolutegravir/rilpivirine.

FDA-RECOMMENDED DOSE

One tablet by mouth once daily with food

HOW SUPPLIED

Dolutegravir (DTG) 50 mg/Rilpivirine (RPV) 25 mg tablets in 30 count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member is currently virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least the previous 6 months with no known substitutions associated with resistance to dolutegravir/rilpivirine; **AND**
- The member must have no history of treatment failure on a previous antiretroviral regimen

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Treatment history

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an infectious disease or HIV specialist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

JUXTAPID™ (LOMITAPIDE)

Updated: November 2, 2023

Length of Authorization:	5 years
Initiative:	PAR: Juxtapid (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

Adjunct to a low-fat diet and other lipid-lowering treatments, including low-density lipoprotein (LDL) apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol, apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH).

FDA-RECOMMENDED DOSE

Initial dose of 5 mg orally once daily; after ≥ 2 weeks of therapy may increase to 10 mg once daily, as tolerated; then at ≥ 4-week intervals, may increase to 20 mg once daily, then to 40 mg once daily, and finally to a maximum dose of 60 mg/day as tolerated.

HOW SUPPLIED

5 mg, 10 mg, 20 mg, 30 mg, 40 mg, and 60 mg capsules in 28-count bottles.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS:

- The member has a diagnosis of homozygous familial hypercholesterolemia (HoFH), as established by at least one of the following:
  - Genetic confirmation of two mutant alleles at the LDL receptor, ApoB, PCSK9 or ARH adaptor protein gene locus;
  - An untreated LDL-C ≥ 190 mg/dL;
  - A treated LDL-C ≥ 100 mg/dL; **AND**
- The member must have had an inadequate response (i.e., LDL-C greater than 70 mg/dL while on at least 12 weeks of therapy) to both Repatha and Praluent; **AND**
- The member must have had an inadequate response (i.e., LDL-C greater than 70 mg/dL while on at least 12 weeks of therapy) to maximally tolerated atorvastatin and rosuvastatin therapy in combination with ezetimibe, unless otherwise contraindicated or intolerant to both atorvastatin and rosuvastatin, or ezetimibe.[1] If unable to take ezetimibe, must have had a 12-week trial of maximally tolerated atorvastatin or rosuvastatin therapy.
- **Note**: Trial of ezetimibe is not required if member could not tolerate or is contraindicated to statin therapy (e.g., coverage does not require ezetimibe monotherapy trial).

[1]Statin intolerance requires the following:

- Attestation of severe and intolerable adverse effects that have occurred with every trial of statin, and other potential causes were ruled out (low vitamin D levels, sudden increase in intense or prolonged physical activity, drug interactions with statins, or other metabolic or inflammatory causes); **AND**
- The member has tried alternate dosing strategies such as every-other-day statin dosing or twice weekly dosing.

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

- Baseline and current lipid panel.
- Documentation of diagnosis.
- Documentation of genetic confirmation, if applicable.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a cardiologist, lipid specialist, or endocrinologist.

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by HICL.

JYNARQUE® AND SAMSCA® (TOLVAPTAN)

Updated May 23, 2023

Length of Authorization:	varies, see below
Initiative:	PAR: Jynarque (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- **Jynarque:** To slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).
- **Samsca:** For the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium <125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH).

FDA-RECOMMENDED STARTING DOSE

- **Jynarque:** One tablet twice daily; initiated at one 45 mg tablet upon waking and one 15 mg tablet 8 hours later, then titrated weekly to target dose of 90 mg upon waking and 30 mg 8 hours later.
- **Samsca:** The usual starting dose is 15 mg administered once daily without regard to meals. Increase the dose to 30 mg once daily, after at least 24 hours, to a maximum of 60 mg once daily, as needed to achieve the desired level of serum sodium. Do not administer for more than 30 days to minimize the risk of liver injury.

HOW SUPPLIED

- **Jynarque:** Supplied in 7-day blister cards (morning dose/evening dose); 90 mg/30 mg, 60 mg/30 mg and 45 mg/15 mg morning and afternoon doses in 14-count blister packs. 14 tablets per blister card.
- **Samsca:** 15 mg and 30 mg tablets in 10-count blister packs.

COVERAGE CRITERIA

For All Initial Coverage Requests:

- For Tolvaptan (Jynarque) Requests:
  - The member has a confirmed diagnosis of ADPKD, defined as either of the following:
    - Family history/genetic confirmation of ADPKD plus three cysts per kidney by sonography or five cysts by CT or MRI.
    - Ten cysts per kidney by any radiologic method plus exclusion of other cystic kidney diseases; **AND**
  - The member is perceived to be at high risk for rapidly progressing ADPKD by the member's nephrologist; **AND**
  - The member is symptomatic or has stage II-IV chronic kidney disease (CKD); **AND**
  - The member must not have progressed to end-stage renal disease, or requires dialysis or transplant; **AND**
  - The member must not have any of the following:
    - Advanced diabetes
    - Evidence of additional significant renal disease
    - Renal cancer
    - Only one kidney

- For Tolvaptan (Samsca) Requests:
  - The member has clinically significant hypervolemic and euvolemic hyponatremia as evidenced by either of the following:
    - Serum sodium < 125 mEq/L; **OR**
    - Symptomatic hyponatremia and has resisted correction with fluid restriction; **AND**
    - The member is not experiencing hypovolemic hypernatremia; **AND**
    - The member is not experiencing anuria; **AND**
    - The member is not taking any strong CYP 3A inhibitors.

For Continuation Coverage Requests:

- For Tolvaptan (Jynarque) Requests:
  - The member continues to tolerate and have a beneficial response to treatment, as attested to by the member's specialist provider.
- For Tolvaptan (Samsca) Requests:
  - The member must meet the same criteria same as initial request; **AND**
  - The member must have been screened for liver injury.

REQUIRED MEDICAL INFORMATION

Samsca: Current serum sodium levels.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a nephrologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- **Jynarque:** 3 months (initial), 12 months (renewal)
- **Samsca:** 2 months (continuation same as initial)

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

KALYDECO® (IVACAFTOR)

Updated: November 3, 2023

Length of Authorization:	Initial: 1 year; Continuation: 5 years
Initiative:	PAR: Kalydeco (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of cystic fibrosis (CF) in patients 1 months of age and older who have one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data

FDA-RECOMMENDED DOSE

- For adults and pediatric patients ages 6 years and older: 150 mg tablet taken orally every 12 hours.
- For pediatric patients 1 month to less than 6 years of age: See Table 1.

Table 1. Pediatric Dosing (< 6 years of age)

Age	Body Weight (kg)	Dosage
1 month to less than 2 months	3 kg or greater	One 5.8 mg packet every 12 hours
2 months to less than 4 months	3 kg or greater	One 13.4 mg packet every 12 hours
4 months to less than 6 months	5 kg or greater	One 25 mg packet every 12 hours
6 months to less than 6 years	5 kg to less than 7 kg	One 25 mg packet every 12 hours
	7 kg to less than 14 kg	One 50 mg packet every 12 hours
	14 kg or greater	One 75 mg packet every 12 hours

HOW SUPPLIED

- 150 mg tablets in 56-count blister-pack cartons and 60-count bottles
- 5.8 mg, 13.4 mg, 25 mg, 50 mg, and 75 mg granule packets in 56-count cartons

UTILIZATION CRITERIA

- **For Initial Coverage Requests:**
  - The member must have a diagnosis of cystic fibrosis; **AND**
  - The member's baseline FEV1 (forced expiratory volume in one second) is at least 40% or higher (as documented by lab report or chart notes); **AND**
- The member does not have either of the following:
  - ALT or AST > 5x upper limit of normal (ULN); **OR**
  - ALT or AST > 3x ULN with bilirubin > 2x ULN; **AND**
- The member has at least one mutation that is responsive to ivacaftor (Table 2).

Table 2: CFTR gene mutations responsive to ivacaftor

2789+5G → A	A1067T	D1152H	E56K	G1069R	G551D*	P67L	R117H*	S1251N*	S945L
3272-26A → G	A455E	D1270N	E831X	G1244E*	G551S*	R1070Q	R347H	S1255P*	S977F
3849+10kbC → T	D110E	D579G	F1052V	G1349D*	K1060T	R1070W	R352Q	S549N	
711+3A → G	D110H	E193K	F1074L	G178R*	L206W	R117C	R74W	S549R*	

*CFTR gating mutation

- **For Continuation Coverage Requests:**
  - The member continues to have a beneficial response to therapy, as assessed and documented by the member's specialist provider, and as supported by one of the following:
    - The member has had maintenance or improvement in FEV1; **OR**
    - The member has had maintenance or improvement in BMI (body mass index); **OR**
    - The member has had reduction in pulmonary exacerbations
- The member does not have either of the following:
  - ALT or AST > 5x ULN.
  - ALT or AST > 3x ULN with bilirubin > 2x ULN.

REQUIRED MEDICAL INFORMATION

- Genomic testing showing required mutation(s).
- FEV1 with date (required for initial and optional for continuation if other criteria met).
- AST or ALT levels.
- Bilirubin levels, if applicable

AGE RESTRICTIONS

1 month of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a pulmonary specialist or Cystic Fibrosis specialist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

- Initial: 1 year
- Continuation: 5 years

QUANTITY RESTRICTIONS

- Refer to formulary
- If member meets criteria for granule packets, then enter a quantity override to permit dosing based on current weight. When calculating restriction, add 10 kg to the member's current weight to allow for growth during their approval cycle.

OPERATIONAL NOTES AND OTHER INFORMATION

If approved, term any active PA for Orkambi®, Trikafta®, or Symdeko®.

KERENDIA® (FINERENONE)

Updated May 30, 2023

Length of Authorization:	12 months
Initiative:	PAR: KERENDIA (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

To reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2DM).

FDA-RECOMMENDED DOSE

The recommended starting dose is 10 mg or 20 mg orally once daily based on estimated GFR and serum potassium thresholds. The dose should be increased after four weeks to the target dose of 20 mg once daily, based on eGFR and potassium. Do not start finerenone if baseline serum potassium is > 5.0 mEq/L.

HOW SUPPLIED

10 mg and 20 mg film-coated tablets in bottles of 30 and 90 tablets

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member has a confirmed diagnosis of T2DM with CKD; **AND**
- The member's baseline serum potassium is ≤ 5.0 mEq/L, **AND**
- The member's baseline eGFR is ≥ 25 mL/min/1.73 m^2; **AND**
- The member has tried and failed a sodium-glucose cotransporter-2 (SGLT2) inhibitor, unless contraindicated; **AND**
- The member will not be using finerenone in combination with an SGLT2 product.

For Continuation Coverage Requests:

- The member has had a positive clinical response to therapy, as documented by the member's provider; **AND**
- The member's current serum potassium is < 5.5 mEq/L; **AND**
- The member's current eGFR is ≥ 25 mL/min/1.73m^2.

REQUIRED MEDICAL INFORMATION

- Kidney function status (eGFR), most recent value collected within the previous three months
- Serum potassium (mEq/L), most recent value collected within the previous three months

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

Must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary quantity limits.

OPERATIONAL INSTRUCTIONS/ ADDITIONAL INFORMATION

Approve by GSN.

KEVEYIS® (DICHLORPHENAMIDE)

Updated July 27, 2023

Length of Authorization:	12 months
Initiative:	PAR: Keveyis (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants

FDA-RECOMMENDED DOSE

Initiate dosing at 50 mg by mouth once or twice daily. The dosage may be increased or decreased based on individual response, at weekly intervals (or sooner in case of adverse reaction). The minimum recommended total daily dosage is 50 mg, and the maximum recommended total daily dosage is 200 mg.

HOW SUPPLIED

50 mg tablets in 100-count bottles

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- For all indications:
  - The member does not have hepatic insufficiency or pulmonary obstruction; **AND**
  - The member has been advised to avoid high dose aspirin during treatment; **AND**
  - The member meets one of the following indication-specific criteria sets.
- For primary hyperkalemic periodic paralysis or Paramyotonia Congenita:
  - The member has a diagnosis of primary hyperkalemic periodic paralysis or Paramyotonia Congenita; **AND**
  - The member has not tolerated, tried without adequate results, or is contraindicated to acetazolamide; **AND**
  - The member has not tolerated, tried without adequate results, or is contraindicated to a thiazide diuretic.
- For primary hypokalemic periodic paralysis:
  - The member has a diagnosis of hypokalemic periodic paralysis; **AND**
  - The member has not tolerated, tried without adequate results, or is contraindicated to acetazolamide; **AND**
  - The member has not tolerated, tried without adequate results, or is contraindicated to spironolactone.

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as attested by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

KEVZARA® (SARILUMAB)

Updated December 18, 2023

Length of Authorization:	12 months
Initiative:	PAR: Kevzara (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs)

FDA-RECOMMENDED DOSE

200 mg once every two weeks as subcutaneous injection

HOW SUPPLIED

150 mg/1.14 mL and 200 mg/1.14 mL pre-filled syringes and pre-filled pens

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib); **AND**
- The member has a diagnosis of moderate to severe RA; **AND**
- The member has had a previous trial of or contraindication to at least one of the following:
  - Methotrexate
  - Leflunomide
  - Hydroxychloroquine
  - Sulfasalazine; **AND**
- The member has had a previous trial of or contraindication to at least **two** of the following without adequate response:
  - Adalimumab
  - Enbrel
  - Xeljanz

For Continuation Coverage Requests:

- Confirmation that the member continues to have a beneficial response to therapy as assessed and documented by the member's specialist provider; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib).

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a rheumatologist

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES ANDOTHER INFORMATION

Approve by HSN

KINERET® (ANAKINRA)

Updated December 18, 2023

Length of Authorization: 12 months
Initiative: PAR: Kineret (IE 2462 / NCPDP 75 – GSN; IE 2641, 15110 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

- For the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis (RA), in patients 18 years of age or older who have failed 1 or more disease-modifying antirheumatic drugs (DMARDs).
- For the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS): Neonatal-Onset Multisystem Inflammatory Disease (NOMID).
- For the treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA).

FDA-RECOMMENDED DOSE

- RA: 100 mg once daily subcutaneously
- CAPS/DIRA: 1–2 mg/kg daily; can be increased to a maximum of 8 mg/kg daily

HOW SUPPLIED

100 mg/0.67 mL single-use syringe in 7- and 28-count package

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

For All Indications:

- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

For the Treatment of RA:

- The member has a diagnosis of moderately to severely active rheumatoid arthritis; **AND**
  - The member has had a previous trial of or contraindication to at least one of the following:
    - Methotrexate
    - Leflunomide
    - Hydroxychloroquine
    - Sulfasalazine; **AND**
  - The member has had a previous trial of or contraindication to at least TWO of the following preferred agents:
    - Adalimumab
    - Enbrel
    - Xeljanz

For the Treatment of CAPS:

- The member has a diagnosis of CAPS: NOMID.

For the Treatment of DIRA:

- The member has a diagnosis of DIRA.

FOR CONTINUATION COVERAGE REQUESTS

- The member continues to have a beneficial response to therapy as assessed by their specialist provider; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

- Rheumatoid Arthritis: 18 years of age or older
- NOMID/DIRA: N/A

PRESCRIBER RESTRICTIONS

- RA: must be prescribed by or in consultation with a rheumatologist.
- CAPS/DIRA: must be prescribed by or in consultation with a rheumatologist or an immunologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

- RA: enter PA with a metric quantity and days' supply to allow 1 syringe per day.
- NOMID/DIRA: enter PA with a metric quantity and days' supply to allow 10 syringes per day.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

KISQALI® (RIBOCICLIB)

Updated May 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Kisqali (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, as initial endocrine-based therapy, in combination with an aromatase inhibitor
- For the treatment of postmenopausal women or men with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy, in combination with fulvestrant

FDA-RECOMMENDED STARTING DOSE

600 mg (three 200 mg tablets) taken orally, once daily for 21 consecutive days followed by 7 days off treatment resulting in a complete cycle of 28 days.

HOW SUPPLIED

200 mg film-coated tablets in 21, 42, and 63-count blister packs

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has not previously progressed on alternative CDK4/6 inhibitor therapy (e.g., palbociclib, abemaciclib); **AND**
- The member has a diagnosis of HR-positive, HER2-negative advanced or metastatic breast cancer; **AND**
  - The member will use ribociclib in combination with an aromatase inhibitor (e.g., letrozole, anastrozole, exemestane) or fulvestrant; **AND**
  - The member meets one of the following designations:
    - The member is postmenopausal; **OR**
    - The member is premenopausal and has been treated with ovarian ablation or suppression.

FOR CONTINUATION COVERAGE REQUESTS

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Tumor status (HR/HER2)

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

KORLYM® (MIFEPRISTONE)

Updated: November 20, 2023

Length of Authorization:	12 months (initial) 5 years (continuation)
Initiative:	PAR: Korlym (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

Indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.

FDA-RECOMMENDED DOSE

300 mg orally once daily

HOW SUPPLIED

300 mg tablets in 28-count or 280-count bottles.

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of hypercortisolism as a result of Cushing's syndrome; **AND**
- The member has a diagnosis of type 2 diabetes or glucose intolerance secondary to hypercortisolism, **AND**
- The member has undergone surgery or radiation treatment for Cushing's without success or is not a candidate for these interventions; **AND**
- The member has taken ketoconazole, mitotane, or Lysodren without adequate control of cortisol levels; **AND**
- The member has failed to achieve blood glucose control with maximally titrated doses of insulin and other agents used to manage hyperglycemia for at least 3 months.

FOR CONTINUATION COVERAGE REQUESTS

- Member has had a positive clinical response to therapy, as documented by the member's prescribing provider.

REQUIRED MEDICAL INFORMATION

- Claims or medical records demonstrating use of previous therapies; **AND**
- Medical records or chart notes supporting diagnosis.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an endocrinologist

REVIEWER REQUIREMENTS

All coverage requests must be review by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 12 months.
- Continuation: 5 years.

QUANTITY RESTRICTIONS

Refer to formulary quantity limits.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

KOSELUGO™ (SELUMETINIB)

Updated May 30, 2023

Length of Authorization:	5 years
Initiative:	PAR: Koselugo (IE 2462 / NCPDP 75; IE 2641, 15110 / NCPDP 76 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).

FDA-RECOMMENDED DOSE

NF1 25 mg/m^2 orally twice daily.

HOW SUPPLIED

10 and 25 mg capsules. in 28- and 60-count bottles.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- Neurofibromatosis Type 1:
  - The member has a documented diagnosis of neurofibromatosis type 1 (NF1); **AND**
  - The member has symptomatic, inoperable plexiform neurofibromas (PN).
- Circumscribed Glioma: The member has a documented diagnosis of recurrent or progressive circumscribed glioma; **AND**
  - The tumor is BRAF fusion or BRAF V600E activating mutation positive.
- Langerhans Cell Histiocytosis:
  - The member has a documented diagnosis of Langerhans cell histiocytosis.

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- Chart notes or medical records supporting diagnosis.
- BRAF fusion or BRAF V600E activating mutation status, if applicable.
- Body Surface Area (BSA)

AGE RESTRICTIONS

2 to 21 years of age.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Quantity limit based on FDA dosing and submitted BSA:

Body Surface Area	Recommended Dosage	Quantity Limit
0.55 – 0.69 m^2	20 mg in the morning and 10 mg in the evening	10 mg caps: MDD 3
0.70 – 0.89 m^2	20 mg twice daily	10 mg caps: MDD 4
0.90 – 1.09 m^2	25 mg twice daily	25 mg caps: MDD 2
1.10 – 1.29 m^2	30 mg twice daily	10 mg caps: MDD 6
1.30 – 1.49 m^2	35 mg twice daily	25 mg caps: MDD 2 10 mg caps: MDD 2
1.50 – 1.69 m^2	40 mg twice daily	10 mg caps: MDD 8
1.70 – 1.89 m^2	45 mg twice daily	25 mg caps: MDD 2 10 mg caps: MDD 4
≥ 1.90 m^2	50 mg twice daily	25 mg caps: MDD 4

OPERATIONAL NOTES

- Enter approval with a maximum daily dose (MDD) based on BSA and FDA dosing listed in the above table.
- Approve by HSN.

KYNMOBI™ (APOMORPHINE)

Updated May 8, 2023

Length of Authorization:	5 years
Initiative:	PAR: Kynmobi (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the acute, intermittent treatment of "off" episodes in patients with Parkinson's disease (PD).

FDA-RECOMMENDED DOSE

10 mg to 30 mg per dose, sublingually, as needed. Not to be given more than five times per day.

HOW SUPPLIED

- 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg films in 30-count cartons.
- Titration kit with two 10 mg, two 15 mg, two 20 mg, two 25 mg, and two 30 mg films (10-count)

COVERAGE CRITERIA

FOR INTIAL COVERAGE REQUESTS

- The member has a diagnosis of Parkinson's disease; **AND**
- The member is currently receiving a carbidopa/levodopa formulation; **AND**
- The member has tried and failed, or has contraindications to, two or more of the following "off" period management strategies:
  - Add-on therapy with a dopamine agonist (i.e., pramipexole, ropinirole, rotigotine)
  - Add-on therapy with an MAO-B inhibitor (i.e., rasagiline, selegiline, safinamide)
  - Add-on therapy with a COMT inhibitor (i.e., entacapone, tolcapone, opicapone)
  - Extended-release carbidopa/levodopa
  - Modifications or alterations to carbidopa/levodopa dose scheduling

FOR CONTINUATION COVERAGE REQUESTS

The member continues to require on-demand treatment for "off" periods and has a beneficial response to treatment, as attested to by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age or older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

Five years.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

LAMPIT® (NIFURTIMOX)

Updated May 8, 2023

Length of Authorization:	Two months (60 days)
Initiative:	PAR: Lampit (IE 2462 / NCPDP 75 – GSN) (IE 15110 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of Chagas disease (Trypanosome cruzi or T. Cruzi) in patients less than 18 years of age.

FDA-RECOMMENDED DOSE

- Dosed orally, three times a day, for 60 days:
  - Body weight 40 kg or greater: total daily dose 8–10 mg/kg.
  - Body weight less than 40 kg: total daily dose 10–20 mg/kg.

HOW SUPPLIED

30 mg and 120 mg tablets in 100-count bottles.

UTILIZATION CRITERIA

FOR INITIAL REVIEW

The member has serologically confirmed T. Cruzi (Trypanosome cruzi, or Chagas disease).

REQUIRED MEDICAL INFORMATION

- Chart notes documenting serologically confirmed T. Cruzi.
- Weight (kg).

AGE RESTRICTIONS

Covered for patients less than 18 years of age.

PRESCRIBER RESTRICTIONS

Must be prescribed by an infectious disease specialist.

REVIEWER REQUIREMENTS

Must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

Two months (60 days).

QUANTITY RESTRICTIONS

Limit approved quantity to the lowest dose per weight-based dosing for 60 days:

- Body weight 40 kg or greater: total daily dose 8–10 mg/kg.
- Body weight less than 40 kg: total daily dose 10–20 mg/kg.

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve both clinical and quantity override by HICL.

LENIOLISIB (JOENJA)

Updated May 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Joenja: (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adult and pediatric patients 12 years of age and older.

FDA-RECOMMENDED DOSE

70 mg by mouth twice daily if greater than 45 kg (no recommended dose if lower weight).

HOW SUPPLIED

70 mg tablets in 60-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of APDS; **AND**
- The member has documentation of either the PIK3CD or PIK3R1 gene mutation.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Documentation of mutation associated with APDS diagnosis.

AGE RESTRICTIONS

12 to 75 years of age.

PRESCRIBER RESTRICTIONS

Must be prescribed by a hematologist, allergist, or immunologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

LENVIMA® (LENVATINIB MESYLATE)

Updated October 25, 2023

Length of Authorization:	5 years
Initiative:	PAR: Lenvima (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC)
- In combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy
- In combination with pembrolizumab for the first-line treatment of adult patients with advanced RCC.
- For the first-line treatment of patients with unresectable hepatocellular carcinoma (HCC)
- In combination with pemprolizumab, for the treatment of patients with advanced endometrial carcinoma (EC) that is mismatch repair proficient (pMMR), as determined by an FDA-approved test, or not microsatellite instability-high (MSI-H), who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation

FDA-RECOMMENDED DOSE

- DTC: 24 mg orally once daily
- RCC: 18 mg orally once daily (with everolimus); 20 mg orally once daily (with pembrolizumab).
- HCC: 12 mg (for patients ≥60 kg) or 8 mg (for patients <60 kg) orally once daily
- EC: 20 mg orally once daily

HOW SUPPLIED

4 mg and 10 mg capsules in 5-day blister cards of 4 mg, 8 mg, 10 mg, 12 mg, 14 mg, 18 mg, 20 mg, and 24 mg daily doses

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member meets one of the following clinical scenarios:
  - The member has a diagnosis of RCC; **AND**
    - Lenvima will be used in combination with everolimus or pembrolizumab.
  - The member has a diagnosis of metastatic or unresectable HCC.
  - The member has a diagnosis of thymic carcinoma.
  - The member has a diagnosis of locally recurrent, metastatic, or progressive DTC; **AND**
    - The member's disease is not amenable to radioactive iodine.
  - The member has a diagnosis of metastatic or unresectable cutaneous melanoma; **AND**
    - Lenvima will be used in combination with pembrolizumab
  - The member has a diagnosis of thyroid carcinoma (including papillary, follicular, and Hurthle cell); **AND**
    - The member's disease is not amenable to radioactive iodine.
  - The member has a diagnosis of medullary carcinoma; **AND**
    - The member has had progression on preferred systemic therapy.
  - The member has a diagnosis of uterine neoplasms (endometrial carcinoma); **AND**
    - Lenvima will be used in combination with pembrolizumab; **AND**
    - The member has documentation that their disease is mismatch repair proficient (pMMR)

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- Documentation of PMMR if applicable
- Claims or medical records demonstrating use of previous therapies

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years.

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

LINZESS® (LINACLOTIDE)

Updated November 30, 2023

Length of Authorization:	12 months
Initiative:	PAR: Linzess (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of:
  - Chronic idiopathic constipation (CIC) in adults
  - Irritable bowel syndrome with constipation (IBS-C) in adults
  - Functional constipation (FC) in pediatric patients 6 to 17 years of age

FDA-RECOMMENDED DOSAGE

- IBS-C: 290 mcg once daily
- CIC: 72 or 145 mcg once daily
- FC: 72 mcg once daily

HOW SUPPLIED

72, 145, and 290 mcg capsules in 30-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member must meet one of the following:
  - Have clinically diagnosed CIC with symptoms persisting for at least 3 months; **OR**
  - Have clinically diagnosed IBS-C with symptoms persisting for at least 3 months; **OR**
  - Have clinically diagnosed FC with symptoms persisting for at least 2 months AND
- The member has attempted lifestyle changes, including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; **AND**
- The member must not have a known or suspected mechanical gastrointestinal obstruction or perforation. **AND**
- The member must not be on concurrent tenapanor, lubiprostone, plecanatide, or prucalopride.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider; **AND**
- The member must not be taking concurrent tenapanor, lubiprostone, plecanatide, or prucalopride.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

- CIC and IBS-C: 18 years of age and older
- FC: 6 to 17 years of age

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a gastroenterologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES OTHER INFORMATION

Approve by GSN.

LITFULO™ (RITLECITINIB)

Updated September 28, 2023

Length of Authorization:	12 months
Initiative:	PAR: Litfulo (IE 2462 / NCPDP 75 – HSN)

FDA-APPROVED INDICATION(S)

For the treatment of patients with severe alopecia areata (AA) in adults and adolescents 12 years and older.

FDA-RECOMMENDED STARTING DOSE

50 mg orally once daily.

HOW SUPPLIED

50 mg capsules in 28-count bottles.

COVERAGE CRITERIA

For initial coverage requests:

- The member has been screened for latent or active tuberculosis (TB) prior to treatment; **AND**
- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib), or other potent immunosuppressives (e.g. azathioprine, cyclosporine); **AND**
- The member has a diagnosis of alopecia areata; **AND**
- The member has tried and failed one of the following or is contraindicated to all of the following:
  - High potency topical corticosteroids
  - Intralesional corticosteroid injections
  - Oral corticosteroids

For continuation coverage requests:

- The member has had a positive clinical response to therapy, as documented by the member's specialist provider; **AND**
- The member's liver enzymes are below three times the upper limit of normal (per lab specified range); **AND**
- The member's lymphocyte count is greater than 500 cells/mm^3; **AND**
- The member's absolute neutrophil count (ANC) is greater than 500 cells/mm^3; **AND**
- The member's hemoglobin level is greater than 8 g/dL; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib), or other potent immunosuppressives (e.g. azathioprine, cyclosporine).

REQUIRED MEDICAL INFORMATION

For continuation: Lymphocyte counts, liver enzymes (AST, ALT), neutrophil counts (ANC), and hemoglobin levels, documented within the six months preceding the coverage request.

AGE RESTRICTIONS

12 years of age or older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a dermatologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HSN

LIVMARLI® (MARALIXIBAT CHLORIDE)

Updated: May 10, 2023

Length of Authorization:
Initiative: Par: Livmarli (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of cholestatic pruritis in patients with Alagille syndrome (ALGS) 3 months of age and older.

FDA-RECOMMENDED DOSE

The recommended dose is 380 mcg/kg once daily, 30 minutes prior to the first meal. Starting dose is 190 mcg/kg orally once daily, to be increased to 380 mcg/kg daily after the first week.

HOW SUPPLIED

9.5 mg/mL solution in 30 mL bottles.

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member has a confirmed diagnosis of ALGS.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Weight (kg), measured within the previous 60 days.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an ALGS specialist.

REVIEWER REQUIREMENTS

Must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY/PARTIAL-FILL RESTRICTIONS

Coverage is limited to the member's current weight; a quantity override will need to be entered for the length of the clinical PA as follows:

- 5 to 6 kg → 0.2 mL/day
- 7 to 9 kg → 0.3 mL/day
- 10 to 12 kg → 0.45 mL/day
- 13 to 15 kg → 0.6 mL/day
- 16 to 19 kg → 0.7 mL/day
- 20 to 24 kg → 0.9 mL/day
- 25 to 29 kg → 1 mL/day
- 30 to 34 kg → 1.25 mL/day
- 35 to 39 kg → 1.5 mL/day
- 40 to 49 kg → 1.75 mL/day
- 50 to 59 kg → 2.25 mL/day
- 60 to 69 kg → 2.5 mL/day
- 70 kg or higher → 3 mL/day

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN (approve the appropriate GSN correlated to the dosing above).

LIVTENCITY™ (MARIBAVIR)

Updated: February 7, 2022

Length of Authorization:	2 months
Initiative:	PAR: Livtencity (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant cytomegalovirus (CMV) infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet.

FDA-RECOMMENDED DOSE

400 mg (two 200 mg tablets) by mouth twice daily.

HOW SUPPLIED

200 mg tablets in 28-count and 56-count bottles.

UTILIZATION CRITERIA

For all coverage requests:

- The member has a current cytomegalovirus (CMV) infection; **AND**
- The member has a history of either a hematopoietic stem cell transplant (HSCT) or a solid organ transplant (SOT); **AND**
- The member has tried and failed one of the following:
  - Valganciclovir Oral
  - Ganciclovir IV
  - Foscarnet IV
  - Cidofovir IV

REQUIRED MEDICAL INFORMATION

- Chart note documentation of transplant status.
- Documentation of IV drug trial if applicable.

AGE RESTRICTIONS

12 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a transplant or infectious disease specialist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

2 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

LOKELMA® (SODIUM ZIRCONIUM CYCLOSILICATE)

Updated July 27, 2023

Length of Authorization:	1 month (initial dose/approval), followed by 12 months (maintenance)
Initiative:	PAR: Lokelma (IE 2462 / NCPDP 75 – HICL) PAR: Loading Dose (IE 15110, 2641, 7001 / NCPDP 76 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of hyperkalemia in adults

FDA-RECOMMENDED STARTING DOSE

10 grams three times daily for up to 48 hours (acute); 5 g every other day to 15 g once daily (maintenance)

HOW SUPPLIED

5 and 10-gram powder packets for oral suspension in 30-count boxes

COVERAGE CRITERIA

FOR ALL INITIAL COVERAGE REQUESTS

- The member has a confirmed diagnosis of hyperkalemia (serum potassium level > 5.0 mmol/L); **AND**
- The member is not on dialysis; **AND**
- The member is not receiving concurrent angiotensin converting enzyme inhibitor (ACE-I) and angiotensin receptor blocker (ARB) therapies; **AND**
- The member has attempted to optimize the dose of all current renin-angiotensin-aldosterone system (RAAS) inhibitors (e.g., ACE-I's, ARB's, aldosterone antagonists), as applicable

FOR CONTINUATION COVERAGE REQUESTS

The member has retained normal potassium levels (3.5–5.0 mmol/L) while on therapy

REQUIRED MEDICAL INFORMATION

Most current serum potassium levels

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a nephrologist or cardiologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

1 month (initial dose/approval), followed by 12 months (maintenance)

QUANTITY RESTRICTIONS

- The first approval should allow one fill for a quantity of 10 grams three times daily (six 10-gram packets per 48 hours), or 38 packets per 30 days.
- Maintenance requests should follow formulary quantity limits.
- **Internal notes:**
  - Loading dose: Enter second PA with a metric quantity and days' supply to allow the initial starting dose of 10 grams three times daily (6 packets per 48 hours), if requested.
    - Use initiative PAR: Loading Dose
    - Select CTI reason code: 2nd O/R for Existing PA Approved. No approval letter is sent with second PA.

OPERATIONAL NOTES

Approve by HSN

LONSURF® (TRIFLURIDINE AND TIPIRACIL)

Updated March 24, 2023

Length of Authorization: 5 years
Initiative: PAR: Lonsurf (IE 2462 / NCPDP 75 – HICL; IE 2641. 15110 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients with metastatic colorectal cancer previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy
- For the treatment of adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy

FDA-RECOMMENDED STARTING DOSE

35 mg/m^2 up to a maximum of 80 mg per dose (based on the trifluridine component) orally twice daily with food on days 1–5 and days 8–12 of each 28-day cycle until disease progression or unacceptable toxicity

HOW SUPPLIED

15 mg/6.14 mg and 20 mg/8.19 mg tablets in 20-count, 40-count, and 60-count bottles

COVERAGE CRITERIA

For All Initial Coverage Requests:

- The member has a diagnosis of one of the following:
  - Advanced or metastatic colorectal cancer
  - Unresectable locally advanced (or not surgical candidates), recurrent or metastatic gastric cancer
  - Unresectable locally advanced (or not surgical candidates), recurrent, or metastatic Gastroesophageal junction adenocarcinoma; **AND**
- The member has previously been treated with two or more prior lines of chemotherapy

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Body surface area (BSA)

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to the following table for quantity limits per authorization request:

Body Surface Area (m2)	<1.07	1.07 – 1.22	1.23 – 1.37	1.38 – 1.52	1.53 – 1.68	1.69 – 1.83	1.84 – 1.98	1.99 – 2.14	2.15 – 2.29	≥2.30
Total Daily Dose (mg)	70	80	90	100	110	120	130	140	150	160
Number of Tablets per Day (15 mg tablets)	2	0	6	4	2	0	6	4	2	0
Number of Tablets per Day (20 mg tablets)	2	4	0	2	4	6	2	4	6	8

OPERATIONAL NOTES AND OTHER INFORMATION

- All coverage requests require confirmation of the dose and should be limited to the lowest combination of tablets possible for requested dose, not to exceed maximum dose for BSA (see Table above).
- Approve by HICL.

Internal note:

- Enter PA with a metric quantity and days' supply sufficient for twice daily dosing of the lowest combination of tablets. If two strengths are required, select appropriate CTI, and send the letter on both approvals.

LORBRENA® (LORLATINIB)

Updated April 25, 2023

Length of Authorization:	5 years
Initiative:	PAR: Lorbrena (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

FDA-RECOMMENDED STARTING DOSE

100 mg orally once daily

HOW SUPPLIED

25 mg and 100 mg tablets in 30-count bottles

COVERAGE CRITERIA

For Initial Coverage Requests:

- **For ALK Positive NSCLC:**
  - The member has a diagnosis of NSCLC; **AND**
  - The member has documentation of ALK rearrangement positive disease.
- **For ROS1 Positive NSCLC:**
  - The member has a diagnosis of NSCLC; **AND**
  - The member has documentation of ROS1 rearrangement positive disease; **AND**
  - The member has a documented previous trial and failure of one of the following therapies:
    - Crizotinib (Xalkori)
    - Ceritinib (Zykadia)
    - Entrectinib (Rozlytrek)
- **For Histiocytic Neoplasms:**
  - The member has a diagnosis of Erdheim Chester Disease (ECD); **AND**
  - The member has documentation of ALK rearrangement positive disease.
- **For B-Cell Lymphoma:**
  - The member has a diagnosis of diffuse large B-cell lymphoma; **AND**
  - The member has documentation of ALK rearrangement positive disease; **AND**
  - The member has relapsed or refractory disease.
- **For Soft Tissue Sarcoma/Uterine Sarcoma:**
  - The member has a diagnosis of inflammatory myofibroblastic tumor (IMT); **AND**
  - The member has documentation of ALK rearrangement positive disease.

For continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's oncologist

REQUIRED MEDICAL INFORMATION

- ALK-positive mutation status; **OR**
- ROS1-positive mutation status

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

LOTRONEX® (ALOSETRON)

Updated July 24, 2023

Length of Authorization:	12 months
Initiative:	PAR: Lotronex (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have:
  - Chronic IBS symptoms (generally lasting 6 months or longer)
  - Had anatomic or biochemical abnormalities of the gastrointestinal tract excluded; **AND**
  - Not responded adequately to conventional therapy.

FDA-RECOMMENDED DOSE

0.5 mg to 1 mg orally twice daily

HOW SUPPLIED

0.5 mg tablets and 1 mg tablets in 30-count bottles

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member is female; **AND**
- The member has a diagnosis of diarrhea predominant chronic irritable bowel syndrome; **AND**
- Symptoms have lasted for at least 6 months; **AND**
- The member has had other GI conditions ruled out that could explain these symptoms (abdominal pain, diarrhea, constipation, bloating, urgency, incomplete evacuation, mucus, sense of incomplete evacuation, or gas), **AND**
- The member has tried and failed, or is contraindicated to, at least one OTC antidiarrheal agent such as loperamide

FOR CONTINUATION COVERAGE REQUESTS

Confirmation that the member continues to have a beneficial response to therapy as attested to by the member's specialist provider

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a gastroenterologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES ANDOTHER INFORMATION

Approve by GSN.

LUCEMYRA® (LOFEXIDINE)

Updated July 27, 2023

Length of Authorization:	Approve for 18 days maximum
Initiative:	PAR: Lucemyra (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the mitigation of opioid withdrawal symptoms to facilitate opioid discontinuation in adults

FDA-RECOMMENDED DOSE

Three 0.18 mg tablets four times daily at 5 to 6-hour intervals for up to 14 days with dosage guided by symptoms

HOW SUPPLIED

0.18 mg tablets in 36 and 96-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a physical dependence on opioids; **AND**
- The member has a formal opioid discontinuation plan; **AND**
- The member is being treated in an intensive outpatient or partial residential program; **AND**
- The member has tried and failed treatment with clonidine.

REQUIRED MEDICAL INFORMATION

Documentation of withdrawal treatment plan

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION (DAYS)

Approve for 18 days maximum

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

- Continuation of therapy beyond 18 days is not covered. Members entering a subsequent withdrawal program must meet criteria for initial therapy.
- Approve by GSN.

LUMAKRAS™ (SOTARASIB)

Updated: March 17, 2023

Length of Authorization: 5 years	
Initiative: PAR: Lumakras (IE 2462 / NCPDP 75 – HICL)	

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) who have received at least one prior systemic therapy.

FDA-RECOMMENDED DOSE

960 mg orally once daily

HOW SUPPLIED

- 120 mg tablets in 240-count bottles
- 320 mg tablets in 90-count bottles

COVERAGE CRITERIA

FOR INITIAL COVERAGE

- The member has a confirmed diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) with KRAS G12C mutation as determined by an FDA approved test; **AND**
- The member has tried and failed at least one prior guideline appropriate systemic therapy

FOR CONTINUATION OF COVERAGE

- The member has had a positive clinical response to therapy, as documented by the member's specialist provider

REQUIRED MEDICAL INFORMATION

- Documentation of most current serum ferritin or transferrin saturation with dates
- Documentation of most current hemoglobin levels with dates

AGE RESTRICTIONS

18 years of age or older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by HSN

LUPKYNIS™ (VOCLOSPORIN)

Updated: July 27, 2023

Length of Authorization: 12 months
Initiative: PAR: Lupkynis (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with active lupus nephritis (LN), in combination with a background immunosuppressive therapy regimen.

FDA-RECOMMENDED DOSE

- 23.7 mg orally twice a day.
- Should be taken in combination with a regimen of mycophenolate mofetil and corticosteroids (not evaluated in combination with cyclophosphamide).

HOW SUPPLIED

7.9 mg capsules in 60-count blister packs

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member must have a diagnosis of Lupus Nephritis (LN); **AND**
- The member must have biopsy guided, ISN/RPS disease classification of class 3 (focal), 4 (diffuse), or 5 (membranous) disease; **AND**
- In addition to voclosporin, the member's planned regimen includes mycophenolate mofetil (MMF) and corticosteroids.

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Chart note documentation of biopsy guided disease classification.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a nephrologist, immunologist, or rheumatologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION
12 months
QUANTITY/PARTIAL-FILL RESTRICTIONS
Refer to formulary.
OPERATION NOTES AND OTHER INFORMATION
Approve by GSN

LYBALVI® (OLANZAPINE AND SAMIDORPHAN)

Updated: February 4, 2022

Length of Authorization:	5 years
Initiative:	PAR: Lybalvi (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of schizophrenia in adults and bipolar I disorder in adults (as acute treatment of manic or mixed episodes as monotherapy and as an adjunct to lithium or valproate, or as maintenance monotherapy).

FDA-RECOMMENDED DOSE

Take one tablet by mouth daily.

Indication	Recommended Starting Dose	Recommended Dose
Schizophrenia	5 mg/10 mg or 10 mg/10 mg	10 mg/10 mg, 15 mg/10 mg, or 20 mg/10 mg
Bipolar I disorder (manic or mixed episodes)	10 mg/10 mg or 15 mg/10 mg	5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg, 20 mg/10 mg
Bipolar I disorder adjunct to lithium or valproate	10 mg/10 mg	10 mg/10 mg, 15 mg/10 mg, 20 mg/10 mg

HOW SUPPLIED

Olanzapine/samidorphan (OLZ/SAM) 5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg, or 20 mg/10 mg tablets in 7-, 30-, or 90-count bottles.

UTILIZATION CRITERIA

For Initial coverage Requests:

- The member has a diagnosis of schizophrenia or bipolar I disorder; **AND**
  - The member has previously tried olanzapine; **AND**
  - The member had a positive response to olanzapine; **AND**
  - The member had unacceptable weight gain on olanzapine; **AND**
  - The member is not currently using opioids and has no history of past opioid use disorder.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a psychiatrist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by HICL.

LYNPARZA® (OLAPARIB)

Updated May 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Lynparza (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy.
- In combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial, ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status.
- For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy
- For the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy
- For the treatment of adult patients with deleterious or suspected deleterious gBRCAm, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting
- For the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen
- For the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone.

FDA-RECOMMENDED STARTING DOSE

300 mg orally twice daily

HOW SUPPLIED

100 mg and 150 mg tablets in 60-count and 120-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **For maintenance therapy of recurrent ovarian, fallopian tube, or primary peritoneal cancer:**
  - The member has a diagnosis of recurrent ovarian, fallopian tube, or primary peritoneal cancer; **AND**
  - The member is in a complete or partial response to primary chemotherapy; **AND**
  - The member has a germline or somatic BRCA1/2 mutation; **OR**
  - The member will be using olaparib in combination with bevacizumab if BRCA1/2 status is wild-type or unknown and homologous recombination (HR) deficient.
- **For BRCA + and Breast Cancer:**
  - The member has a diagnosis of breast cancer; **AND**
  - The member has documentation of deleterious or suspected deleterious gBRCAm disease
- **For metastatic pancreatic adenocarcinoma:**
  - The member a diagnosis of metastatic pancreatic adenocarcinoma; **AND**
  - The member has documentation of deleterious or suspected deleterious gBRCA disease; **AND**
  - The member's disease has **not** progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.
- **For HRR mutated mCRPC:**
  - The member has diagnosis of metastatic castration resistant prostate cancer; **AND**
  - The member has documentation of germline or somatic HRR gene-mutated (BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D, or RAD54L) disease as evidenced by an FDA approved companion diagnostic; **AND**
  - The member has progressed following treatment with androgen receptor-directed therapy.
- **For Uterine Neoplasms:**
  - The member must have a diagnosis of a BRCA altered uterine leiomyosarcoma (uLMS); **AND**
  - The member has tried and failed at least one other therapy for uLMS.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Confirmatory diagnostic information, as applicable per indication

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approve by HICL.

LYTGOBI® (FUTIBATINIB)

Updated February 1, 2024

Length of Authorization:	5 years
Initiative:	PAR: Lytgobi (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with previously treated, unresectable, locally advanced, or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements.

FDA-RECOMMENDED DOSE

- 20 mg orally (five 4 mg tablets) once daily until disease progression or unacceptable toxicity occurs
- Recommended dose reductions for adverse reactions
  - First dose reduction: 16 mg (four 4 mg tablets) orally once daily
  - Second dose reduction*: 12 mg (three 4 mg tablets) orally once daily
  - *Permanently discontinue if unable to tolerate 12 mg orally once daily

HOW SUPPLIED

4 mg tablets in 20 mg, 16 mg, and 12 mg daily dose cartons containing 7-day supply blister cards

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a documented diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma; **AND**
- The member has a documented FGFR2 fusion or other rearrangement, as detected by an FDA-approved test; **AND**
- The member has received at least one prior systemic cancer therapy.

FOR CONTINUATION COVERAGE REQUESTS:

The member continues to have a beneficial response to therapy, as assessed by the member's oncologist.

REQUIRED MEDICAL INFORMATION

FGFR test results

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by HSN

MAVYRET™ (GLECAPREVIR/PIBRENTASVIR)

Updated: October 26, 2023

Length of Authorization:	Varies, see below
Initiative:	PAR: Mavyret (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of:
  - Adult and pediatric patients 3 years and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A).
  - Adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both.

FDA-RECOMMENDED DOSE

- Tablets: three tablets by mouth with food for adult patients.
- Oral Pellets: weight-based dosing (table) for pediatric patients 3 to less than 12 years old or weighing less than 45 kg.
- **Table**: recommended dosage in pediatric patients 3 years of age and older

Body weight (kg) or age (yrs)	Daily dose of glecaprevir/pibrentasvir with food	Dose
Less than 20 kg	150 mg/60 mg per day	Three 50 mg/20 mg packets of oral pellets once daily
20 kg to less than 30 kg	200 mg/80 mg per day	Four 50 mg/20 mg packets of oral pellets once daily
30 kg to less than 45 kg	250 mg/150 mg per day	Five 50 mg/20 mg packets of oral pellets once daily
45 kg and greater **or** 12 years of age and older	300 mg/120 mg per day	Three 100 mg/40 mg tablets once daily*

*Pediatric patients weighing 45 kg and greater and unable to swallow tablets may take six 50 mg/20 mg packets of oral pellets once daily.

- Duration of treatment varies based on clinical factors; please see package insert for details.

HOW SUPPLIED

- Tablets: glecaprevir 100 mg/pibrentasvir 40 mg tablet dispensed in 84-count 4-week carton, 168-count 8-week carton, or 84-count bottle.
- Oral pellets: glecaprevir 50 mg/ pibrentasvir 20 mg packets dispensed in a 28-packet carton.

UTILIZATION CRITERIA

FOR ALL COVERAGE REQUESTS

- The member has a diagnosis of HCV with HCV RNA drawn and measured within the previous 6 months; **AND**
- The member has been evaluated to be absent of current alcohol or other substance abuse issues, and has been advised/cautioned on such activities; **AND**
- The member does not have documentation of decompensated cirrhosis (Child-Pugh B, C); **AND**

- For members with HCV genotype 1, the member has not previously received treatment with both an NS5A and an NS3/4A inhibitor.

REQUIRED MEDICAL INFORMATION

- HCV RNA viral load with date, HCV genotype if treatment-experienced**.**
- Previous treatment history, Child-Pugh Score.

AGE RESTRICTIONS

Member must be 3 years of age or older

PRESCRIBER RESTRICTIONS

Must be prescribed by a gastroenterologist, hepatologist, or infectious disease specialist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION (MONTHS)

- Approve for the following durations based on indicated clinical parameters.
  - PA duration for Treatment-Naïve Patients: 8 weeks.
  - PA duration for Treatment-Experienced Patients (Table).
  - PA duration for patients post kidney transplant regardless of treatment experience: 12 weeks.
- Table: PA Durations per Previous Regimen and Genotype

Genotype	Previous Regimen Contains	No Cirrhosis	Cirrhosis
1	An NS5A inhibitor without prior treatment with an NS3/4A protease inhibitor (PI)	16 weeks	16 weeks
	An NS3/4A PI without prior treatment with an NS5A inhibitor	12 weeks	12 weeks
1-2, 4-6	PRS	8 weeks	12 weeks
3	PRS	16 weeks	16 weeks

- PRS= Prior treatment experience with regimens containing (peg) interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor.

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

MEDICAL NECESSITY FOR BRAND

Updated: October 19, 2023

Length of Authorization:	**Varies, see coverage duration**
Initiative:	EXC: DAW Penalty Exception (ID 278 / NCPDP 75 – GSN) *Pharmacists refer to internal process below for approvals

POLICY OVERVIEW

- The University of Michigan Prescription Drug Plan allows the waiving of a product selection penalty (DAW penalty) for members who meet defined criteria.
- In general, drug products are allowed to be filled without incurring a DAW penalty if they are recognized as having a "narrow therapeutic index" (NTI) by the FDA or are used in the treatment of seizures and 1) have not yet been evaluated for NTI status and 2) are not a benzodiazepine. All other brand products require confirmation of the coverage criteria outlined in this policy.
- **This policy does not apply when an authorized generic (AG) is commercially available.** Authorized generics are identical to the brand medication and have no difference in inactive ingredients, safety, efficacy, or product quality. In most cases, the AG product is made in the same facility as the brand product and only differs by the label.
- The University of Michigan Prescription Drug Plan (PDP) allows coverage of tier 3 non-preferred multisource brand formulary contraceptive products at zero cost share (tier 0) when the coverage criteria outlined in this policy has been met.

COVERAGE CRITERIA

For initial coverage requests

- The requested product does not have a commercially available authorized generic*, **AND**
- One or more of the following criteria is met:
  - The requested product is an FDA-recognized NTI product†; **OR**
  - The requested product is used in the treatment of seizure disorders, is not a benzodiazepine, and has not yet been evaluated for NTI status‡; **OR**
  - The member has tried generic equivalents from at least two different manufacturers, or from one manufacturer if only one is available on market, and both of the following criteria are met:
    - The member has experienced one or more of the following outcomes from each generic equivalent(s) of the requested brand medication:
      - Life-threatening adverse reaction
      - Documented allergic response
      - Therapeutic failure, confirmed by measurable outcomes, while taking the generic equivalent
    - The patient, provider, or pharmacy has completed a MedWatch form (Form 3500/3500B) for each generic product tried and failed.

For continuation of coverage requests

- The member's provider attests that the brand medication is still medically necessary; **AND**
- The requested product does not have an authorized generic available*

* A current list of authorized generic drugs is maintained by the FDA and available here: https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/fda-listing-authorized-generics. **If an authorized generic is currently in shortage,** the request may proceed as though the authorized generic is not available. If approved, these requests are limited to 6 months (see Coverage Duration). If the authorized generic is still not available after 6 months, these requests may be approved for an additional 6 months.

†Products that have been identified as NTI should automatically process without a DAW penalty when a DAW code of '1' is applied. As of June 2022, the following products have been identified as NTI and should process without a DAW penalty: carbamazepine, cyclosporine modified, digoxin, levothyroxine, liothyronine, phenytoin, tacrolimus, valproic acid, and warfarin. The plan will continue to monitor and adjust this list as necessary.

‡For products identified as NTI by the requestor but not included on the plan's automatic bypass list, the request must include evidence or supporting material that the product is an FDA-recognized NTI product.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- For medication requests for which an authorized generic is listed on the FDA's "List of Authorized Generic Drugs" but is not available due to a shortage: 6 months.
- For all other requests: 5 years.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

- Contact the plan with any questions or concerns regarding availability of authorized generics.
- Approved non-preferred brand contraceptive agents should be approved at tier 0.
- The FDA has confirmed that lamotrigine, levetiracetam, and topiramate are **not** NTI; all DAW override requests for these products should be reviewed per the coverage criteria outlined in this document.
- If an authorized generic is currently in shortage, the request may proceed as though the authorized generic is not available.
  - If approved, these requests are limited to 6 months (refer to Coverage Duration)
  - If the authorized generic is still not available after 6 months, these requests may be approved for an additional 6 months

ADDITIONAL INTERNAL PROCESS FOR PHARMACISTS

- If DENIED, follow normal denial procedures.
- If APPROVED, follow normal approval procedures, **AND** follow additional steps below to inform the DAW technician team:
  - Once approved, duplicate the Contact Detail.
    - Select CTI:
      - Override Inquiry → Guidelines → Information Given
    - Leave in: **MAP: Supervisor** queue
    - Assign to: "DAW"
    - Add Work Log Note: "Requires DAW override in FirstRx℠ for {drug}"
    - Leave Contact Detail: In Progress
    - Save.
  - Send message to Microsoft Teams group chat, "EMP/HP Fax Work," that an approved DAW request requiring a DAW FirstRx℠ override has been sent to the MAP: Supervisor Queue. The Senior Technician will send a request to the Account Team via Client Services.

MEKINIST® (TRAMETINIB)

Updated: June 27, 2023

Length of Authorization:	5 years
Initiative:	PAR: Mekinist (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- As a single agent in BRAF-inhibitor treatment-naïve patients or in combination with dabrafenib, for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test.
- In combination with dabrafenib, for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection.
- In combination with dabrafenib, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test.
- In combination with dabrafenib, for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options.
- In combination with dabrafenib, for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.
- In combination with dabrafenib, for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy.

FDA-RECOMMENDED STARTING DOSE

- Adult patients: 2 mg orally once daily
- Pediatric patients: tablets and oral solution doses are based on body weight. Refer to package insert.

HOW SUPPLIED

- 0.5 mg and 2 mg tablets in 30-count bottles
- 0.05 mg/1 mL oral solution in a 90 mL bottle.

COVERAGE CRITERIA

For All Initial Coverage Requests:

- The member meets one of the following clinical scenarios:
  - The member has confirmed BRAF V600E or V600K mutation; **AND**
    - The member has a confirmed diagnosis of one of the following:
      - Melanoma
      - NSCLC
      - ATC
      - CNS Cancer
      - Biliary Tract Cancer
      - Ovarian, fallopian tube, or primary peritoneal cancer
      - Unresectable or metastatic solid tumor that has progressed following prior treatment with no satisfactory treatment alternatives; **OR**

- The member has a confirmed diagnosis of one of the following:
  - Langerhans Cell Histiocytosis (LCH)
  - Erdheim-Chester Disease (ECD)
  - Rosai-Dorfman Disease; **OR**
- The member has a diagnosis of a solid tumor; **AND**
  - The member's disease is unresectable or metastatic; **AND**
  - The member has confirmed BRAF V600E mutation; **AND**
  - The member progressed following prior treatment and has no satisfactory alternative treatment options; **OR**
- The member has a diagnosis of LGG; **AND**
  - The member has confirmed BRAF V600E mutation; **AND**

- If request is for the solution, then the member must meet one of the following criteria:
  - Has documented difficulty in swallowing or dysphagia
  - Requires tube feeding
  - Requires a dosage unobtainable with the conventional dosage form
  - Is under 11 years of age

For Continuation Coverage Requests:

- The member has had a positive response to therapy, as attested to by the member's oncology provider; **AND**
- If request is for solution, then the member must meet one of the following criteria:
  - Has documented difficulty in swallowing or dysphagia
  - Requires tube feeding
  - Requires a dosage unobtainable with the conventional dosage form
  - Is under 11 years of age

REQUIRED MEDICAL INFORMATION

- BRAF V600E or V600K mutation status as applicable.
- Claims or medical records demonstrating use of previous therapies, as applicable.

AGE RESTRICTIONS

- LGG with a BRAF V600E mutation: 1 year of age and older.
- Other indications previously listed: 6 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY/PARTIAL-FILL RESTRICTIONS

If member meets criteria for solution, then enter a quantity override to permit dosing based on current weight. When calculating restriction, add 10 kg to the member's current weight to allow for growth during their approval cycle.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

MEKTOVI® (BINIMETINIB)

Updated: January 16, 2024

Length of Authorization: 5 years
Initiative: PAR: Braftovi and Mektovi (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For use in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation.

For use in combination with encorafenib, for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation.

FDA-RECOMMENDED STARTING DOSE

45 mg twice daily, 12 hours apart

HOW SUPPLIED

15 mg tablets in 180-count bottles

COVERAGE CRITERIA

For Initial Coverage Requests:

- **For melanoma:**
  - The member has a confirmed diagnosis of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation; **AND**
  - Binimetinib will be used in combination with encorafenib.
- **For histiocytic neoplasm:**
  - The member has a confirmed diagnosis of Langerhans Cell Histiocytosis (LCH)
- **For NSCLC:**
  - The member has a confirmed diagnosis of metastatic NSCLC with a BRAF V600E mutation; **AND**
  - Binimetinib will be used in combination with encorafenib.

For Continuation Coverage Requests:

- The member has had a positive response to therapy, as attested to by the member's oncology provider.

REQUIRED MEDICAL INFORMATION

BRAF V600E or V600K mutation status (as applicable).

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES

Approve by GSN.

METYROSINE (DEMSER®)

Updated: January 4, 2024

Length of Authorization: 1 month
Initiative: PAR: Demser: (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- The treatment of patients with pheochromocytoma for:
  - Preoperative preparation of patients for surgery
  - Management of patients when surgery is contraindicated
  - Chronic treatment of patients with malignant pheochromocytoma

FDA-RECOMMENDED DOSE

- The recommended initial dosage for adults and children 12 years of age and older is 250 mg orally four times daily. This may be increased by 250 mg to 500 mg every day to a maximum of 4 g/day in divided doses.
- Use in children under 12 years of age has been limited and a dosage schedule for this age group cannot be given.

HOW SUPPLIED

250 mg capsules in 100- and 30-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of pheochromocytoma; **AND**
  - The member has surgical resection planned; **OR**
  - Surgery is contraindicated; **OR**
  - Patient has malignant pheochromocytoma, **AND**
- The member has tried and failed a selective alpha 1-adrenergic receptor blocker (e.g., doxazosin, terazosin and prazosin); **AND**
- The member has tried and failed a dihydropyridine calcium channel blocker (e.g., amlodipine, nifedipine, nimodipine)

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

- Chart notes or medical records supporting diagnosis.
- Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

12 years of age and older

PRESCRIBER RESTRICTIONS

Prescribed by a physician who specializes in the management of pheochromocytoma

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

1 month

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN

MIRIKIZUMAB-MRKZ (OMVOH)

Updated: 3/1/2024

Length of Authorization:	12 months
Initiative:	PAR: Omvoh: (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of moderately to severely active ulcerative colitis in adults.

FDA-RECOMMENDED DOSE

- **Induction**: 300 mg administered by IV infusion over at least 30 minutes at weeks 0, 4, and 8.
- **Maintenance**: 200 mg administered by subcutaneous injection (given as two consecutive injections of 100 mg each) at week 12, and every 4 weeks thereafter.

HOW SUPPLIED

- 300 mg/15 mL (20 mg/mL) single-dose vials
- 100 mg/mL Single-dose prefilled pen – carton of two

UTILIZATION CRITERIA

For initial coverage requests:

- The member has a diagnosis of moderate to severely active Ulcerative Colitis; **AND**
- The member has had a previous trial of, or contraindication to, at least one of the following:
  - Thiopurines (i.e., 6-mercaptopurine or azathioprine)
  - Corticosteroids; **OR**
- The member has tried and failed one or more previous biologic therapies (e.g., infliximab, certolizumab, vedolizumab, golimumab, ustekinumab, or natalizumab); **AND**
- The member has had a previous trial of, or contraindication to, at least two of the following preferred agents:
  - Adalimumab
  - Stelara
  - Xeljanz; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib), or other potent immunosuppressives (e.g., azathioprine, cyclosporine).

For continuation coverage requests:

- The member meets one of the following clinical scenarios:
  - The member is new to the subcutaneous dosage form **and** has received at least three IV infusions; **OR**
  - The member has been established on the subcutaneous mirikizumab regimen; **AND**
- The member has a diagnosis of moderate to severely active Ulcerative Colitis; **AND**
- The member continues to have a beneficial response to therapy, as assessed by the member's provider; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib), or other potent immunosuppressives (e.g. azathioprine, cyclosporine).

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by, or in consultation with, a gastroenterologist.

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY RESTRICTIONS

Refer to Formulary.

OPERATION NOTES AND OTHER INFORMATION

- Approve by GSN.
- IV therapy on the medical benefit is required for new starts.
- Members are not able to start mirikizumab therapy with the subcutaneous formulation.

MOMELOTINIB (OJJAARA)

Updated: November 22, 2023

Length of Authorization:	5 years
Initiative:	PAR: Ojjaara (IE 2462 / NCPDP 75 – HSN)

FDA-APPROVED INDICATION(S)

For the treatment of Intermediate or high-risk myelofibrosis (MF) including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia.

FDA-RECOMMENDED DOSE

Take one tablet once daily.

HOW SUPPLIED

Tablet, 100, 150, or 200 mg; 30-count bottles.

UTILIZATION CRITERIA

- For initial coverage requests:
  - The member has a diagnosis of MF; **AND**
  - The member has anemia, defined as Hgb <10 g/dL; **AND**
  - The member has tried and failed, or is contraindicated to, ruxolitinib (Jakafi).
- For continuation coverage requests:
  - The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies (if not contraindicated)

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a hematologist or oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by HSN.

MOTEGRITY® (PRUCALOPRIDE)

Updated: November 30, 2023

Length of Authorization:	12 months
Initiative:	PAR: Motegrity (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of chronic idiopathic constipation (CIC) in adults

FDA-RECOMMENDED DOSAGE

- Adult patients: 2 mg once daily
- Severe renal impairment (CrCl < 30 mL/min): 1 mg once daily

HOW SUPPLIED

1 and 2 mg tablets in 30-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member must have clinically diagnosed CIC with symptoms persisting for at least 3 months; **AND**
- The member has attempted lifestyle changes, including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; **AND**
- The member must not have a known or suspected mechanical gastrointestinal obstruction or perforation; **AND**
- The member must not be on concurrent lubiprostone, plecanatide, or linaclotide.

For Continuation Coverage Requests:

- The member must not be taking concurrent lubiprostone, plecanatide, or linaclotide; **AND**
- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a gastroenterologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

MULPLETA® (LUSUTROMBOPAG)

Updated: May 8, 2023

Length of Authorization:	30 days, to allow for the one-time 7-day course of therapy.
Initiative:	PAR: Mulpleta (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

FDA-RECOMMENDED DOSE

3 mg (1 tablet) once daily for 7 days, starting 8–14 days prior to the scheduled procedure

HOW SUPPLIED

3 mg tablets in 7-count blister packs

UTILIZATION CRITERIA

For All Coverage Reviews:

- The member has a confirmed diagnosis of chronic liver disease; **AND**
- The member has an initial platelet count less than 50x10^9/L; **AND**
- The member has a planned invasive, high risk, procedure to be performed 8-14 days after initiation date of lusutrombopag; **AND**
- The member is not receiving, or plans to receive, other TPO-Ras (i.e., romiplostim, avatrombopag, eltrombopag).

REQUIRED MEDICAL INFORMATION

- Date of scheduled procedure.
- Documentation of platelet count.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by a hepatologist or hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

30 days, to allow for the one-time 7-day course of therapy.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

MULTAQ® (DRONEDARONE)

Updated: October 30, 2023

Length of Authorization:	5 years
Initiative:	PAR: Multaq (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

Indicated to reduce the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation (AF)

FDA-RECOMMENDED DOSE

400 mg twice daily

HOW SUPPLIED

400 mg tablets

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of atrial arrhythmia, such as atrial fibrillation or atrial flutter; **AND**
- The member must **not** be either pregnant or breastfeeding at the point of request for this medication; **AND**
- The member must **not** be on concomitant therapy with any strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, voriconazole, cyclosporine, telithromycin, clarithromycin, nefazodone, and ritonavir); **AND**
- The member must **not** be on any concomitant use of drugs or herbal products that prolong QT interval (e.g., phenothiazine anti-psychotics, tricyclic antidepressants, certain oral macrolide antibiotics, and Class I and II antiarrhythmics); **AND**
- The member must **not** have any of the following:
  - History of NYHA Class IV heart failure, or history of NYHA Class II–III heart failure with a recent decompensation requiring hospitalization or referral to a specialized heart failure clinic.
  - Second or third degree atrioventricular (AV) block or sick sinus syndrome without the presence of a functioning pacemaker.
  - QTc interval greater than or equal to 500 ms or PR interval greater than 280 ms
  - Severe hepatic impairment.

For Continuation of Coverage:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

The coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

MUPIROCIN CREAM (BACTROBAN)

Updated: May 22, 2023

Length of Authorization:	2 months (initial and renewal)
Initiative:	PAR: Mupirocin Cream (IE 2462 / NCPDP 75 – HICL) STP: Mupirocin (IE 31121 / NCPDP 608 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of secondarily infected traumatic skin lesions (up to 10 cm in length or 100 cm^2 in area) due to susceptible isolates of *Staphylococcus aureus (S. aureus)* and *Streptococcus pyogenes (S. pyogenes).*

FDA-RECOMMENDED DOSE

A small amount of mupirocin cream is applied with a cotton swab or gauze pad to the affected area 3 times daily for 10 days.

HOW SUPPLIED

As 2% w/w mupirocin calcium (equivalent to 2% mupirocin free acid) in 15-gram and 30-gram tubes.

UTILIZATION CRITERIA

For Coverage Requests:

- The member has an active diagnosis of secondarily infected traumatic skin lesions (up to 10 cm in length or 100 cm^2 in area) due to susceptible isolates of *S. aureus* and *S. pyogenes*; **AND**
- The member has tried and failed an adequate trial of mupirocin ointment, verifiable through medical records or pharmacy claims, unless otherwise contraindicated.

REQUIRED MEDICAL INFORMATION

Medical records with therapeutic history, including reason(s) why mupirocin ointment is contraindicated, if applicable

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

N/A

COVERAGE DURATION

2 months (initial and renewal)

QUANTITY RESTRICTIONS

Refer to formulary.

MYALEPT® (METRELEPTIN)

Updated: November 2, 2023

Length of Authorization:	Initial: 6 months Continuation: 2 years
Initiative:	PAR: Myalept (ID 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

Indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy.

FDA-RECOMMENDED DOSE

- Administer as a subcutaneous injection once daily.

Patient Population	Initial Dose	Max Daily Dose
Patients ≤ 40 kg	0.06 mg/kg/day	0.13 mg/kg
Males > 40 kg	2.5 mg/day	10 mg/day
Females > 40 kg	5 mg/day	10 mg/day

HOW SUPPLIED

Single carton containing one vial for reconstitution; each vial contains 11.3 mg metreleptin (as a sterile, white, solid, lyophilized cake) to deliver 5 mg per mL of metreleptin when reconstituted.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of congenital or acquired generalized lipodystrophy associated with leptin deficiency; **AND**
- The member's condition has not been adequately controlled with diet modification and lifestyle changes; **AND**
- The member will be using metreleptin as an adjunct to diet modification; **AND**
- The member has one of the following complications associated with generalized lipodystrophy:
  - Diabetes mellitus with high insulin requirements (≥ 200 units/day or requiring U-500 insulin).
  - Severe hypertriglyceridemia (≥ 250 mg/dL) despite diet changes and medical therapy (e.g., fibrates, statins) at maximum-tolerated doses
  - Non-alcoholic steatohepatitis in a non-obese individual.

For Continuation Coverage Requests:

- The member has experienced or maintained a reduction from baseline in one of the following:
  - HbA1c
  - Serum triglycerides
  - NASH score
  - Daily insulin requirement.

REQUIRED MEDICAL INFORMATION

- The member's current weight (for quantity limit assessment).
- For Congenital Lipodystrophy: Genetic testing confirmation required.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an endocrinologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 6 months
- Continuation: 2 years

QUANTITY RESTRICTIONS

- Limit to maximum daily dose per FDA label
- For patients < 40 kg: When calculating restriction add 10 kg to the member's current weight to allow for growth during their approval cycle

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

MYCAPSSA® (OCTREOTIDE)

Updated: October 25,, 2023

Length of Authorization:	12 months
Initiative:	PAR: Mycapssa (ID 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

FDA-RECOMMENDED DOSE

40 mg daily (20 mg twice daily) initially, titrated up to a maximum dose of 80 mg daily.

HOW SUPPLIED

20 mg capsules in 28-count blister packs

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a documented diagnosis of acromegaly; **AND**
- The member has responded to and tolerated treatment with octreotide or lanreotide; **AND**
- The member's previous regimen has been stable for six months or longer.

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating diagnosis of acromegaly and use of previous therapies.

AGE RESTRICTIONS

18 years of age or older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an endocrinologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN

MYFEMBREE® (RELUGOLIX, ESTRADIOL, NORETHINDRONE ACETATE)

Updated: November 15, 2023

Length of Authorization:	Initial: approve for 24 months. Renewal: approve for the remainder of treatment course (maximum 24 months)
Initiative:	PAR: MYFEMBREE (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the management of heavy menstrual bleeding (HMB) associated with uterine leiomyomas (fibroids) in premenopausal women.
- For the management of moderate to severe pain associated with endometriosis in premenopausal women

FDA-RECOMMENDED DOSE

- One tablet of Relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg taken orally once daily.
- Maximum duration of therapy: 24 months.

HOW SUPPLIED

Fixed-dose combination tablet with relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg in 28-count bottles.

UTLILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a confirmed diagnosis of HMB associated with fibroids or moderate to severe pain associated with endometriosis; **AND**
- The member has tried and failed, or has contraindications to, an adequate trial of progestin-containing contraceptive preparation (combination hormonal contraceptive preparation, progestin-only contraceptive preparation); ***AND***
- The member has not had a cumulative lifetime exposure to GnRH antagonists (e.g., relugolix, elagolix) of greater than 24 months.

FOR CONTINUATION COVERAGE REQUESTS

- The member has had a beneficial response to therapy, as attested to by the member's specialist provider; **AND**
- The member has not received more than 24 months of GnRH antagonist therapy.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age or older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an obstetrician-gynecologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- If initial request, approve for 24 months or shorter of 24 months of lifetime GnRH antagonist therapy, if known.
- If continuation request, then approve for the remainder of treatment course (max 24 months).

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN

NATPARA® (PARATHYROID) HORMONE INJECTION

Updated: November 27, 2023

Length of Authorization:	12 months
Initiative:	PAR: Natpara (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

Indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.

FDA-RECOMMENDED DOSE

- Initiate at 50 mcg once daily as a subcutaneous injection in the thigh (alternate thigh every day).
- Dose is adjusted per serum calcium levels (see package insert).

HOW SUPPLIED

25, 50, 75, 100 mcg multi-dose cartridges containing powder and diluent for reconstitution

COVERAGE CRITERIA

For Initial Reviews:

- The member has a diagnosis of hypocalcemia secondary to hypoparathyroidism; **AND**
- The member must currently be treated with calcitriol and calcium; **AND**
- The member must not have hypoparathyroidism secondary to a calcium sensing receptor mutation; **AND**
- The total serum calcium level (albumin corrected) is above 7.5 mg/dL; **AND**
- The member must not have hypoparathyroidism secondary to surgery that occurred within the last 30 days.

For Continuation Reviews:

- Member has had a positive clinical response to therapy, as documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- Chart notes or medical records confirming diagnosis; **AND**
- Claims or medical records demonstrating use of current treatments.

AGE RESTRICTIONS

18 years of age.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an endocrinologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

All strengths: Approval is limited to a quantity of 2 cartridges per 28 days

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by HSN

NAYZILAM® (MIDAZOLAM) NASAL SPRAY

Updated: May 9, 2023

Length of Authorization:	Five years
Initiative:	PAR: Nayzilam (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older.

FDA-RECOMMENDED DOSE

- One spray (5 mg dose) into one nostril, followed by a second spray in the opposite nostril, as needed
- Should be used no more than one episode every three days and no more than five episodes every month.

HOW SUPPLIED

In boxes of two 5 mg/0.1 mL solution nasal spray units

UTILIZATION CRITERIA

For all coverage requests:

- The member has a history of intermittent, stereotypic episodes of frequent seizure activity.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

12 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a neurologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

Five years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

NERLYNX® (NERATINIB)

Updated: May 1, 2023

Length of Authorization:	12 months
Initiative:	PAR: Nerlynx (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the extended adjuvant treatment of adult patients with early-stage human epidermal growth factor receptor 2 (HER2)-positive breast cancer, to follow adjuvant trastuzumab based therapy.
- In combination with capecitabine, for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting.

FDA-RECOMMENDED DOSE

- Early-Stage Breast Cancer: 240 mg orally once daily continuously for one year.
- Advanced or Metastatic Breast Cancer: 240 mg (six tablets) given orally once daily with food on days 1–21 of a 21-day cycle plus capecitabine (750 mg/m^2 given orally twice daily) on days 1–14 of a 21-day cycle until disease progression or unacceptable toxicities.
- Two-week dose escalation may be considered.

HOW SUPPLIED

40 mg tablets in 126, 133, and 180-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a confirmed diagnosis of HER2+ breast cancer; **AND**
- The member meets one of the following clinical scenarios:
  - The member has stage IV, recurrent disease, or brain metastases and will use in combination with capecitabine; **OR**
  - The member has HR+ disease and will be using neratinib as extended adjuvant therapy following a trastuzumab containing regimen.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider. Toxicities.

REQUIRED MEDICAL INFORMATION

Breast cancer tumor status (HER2/HR as applicable)

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Coverage of neratinib for the treatment of early-stage HER2+ breast cancer is limited to a total duration of 12 months.

NEXAVAR® (SORAFENIB)

Updated: February 1, 2024

Length of Authorization:	5 years
Initiative:	PAR: Nexavar (IE 2462/NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of the following:
  - Unresectable hepatocellular carcinoma; **AND**
  - Advanced renal cell carcinoma; **AND**
  - Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) refractory to radioactive iodine treatment.

FDA-RECOMMENDED DOSE

400 mg orally twice daily.

HOW SUPPLIED

200 mg tablets in 120-count bottles.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has one of the following indications:
  - Recurrent chordoma; **OR**
  - Relapsed, refractory, or metastatic osteosarcoma; **OR**
  - FLT3 rearrangement positive acute myeloid leukemia (AML); **OR**
  - For Unresectable or metastatic Hhepatocellular carcinoma (HCC); **OR**
  - Unresectable, recurrent/progressive, or metastatic gastrointestinal stromal tumor (GIST) that has progressed on imatinib, sunitinib, regorafenib, and standard dose ripretinib; **OR**
  - Desmoid tumors (aggressive fibromatosis); **OR**
  - Angiosarcoma; **OR**
  - Solitary fibrous tumor; **OR**
  - FLT3 rearrangement positive myeloid/lymphoid neoplasm with eosinophilia; **OR**
  - Recurrent or platinum resistant ovarian, fallopian tube, or primary peritoneal cancer; **OR**
  - Follicular Thyroid Carcinoma; **OR**
  - Hürthle Cell Thyroid Carcinoma (aka Oncocytic Carcinoma); **OR**
  - Papillary Thyroid Carcinoma; **OR**
  - Medullary Thyroid Carcinoma; **OR**
  - Advanced Renal Cell Carcinoma (RCC); **OR**

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Chart notes or medical records confirming diagnosis and genetic testing where appropriate

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN

NEXLETOL™ AND NEXLIZET™ (BEMPEDOIC ACID)

Updated: October 30, 2023

Length of Authorization:	Five years
Initiative:	PAR: Nexletol (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

An adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of LDL-C.

FDA-RECOMMENDED DOSE

One tablet (180 mg bempedoic acid) by mouth once daily.

HOW SUPPLIED

- Nexletol: 180 mg bempedoic acid tablets in 30-count and 90-count bottles.
- Nexlizet: 180 mg bempedoic acid/10 mg ezetimibe in 30-count and 90-count bottles.

UTILIZATION CRITERIA

For Initial Coverage:

- The member must have one of the following diagnoses:
  - Established ASCVD as evidenced by supporting documentation of atherosclerotic cardiovascular disease (e.g., history of hospital admission, imaging study, or surgical procedure).
  - **Note**: examples of ASCVD include the following:
    - History of myocardial infarction or other acute coronary syndrome
    - Coronary or other revascularization procedure
    - Transient ischemic attack, or ischemic stroke
    - Atherosclerotic peripheral arterial disease; **AND**
    - Documented atherosclerotic disease such as coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, or carotid plaque with 50% or more stenosis).
  - Heterozygous Familial Hypercholesterolemia (HeFH) as established by **one** of the following*:*
    - Dutch Lipid Network clinical criteria, score greater than 6; **OR**
    - Simon-Broome Criteria (definite HeFH); **OR**
    - Confirmed genetic testing; **AND**
- The member must have had an inadequate response (i.e., LDL-C greater than 70 mg/dL while on at least 12 weeks of therapy) to maximally tolerated atorvastatin or rosuvastatin therapy in combination with ezetimibe, unless otherwise contraindicated or intolerant to both atorvastatin and rosuvastatin, or ezetimibe.[1] If unable to take ezetimibe, must have had a 12-week trial of maximally tolerated atorvastatin or rosuvastatin therapy.
- **Note:** trial of ezetimibe is not required if member could not tolerate or is contraindicated to statin therapy (i.e., coverage does not require ezetimibe monotherapy trial).

[1]Statin intolerance requires the following:

- Attestation of severe and intolerable adverse effects that have occurred with every trial of statin, and other potential causes were ruled out (low vitamin D levels, sudden increase in intense or prolonged physical activity, drug interactions with statins, or other metabolic or inflammatory causes); **AND**
- The member has tried alternate dosing strategies such as every-other-day statin dosing or twice weekly dosing.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

For Initial Reviews:

- Baseline fasting lipid panel; **AND**
- ASCVD event documentation.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a cardiologist, lipid specialist, or endocrinologist

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

Five years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

- Approve by GSN.
- Allow both products per PA request (e.g., a request for Nexlizet does not require additional clinical review if previously approved for Nexletol).

NINLARO® (IXAZOMIB)

Updated: April 25, 2023

Length of Authorization:	5 years
Initiative:	PAR: Ninlaro (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

In combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

FDA-RECOMMENDED DOSE

4 mg administered orally once a week on days 1, 8, and 15 of a 28-day treatment cycle.

HOW SUPPLIED

4 mg, 3 mg, and 2.3 mg capsules in 1-count blister packs and 3-count cartons.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **Multiple Myeloma (MM), previously treated:**
  - The member has a diagnosis of multiple myeloma; **AND**
  - The member has received at least one prior therapy for MM; **AND**
  - The requested medication will be used
    - In combination with lenalidomide and dexamethasone; **OR**
    - In combination with cyclophosphamide and dexamethasone; **OR**
    - In combination with dexamethasone; **OR**
    - In combination with dexamethasone and pomalidomide (for patients who have received at least two prior therapies including an immunomodulatory agent and a proteasome inhibitor and who have demonstrated disease progression on or within 60 days of completion of the last therapy); **OR**
    - As monotherapy maintenance therapy after response to primary therapy.
- **For MM, primary treatment:**
  - The member has a diagnosis of multiple myeloma; **AND**
  - The requested medication will be used in combination with:
    - Lenalidomide and dexamethasone; **OR**
    - Cyclophosphamide and dexamethasone (if the member is a transplant candidate).
- **For Systemic Light Chain Amyloidosis:**
  - The member has a diagnosis of relapsed or refractory Systemic Light Chain Amyloidosis; **AND**
  - The member has received at least one prior line of therapy for their condition; **AND**
  - The requested medication will be used in combination with dexamethasone.
- **For Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL):**
  - The member has a diagnosis of either Waldenström Macroglobulinemia or Lymphoplasmacytic Lymphoma; **AND**
  - The requested medication will be used in combination with rituximab and dexamethasone.

For Continuation Coverage Requests:

- The member has had a positive clinical response to therapy, as documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

NITYR® AND ORFADIN® (NITISINONE)

Updated: May 22, 2023

Length of Authorization:	12 months
Initiative:	PAR: Nityr (IE 2462 / NCPDP 75 – GSN; IE 2641, 15110 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine

FDA-RECOMMENDED DOSE

Starting Dose:

- 0.5 mg/kg orally twice daily, rounded up to the nearest dose achievable with available tablet strengths

Maintenance Dose:

- Titrated up to a maximum dose of 2 mg/kg orally twice daily, rounded up to the nearest dose achievable with available tablet strengths. In patients ≥ 5 years of age who have undetectable serum and urine succinylacetone concentrations after at least 4 weeks on a stable dose, the total daily dose may be given once daily.

HOW SUPPLIED

2 mg, 5 mg, and 10 mg tablets in 60-count bottles

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member has a documented diagnosis of HT-1; **AND**
- The member is on a dietary plan that restricts tyrosine and phenylalanine.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Member's current weight (kg)

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an HT-1 specialist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Coverage is limited to the lesser-of the daily requested dose or 2 mg/kg twice daily, rounded up to the nearest dose achievable with available strengths. The maximum daily dose should be calculated by the clinical reviewer using the most current weight provided by the prescriber.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by requested GSN.

NON-FORMULARY POLICY

Updated: April 22, 2024

Length of Authorization:	Shorter of 12 months or planned duration of therapy
Initiative:	EXC: Non-Formulary Product (IE 50076 / NCPDP 70 – GSN, IE 50084 / NCPDP 78 – GSN)

POLICY OVERVIEW

- The University of Michigan Prescription Drug Plan (PDP) allows coverage of non-formulary (NF) products in cases in which the member's request for coverage meets the plan's formulary exception (FE) coverage criteria.
- The plan's FE review process is to be applied to all products classified by the PDP as NF that are not otherwise managed by drug-specific coverage criteria.
- The PDP must be consulted for all non-contraceptive overrides where the anticipated cost per claim exceeds $2,000.

COVERAGE CRITERIA

For contraceptive agents:

- The member's provider states that the NF contraceptive agent is the only medically appropriate contraceptive agent for the member.

For biologic products with biosimilars:

- The request for coverage is for the product's FDA-approved indication; **AND**
- The member has undergone an adequate therapeutic trial with, or have contraindications to, all formulary alternative biosimilars. In general, an adequate therapeutic trial is defined as one or more months of therapy or must be accompanied by attestation from the provider that such therapy was ineffective, intolerable, or unsafe.

For intravenous (IV) products with self-administered formulations:

- The member is currently established on the NF product, either through a previous FE authorization or through coverage from a previous insurer, and the member's provider attests that altering the current treatment plan would result in patient harm or significantly adverse clinical outcomes; **OR**
- The member meets all of the following:
  - The request for coverage is for the product's FDA-approved indication; **AND**
  - The member must be clinically ineligible for intravenous infusions with documentation in chart notes; **AND**
  - The member meets one of the following:
    - The member has tried and failed all formulary alternatives; **OR**
    - The member is established on the IV formulation but has documented reason they can no longer continue.

For all other agents:

- The request for coverage is for the product's FDA-approved indication; **AND**
- The member has undergone an adequate therapeutic trial with, or have contraindications to, all formulary alternatives for the product's intended indication. In general, an adequate therapeutic trial is defined as one or more months of therapy or must be accompanied by attestation from the provider that such therapy was ineffective, intolerable, or unsafe; **OR**
- The member is currently established on the NF product, either through a previous FE authorization or through coverage from a previous insurer, and the member's provider attests that altering the current treatment plan would result in patient harm or significantly adverse clinical outcomes.

REQUIRED MEDICAL INFORMATION

- Documentation of trials of formulary alternatives.
- Documentation of ineligibility for IV therapy, as applicable.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

The shorter of 12 months or planned duration of therapy

OPERATIONAL NOTES AND OTHER INFORMATION

- All approvals should be entered at the GSN level. Formulary alternatives include all clinically equivalent products. Products within the same GSN do not need to be trialed more than once.
- Approved NF contraceptive agents should be approved at tier 0
  - The PDP does **not** need to be consulted for NF contraceptive overrides where the anticipated cost per claim exceeds $2,000 (example, Annovera does not need to go to the client for approval).
- In general, a member's use of drug samples does not meet the criteria for having been established on therapy. Drug samples may only be considered in cases where a member has initiated use of a NF product for the treatment of a psychiatric illness, and the provider attests that the member may decompensate if therapy is interrupted or modified.
- If a drug is classified as "excluded" by the PDP, the member and provider are both to receive a denial letter with instructions on how to appeal the decision to the State of Michigan.
- Biologic products with a biosimilar alternative(s) on formulary are not eligible for continuation from previous insurers.

INTERNAL NOTES

- Refer to Non-Formulary Requests Exceeding $2,000 where the anticipated cost per claim exceeds $2,000.
- For requests **not** over $2,000, select appropriate CTI starting with Call Category: *MAP PA Inquiry.*

NOURIANZ™ (ISTRADEFYLLINE)

Updated: July 28, 2023

Length of Authorization:	12 months
Initiative:	PAR: Nourianz (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

As an adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes.

FDA-RECOMMENDED DOSE

20 mg to 40 mg orally once daily.

HOW SUPPLIED

20 mg and 40 mg tablets in 90-count bottles.

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of Parkinson's disease; **AND**
- The member is currently receiving a carbidopa/levodopa formulation; **AND**
- The member has tried and failed all of the following "off" period management strategies, unless contraindicated:
  - Add-on therapy with a dopamine agonist (e.g., pramipexole, ropinirole, rotigotine)
  - Add-on therapy with an MAO-B inhibitor (e.g., rasagiline, selegiline, safinamide)
  - Add-on therapy with a COMT inhibitor (e.g., entacapone, tolcapone)
  - Extended-release carbidopa/levodopa
  - Modifications or alterations to carbidopa/levodopa dose scheduling

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION
12 months
QUANTITY/PARTIAL-FILL RESTRICTIONS
Refer to formulary
OPERATIONAL NOTES AND OTHER INFORMATION
N/A

NOXAFIL® (POSACONAZOLE)

Updated: September 29, 2023

Length of Authorization:	For prophylaxis of invasive Aspergillus and Candida infection: 6 months For treatment of invasive aspergillosis: 3 months For treatment of oropharyngeal candidiasis: 1 month
Initiative:	PAR: Noxafil (IE 2462 / NCPDP 75 – GSN; IE 15110 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of oropharyngeal candidiasis, including oropharyngeal candidiasis refractory to itraconazole and/or fluconazole, in patients 13 years of age or older (Noxafil suspension only).
- For prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy.
  - Noxafil DR tablets: 2 years of age or older who weigh greater than 40 kg.
  - Noxafil IR oral suspension: 13 years of age or older.
  - Noxafil PowderMix for DR oral suspension: pediatric patients 2 years of age or older who weigh 40 kg or less.
- For the treatment of invasive aspergillosis in patients 13 years of age or older (DR tablets only).

FDA-RECOMMENDED DOSE

- Refer to package insert.

HOW SUPPLIED

- 100 mg delayed-release (DR) tablets in 60-count bottles.
- 40 mg/mL immediate release (IR) suspension in 105 mL glass bottles.
- 300 mg Noxafil PowderMix for DR Oral Suspension.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- For the treatment of oropharyngeal candidiasis (IR suspension only):
  - The member has a diagnosis of oropharyngeal candidiasis; **AND**
  - Fungal culture report has been obtained prior to initiation of antifungal therapy; **AND**
  - One or more of the following is met:
    - The member has tried and failed or has a contraindication to both fluconazole and itraconazole.
    - Fungal culture report shows sensitivity to only posaconazole.
- For the prophylaxis of invasive Aspergillus and Candida infections (IR suspension, DR PowderMix suspension, and tablet)
- The member meets one of the following clinical scenarios:
  - The member is at high risk of developing *Aspergillus* and *Candida* infections due to being a hematopoietic stem cell transplant (HSCT) recipient with graft-versus-host disease (GVHD); **OR**
  - The member has a hematologic malignancy with prolonged neutropenia (i.e., ANC of less than 1500/µL) from chemotherapy; **AND**
  - If requesting DR PowderMix suspension, the member weighs ≤40kg.
- For the treatment of invasive aspergillosis (DR tablet only)
  - The member has a diagnosis of invasive aspergillosis; **AND**
  - Fungal culture report has been obtained prior to initiation of antifungal therapy; **AND**

- One or more of the following is met:
  - The member has tried and failed, or has contraindication to, voriconazole
  - Fungal culture report shows sensitivity to only posaconazole

- For the prophylactic treatment of fungal infections in patients receiving a bone-marrow transfusion (IR suspension, DR PowderMix suspension, and DR tablet)
  - The member is receiving a bone-marrow transfusion; **AND**
  - The member is high-risk per specialist attestation; **AND**
  - The member has tried and failed, or has contraindication to, voriconazole

For Continuation Coverage Requests

- For the continued treatment of oropharyngeal candidiasis
  - Member continues to have a diagnosis of oropharyngeal candidiasis; **AND**
  - Fungal culture report shows continued sensitivity to posaconazole.
- For the continued prophylaxis of invasive Aspergillus and Candida infections
  - The member must meet initial criteria for coverage.
- For the continued treatment of invasive aspergillosis
  - The member continues to have a diagnosis of invasive aspergillosis; **AND**
  - Fungal culture report shows continued sensitivity to posaconazole.
- For continued infection prophylaxis in patients receiving a bone-marrow transfusion
  - The member remains at high risk of infection due to prior bone marrow transfusion.

REQUIRED MEDICAL INFORMATION

- Fungal culture reports, as needed per coverage criteria
- If requesting DR suspension, weight documentation is required

AGE RESTRICTIONS

- Delayed-release tablet: 2 years of age or older
- IR Suspension: 13 years of age or older
- DR Suspension: 2–18 years of age

SUSPENSION: 13 YEARS OF AGE AND OLDER. PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an infectious disease specialist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

- For prophylaxis of invasive *Aspergillus* and *Candida* infections: 6 months
- For the prophylactic treatment of fungal infections in patients receiving a bone-marrow transfusion: 6 months
- For treatment of invasive aspergillosis: 3 months
- For treatment of oropharyngeal candidiasis: 1 month

QUANTITY RESTRICTIONS

- For prophylaxis of invasive *Aspergillus* and *Candida* infections:
  - For DR tablets: Approve a quantity allowing up to 543 tablets per 180 days.
  - For oral IR suspension: Approve a quantity allowing up to 2,700 mL per 180 days.
  - For oral DR suspension: Approve a quantity allowing up to 1,448 mL per 180 days.
- For treatment of oropharyngeal candidiasis:
  - For oral IR suspension: Approve a quantity allowing up to 600 mL per 30 days. 1 occurrence
- For treatment of invasive aspergillosis:
  - For DR tablets: Approve a quantity allowing up to 258 tablets per 84 days.
- For the prophylactic treatment of fungal infections in patients receiving a bone-marrow transfusion:
  - For DR tablets: Approve a quantity allowing up to 543 tablets per 180 days.
  - For oral IR suspension: Approve a quantity allowing up to 2,700 mL per 180 days.
  - For oral DR suspension: Approve a quantity allowing up to 1,448 mL per 180 days.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

NUBEQA™ (DAROLUTAMIDE)

Updated: April 28, 2023

Length of Authorization:	5 years
Initiative:	PAR: Nubeqa (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients with non-metastatic castration-resistant prostate cancer (NM-CRPC).
- For the treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel.

FDA-RECOMMENDED DOSE

- nmCRCP: 600 mg orally twice daily via two 300 mg tablets for a total daily dose of 1200 mg
- mHSPC: administer the first cycle of docetaxel within 6 weeks after the start of darolutamide treatment: dosed concurrently with a gonadotropin-releasing hormone (GnRH) analog, or without in patients with a bilateral orchiectomy.

HOW SUPPLIED

300 mg tablets in 120-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **NM-CRPC:**
  - The member has a diagnosis of NM-CRPC; **AND**
  - The member has undergone bilateral orchiectomy or will concurrently receive a GnRH analog.
- **mHSPC:**
  - The member has a diagnosis of mHSPC; **AND**
  - Darolutamide will be used in combination with docetaxel; **AND**
  - The member has undergone bilateral orchiectomy **or** will concurrently receive a GnRH analog.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

NUCALA® (MEPOLIZUMAB)

Updated: April 1, 2024

Length of Authorization:	12 months
Initiative:	PAR: Nucala (IE 2462 / NCPDP 75 – GSN; (IE 7001 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

- For the add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype.
- For the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
- For the add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.
- For the treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause.

FDA-RECOMMENDED DOSE

Severe asthma:

- 6 to 11 years of age: 40 mg administered subcutaneously once every 4 weeks.
- 12 years of age and older: 100 mg administered subcutaneously once every 4 weeks.
- **EGPA:** 300 mg administered subcutaneously once every 4 weeks (3 separate 100 mg injections).
- **CRSwNP**: 100 mg administered subcutaneously once every 4 weeks.
- **HES**: 300 mg administered subcutaneously once every 4 weeks (3 separate 100 mg injections).

HOW SUPPLIED

- 100 mg in a single-dose vial for reconstitution (non-self-administered)
- 100 mg/mL solution in a single-dose prefilled autoinjector or a single-dose prefilled glass syringe (self-administered)

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

For All Indications:

- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

Severe Eosinophilic Asthma:

- The member has a confirmed diagnosis of severe asthma; **AND**
- The member is currently utilizing a high dose inhaled corticosteroid (ICS) product plus either a long-acting beta-2 agonist (LABA) or long-acting muscarinic antagonist (LAMA); **AND**
- The member has documentation of blood eosinophils ≥300 cells/mcL within previous 12 months or ≥ 150 cells/mcL within preceding six weeks **or** the member has been established on an alternative anti-IL-4/5 product (e.g., reslizumab, benralizumab, or dupilumab).

EGPA:

- The member has a confirmed diagnosis of eosinophilic granulomatosis with polyangiitis; **AND**
- The member has tried and failed therapy management with a monotherapy corticosteroid regimen

CRSwNP:

- The member has a diagnosis of CRSwNP; **AND**
- The member will use mepolizumab in combination with intranasal corticosteroids unless unable to tolerate or contraindicated; **AND**
- The member has tried and failed **one** of the following
  - Intranasal corticosteroids; **OR**
  - Surgical intervention

HES:

- The member has a confirmed diagnosis of hypereosinophilic syndrome for ≥ 6 months; **AND**
- The member's HES diagnosis does not have an identifiable non-hematologic cause (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, or non-hematologic malignancy); **AND**
- The member's diagnosis is not associated with FIP1L1-PDGFR-alpha kinase mutation; **AND**
- The member experienced at least 2 HES flares within the past 12 months; **AND**
- The member has documentation of blood eosinophils greater than or equal to 1000 cells/mcL at initiation of therapy; **AND**
- The member has been on stable HES therapy for at least 4 weeks (e.g., chronic, or episodic oral corticosteroids, immunosuppressive, cytotoxic therapy).

FOR CONTINUATION OF COVERAGE REQUESTS

For All Indications:

- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib).

Severe Eosinophilic Asthma:

- The member has experienced a decrease in the frequency of exacerbations and improvement in symptoms, as attested to by the member's specialist provider.

EGPA, CRSwNP, HES:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialty provider

REQUIRED MEDICAL INFORMATION

- For eosinophilic asthma, documentation of blood eosinophil count (cells/mcL) with date
- For HES, documentation of blood eosinophil counts at initiation of therapy.

AGE RESTRICTIONS

- **Severe asthma:** 6 years of age and older
- **CRSwNP and EGPA:** 18 years of age and older
- **HES:** 12 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an asthma specialist, immunologist, allergist, pulmonologist, rheumatologist, or an ear, nose, and throat (ENT) specialist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Severe asthma and CRSwNP:

- Refer to formulary
  - **Internal note**: Enter PA with a metric quantity and days' supply of #1/28 DS.

EGPA and HES:

- Enter PA with a metric quantity and days' supply of #3/28 DS.

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve by GSN.
- Members transitioning from medical benefit to the pharmacy benefit should be treated as a continuation of therapy requests.

NUCYNTA® AND NUCYNTA® ER (TAPENTADOL)

Updated: May 30, 2023

Length of Authorization:	For acute pain (IR only): 2 months All other requests: 12 months
Initiative:	PAR: Nucynta (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

The IR formulation is indicated for the following:

- The management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults.

The ER formulation is indicated for the following:

- Pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate
- Neuropathic pain associated with diabetic peripheral neuropathy (DPN) severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

FDA-RECOMMENDED DOSE

- **IR:** 50 mg to 100 mg every 4 to 6 hours as needed for pain. Up to 700 mg per day.
- **ER:** 50 mg tablet orally twice daily (approximately every 12 hours). Up to 500 mg ER per day

HOW SUPPLIED

- **IR:** 50, 75, or 100 mg immediate-release tablets
- **ER:** 50, 100, 150, 200, or 250 mg extended-release tablets

COVERAGE CRITERIA

FOR ALL COVERAGE REQUESTS

For All Indications:

- The member does not have impaired pulmonary function; **AND**
- The member does not have or is suspected of having paralytic ileus; **AND**
- The member is not currently using, or has used in the last 14 days, a monoamine oxidase inhibitor; **AND**
- The member does not have severe renal or hepatic impairment; **AND**
- The member meets the indication specific criteria below.

For Acute Pain (IR Only):

- The member has a diagnosis of moderate to severe acute pain; **AND**
- The member has tried and failed, or had an intolerance to, at least three formulary alternative immediate-release narcotic medications (e.g., morphine sulfate, oxycodone, hydromorphone, hydrocodone/APAP, etc.); **AND**

For Breakthrough Pain (IR Only):

- The member has a diagnosis of breakthrough pain; **AND**
- The member has tried and failed, or had an intolerance to, at least three formulary alternative immediate-release narcotic medications (e.g., morphine sulfate, oxycodone, hydromorphone, hydrocodone/APAP, etc.); **AND**
- The member's treatment plan must include use of Nucynta ER for chronic pain.

FOR ALL COVERAGE REQUESTS (CONTINUED)

For Chronic Pain (ER Only):

- The member has a diagnosis of chronic pain; **AND**
- The member requires around-the-clock, chronic pain management with an opioid; **AND**
- The member has tried and failed at least two long-acting formulary alternative opioid products.

For Neuropathic Pain (ER Only)

- The member has a diagnosis of neuropathic pain; **AND**
- The member has tried and failed at least two of the following agents with a minimum of a 14-day trial:
  - pregabalin
  - gabapentin
  - sodium valproate
  - amitriptyline
  - venlafaxine
  - duloxetine

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

N/A

COVERAGE DURATION

- Acute pain: 2 months
- All other indications: 12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

Approve by GSN

NUEDEXTA® (DEXTROMETHORPHAN/QUINIDINE)

Updated: November 29, 2023

Length of Authorization:	12 months
Initiative:	PAR: Nuedexta (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

Treatment of pseudobulbar affective disorder (PBA).

FDA-RECOMMENDED DOSE

One capsule daily for seven days, followed by two capsules every twelve hours thereafter

HOW SUPPLIED

20 mg–10 mg (dextromethorphan-quinidine) capsules in bottles of 60 capsules.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a confirmed diagnosis of pseudobulbar affective disorder (PBA); ***AND***
- The member has an underlying neurological condition causing symptoms of PBA (e.g., multiple sclerosis, amyotrophic lateral sclerosis, Parkinson's Disease, stroke, traumatic brain injury).

FOR CONTINUATION COVERAGE REQUESTS

- The member has had a confirmed reduction in the number of episodes of inappropriate laughing or crying episodes per day while being treated with dextromethorphan/quinidine.

REQUIRED MEDICAL INFORMATION

- Medical records or chart notes demonstrating diagnosis; **AND**
- Medical records or chart notes demonstrating underlying neurological condition causing symptoms of PBA; **AND**
- Number of episodes of inappropriate laughing or crying per day.

AGE RESTRICTIONS

18 years of age and older.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

PRESCRIBER RESTRICTIONS

Prescribed by or in consultation with a neurologist, psychiatrist, or neuropsychologist.

COVERAGE DURATION

12 months.

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve by GSN
- Evidence to support the use of dextromethorphan/quinidine to manage agitation and/or aggression in patients with dementia or Alzheimer's without pseudobulbar affect is limited. Therefore, this use is considered experimental. Experimental treatments are excluded by the plan.

NUPLAZID® (PIMAVANSERIN)

Updated: November 17, 2023

Length of Authorization:	5 years
Initiative:	PAR: Nuplazid (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of hallucinations and delusions associated with Parkinson's disease psychosis

FDA-RECOMMENDED DOSE

34 mg taken orally once daily, without titration.

HOW SUPPLIED

- 10 mg tablets in a 30-count bottle.
- 34 mg capsules in a 30-count bottle.

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member must have a diagnosis of Parkinson's disease; **AND**
- The member has tried and failed, or is not a candidate for, quetiapine and clozapine.

For Continuation Coverage Requests:

- Member has had a positive clinical response to therapy, as documented by the member's provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by a behavioral health specialist, neurologist, or geriatric specialist.

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

Five years.

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION INSTRUCTIONS AND OTHER INFORMATION

Approve by GSN.

NUZYRA® (OMADACYCLINE)

Updated: May 23, 2023

Length of Authorization:	2 months
Initiative:	PAR: Nuzyra (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with the following infections caused by susceptible microorganisms:

- Community-acquired bacterial pneumonia (CABP)
- Acute bacterial skin and skin structure infections (ABSSSI)

FDA-RECOMMENDED DOSAGE

- CABP:
  - 200 mg IV on day 1, followed by 100 mg IV once daily or 300 mg tablet once daily
  - 100 mg IV twice on day 1, followed by 100 mg IV once daily or 300 mg tablet once daily
  - 300 mg tablet twice daily on day 1, followed by 300 mg once daily.
- ABSSSI:
  - 450 mg tablet orally once daily on days 1 and 2, followed by 300 mg once daily
  - 200 mg IV on day 1, followed by 100 mg IV once daily or 300 mg tablet once daily.
  - 100 mg IV twice on day 1, followed up 100 mg IV once daily or 300 mg tablet once daily.
- The FDA-approved treatment duration for both CABP and ABSSSI is 7 to 14 days.

HOW SUPPLIED

- 100 mg single-dose vials
- 150 mg tablets in 6 and 30 count blister packs

COVERAGE CRITERIA

For All Coverage Requests:

- The member has a diagnosis or CABP or ASSSI caused by a susceptible microorganism; **AND**
- The member has initiated omadacycline in an inpatient setting.

REQUIRED MEDICAL INFORMATION

- Susceptibility results.
- Chart notes to confirm diagnosis and number of doses received inpatient.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Prescribed by or in consultation with an infectious disease specialist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

2 months.

QUANTITY RESTRICTIONS

Max 14 tablets allowed per approval.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

OCALIVA® (OBETICHOLIC ACID)

Updated: August 16, 2023

Length of Authorization:	Varies, see below
Initiative:	PAR: Ocaliva (IE 2462 / NCPDP 75 – GSN; IE 2641, 15110 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.

FDA-RECOMMENDED DOSE

5 mg orally once daily, titrated to a maximum dose of 10 mg once daily.

HOW SUPPLIED

5 and 10 mg tablets in 30-count bottles.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of PBC as confirmed by at least two of the following criteria:
  - An alkaline phosphatase (ALP) level of at least 1.5 times the upper limit of normal (ULN)
  - The presence of antimitochondrial antibodies at a titer of 1:40 or higher
  - Histologic evidence of PBC (e.g., non-suppurativa destructive cholangitis and destruction of interlobular bile ducts); **AND**
- The product will be used in combination with ursodeoxycholic acid (UDCA) (e.g., Ursodiol, Urso 250, Urso Forte) in adults with an inadequate response to ursodeoxycholic acid (UDCA) at a dosage of 13–15 mg/kg/day for at least 1 year OR as monotherapy in adults unable to tolerate ursodeoxycholic acid (UDCA); **AND**
- The member does not have complete biliary obstruction.

FOR CONTINUATION COVERAGE REQUESTS

- The member has had a positive response to therapy, as documented by the member's specialty provider; **AND**
- The following three criteria are met:
  - ALP is less than 1.67 times the ULN
  - Total bilirubin is less than or equal to ULN
  - ALP has decreased at least 15% from pre-treatment levels

REQUIRED MEDICAL INFORMATION

For Initial Coverage Requests:

- Chart notes/lab results demonstrating ALP level, antibody titer, or histologic confirmation, as applicable.
- Chart notes/lab results demonstrating Child-Pugh Score.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a gastroenterologist or hepatologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- 3 months plus 9 months (initial)
- 12 months (continuation)

QUANTITY RESTRICTIONS

- **For Child-Pugh Score of "A":** New start authorizations should consist of an initial three-month approval of 5 mg per day, followed by a second nine-month approval of up to 10 mg per day.
  - Internal Note:
    - Approval 1 (Days 1–90) Enter PA with a metric quantity and days' supply of #30/30 days of the 5 mg tablet.
    - Approval 2 (Days 91–365) Enter PA with a metric quantity and days' supply of #30/30 days of the 10 mg tablet (starting the day after approval 1 ends).
    - Select appropriate CTI and send the letter on both approvals.
- **For Child-Pugh Scores of "B" or "C":** New start authorizations should consist of an initial max daily dose of 5 mg per week for the first three months, followed by approval of up to 10 mg twice weekly (two 10 mg tablets per week) for the following nine months.
  - Internal Note:
    - Approval 1 (Days 1–90) Enter PA with a metric quantity and days' supply of #4/28 days of the 5 mg tablet.
    - Approval 2 (Days 91–365) Enter PA with a metric quantity and days' supply of #8/28 days of the 10 mg tablet (starting the day after approval 1 ends).
    - Select appropriate CTI and send the letter on both approvals.
- **Continuation requests:** Should allow for the maintenance dosing per liver status.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HSN.

ODACTRA® (HOUSE DUST MITE ALLERGEN EXTRACT)

Updated: November 3, 2023

Length of Authorization:	6 months (initial), 12 months (continuation)
Initiative:	PAR: Odactra (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For house dust mite (HDM)-induced allergic rhinitis with or without conjunctivitis, confirmed by positive in-vitro testing for IgE antibodies or skin testing.

FDA-RECOMMENDED DOSE

One tablet (12 SQ-HDM) dissolved sublingually for 10 seconds each day without water.

HOW SUPPLIED

12 SQ-HDM sublingual tablets supplied in three blister packs of 10 tablets each.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of allergic rhinitis induced by house dust mite allergy, which is confirmed by positive skin testing or in-vitro testing to confirm the presence of IgE antibodies to Dermatophagoides farina or Dermatophagoides pteronyssinus; **AND**
- The member does not have severe, unstable, or uncontrolled asthma; **AND**
- The member does not have a history of eosinophilic esophagitis; **AND**
- The member's first dose will be monitored for 30 minutes by a health care provider; **AND**
- The prescriber attests to the member having a current prescription for self-injectable epinephrine; **AND**
- The member has tried and failed 2 of, or has a contraindication to all, the following:
  - Oral antihistamine
  - Intranasal antihistamine
  - Intranasal corticosteroid
  - Leukotriene inhibitor

FOR CONTINUATION COVERAGE REQUESTS

The member has had a positive clinical response to therapy, as documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- Medical records or chart notes confirming diagnosis of house dust mite allergy; **AND**
- Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

12 years to 65 years of age.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an allergy specialist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 6 months.
- Continuation: 12 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

ODOMZO® (SONIDEGIB)

Updated: March 10, 2023

Length of Authorization:	5 years
Initiative:	PAR: Odomzo

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with locally advanced basal cell carcinoma that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.

FDA-RECOMMENDED DOSE

200 mg taken orally once daily

HOW SUPPLIED

200 mg capsules in 30-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **For diffuse disease:**
  - The member has a diagnosis of diffuse BCC caused by a genetic disorder (e.g., Gorlin syndrome).
- **For locally advanced disease:**
  - The member has a diagnosis of locally advanced BCC; **AND**
  - The member meets one of the following scenarios:
    - The member has experienced a recurrence of their BCC after surgery or radiation; **OR**
    - The member is not a candidate for surgery or radiation; **OR**
    - The member needs additional treatment for positive margins after surgery.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

OFEV® (NINTEDANIB)

Updated: November 17, 2023

Length of Authorization:	12 months
Initiative:	PAR: Ofev (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of idiopathic pulmonary fibrosis (IPF)
- For the treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.
- To slow the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD)

FDA-RECOMMENDED DOSE

150 mg by mouth every 12 hours

HOW SUPPLIED

100 mg and 150 mg capsules in 60-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a documented, confirmed diagnosis of IPF, chronic fibrosing ILD with a progressive phenotype, or SSc-ILD; **AND**
- If member has a confirmed diagnosis of SSc-ILD, evidence of trial and treatment failure of mycophenolate mofetil or cyclophosphamide; **AND**
- The member does not have moderate or severe hepatic impairment (Child Pugh B or C);

For Continuation Coverage Requests:

- The member has experienced a positive clinical response as attested to by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

For initial requests: Documentation of confirmed diagnosis and claims or medical records demonstrating use of previous therapies

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a pulmonologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

N/A

OFF-LABEL USE AND QUANTITY-LIMIT EXCEPTION POLICY

Updated: May 30, 2023

Length of Authorization:	Limited to the shorter of 12 months or planned duration of therapy
Initiative:	Drug specific

UNIVERSITY OF MICHIGAN'S PRESCRIPTION DRUG PLAN

- The University of Michigan (U-M) Prescription Drug Plan (PDP) utilizes an evidence-based medicine approach to coverage policy and formulary management. Resources used include, but are not limited to, published clinical trial data, meta-analyses and/or review articles, FDA-approved product labeling, treatment and/or consensus guidelines, University subject matter experts, and other clinical resources.
- The Pharmacy Benefits Advisory Committee (PBAC) acts as an independent advisory panel of University of Michigan physicians, pharmacists, and PDP staff, charged to evaluate drug products for coverage on the U-M PDP formulary. All PBAC members are required to submit annual conflict of interest disclosures.
- The U-M PDP is responsible for the final determination of recommendations, implementation, operations, coordination, and follow-up of drug review decisions recommended by PBAC with the contracted pharmacy benefit manager (PBM).
- Drug formulary coverage is evaluated on several criteria, including efficacy, safety, clinical appropriateness, place in therapy, treatment guidelines, clinical expert opinion, therapeutic alternatives, cost, and projected utilization.
- In order to meet the requirement that the use of the drug is reasonable and necessary for the treatment of disease, the drug must be safe and effective for its intended use. Drugs approved for marketing by the Food and Drug Administration (FDA) are generally considered safe and effective when used for indications specified on the labeling. An "off-label" use of a drug is defined as a use for a non-FDA approved indication or for use in quantities that differ from the FDA-approved label. That is, one that is not listed on the drug's official label/prescribing information.

COVERAGE CRITERIA

- The plan will accept non-FDA approved indications for coverage, or quantities that differ from the FDA-approved regimens, where supported by the following Center for Medicare and Medicaid Services (CMS) approved compendia or peer-reviewed sources:
  - American Hospital Formulary Service-Drug Information (AFHS-DI) – indication is supportive; **OR**
  - Micromedex DrugDex – indication is Class I, Class IIa, or Class IIb; **OR**
  - Clinical Pharmacology – indication is supportive; **OR**
  - Lexi-Drugs – Evidence Level A; **OR**
  - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium – Category 1 or 2A; **OR**
  - Peer-reviewed research article appearing in a medical journal approved under section 50.4.5 of Chapter 15 of the Medicare Benefit Policy Manual, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ bp102c15.pdf.
- In the event that an off-label indication is not supported by a reference listed within this policy, the plan will allow coverage when supported by societal guidelines or at least two well-designed clinical trials, published in peer-reviewed medical journal(s), that clearly establish safety and efficacy for the member's specific diagnosis or condition. "Well-designed" trials must, at a minimum, be randomized, blinded, and multi-arm studies.
- In the event that an off-label indication has been previously approved under the plan (via initial review, the appeal process, or at the state level), please allow continuation of therapy if the member has had a positive clinical response to therapy, as documented by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

Must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

The shorter of 12 months or the planned duration of therapy.

QUANTITY/PARTIAL-FILL RESTRICTIONS

N/A

OPERATIONAL NOTES

- All approvals should be entered at the GSN level.
- Requests for continuation of coverage must go through the initial prior authorization process.

Internal note:

- Notification of approval using Off-Label Use criteria (diagnosis off-label or quantity is over the FDA approved limit) is sent to the client using the "Approved using Off-Label Criteria" email template, and logged on the Umich off-label approval spread sheet (this applies to initial, reconsideration, appeals and external review approvals).

OGSIVEO (NIROGACESTAT)

Updated: February 1, 2024

Length of Authorization:	5 years
Initiative:	PAR: Ogsiveo (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For adult patients with progressing desmoid tumors who require systemic treatment

FDA-RECOMMENDED DOSE

150 mg orally twice daily.

HOW SUPPLIED

50 mg tablets in 180-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member must have a diagnosis of a Desmoid Tumor (or Aggressive Fibromatosis) requiring systemic treatment; **AND**
- The member is not a candidate for sorafenib (Nexavar); **AND**
- The member is not a candidate for surgical resection; **AND**
- The member is not a candidate for targeted radiation therapy.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

OLUMIANT® (BARICITINIB)

Updated: December 18 , 2023

Length of Authorization:	Initial: 12 months Continuation: 12 months
Initiative:	PAR: Olumiant (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies
- For the treatment of adult patients with severe alopecia areata (AA)

FDA-RECOMMENDED STARTING DOSE

- RA: 2 mg orally, once daily
- AA: 2 mg orally, once daily unless severe, then 4 mg orally, once daily. Once patients achieve an adequate response to treatment with 4 mg, decrease the dosage to 2 mg once daily.

HOW SUPPLIED

1 mg, 2 mg, and 4 mg tablets in 30-count bottles

COVERAGE CRITERIA

For all Initial Reviews:

- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

For the Treatment of RA:

- The member has a confirmed diagnosis of moderate to severely active RA; **AND**
- The member has tried and failed or has contraindications to a TNF-inhibitor (e.g., Humira, Enbrel); **AND**
- The member has had a previous trial of, or contraindication to, at least one of the following:
  - Methotrexate
  - Leflunomide
  - Hydroxychloroquine
  - Sulfasalazine; **AND**
- The member has had a previous trial of, or contraindication to, at least **two** of the following preferred agents:
  - Adalimumab
  - Enbrel
  - Xeljanz

For the treatment of AA:

- The member has a diagnosis of alopecia areata; **AND**
- The member has tried and failed **one** or is contraindicated to **all** of the following:
  - High potency topical corticosteroids
  - Intralesional corticosteroid injections
  - Oral corticosteroids

For Continuation:

- For all indications:
  - The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)
  - The member has had a positive clinical response to therapy, as documented by the member's specialist provider; **AND**
  - The member's liver enzymes are below three times the upper limit of normal (per lab specified range); **AND**
  - The member's lymphocyte count is greater than 500 cells/mm^3; **AND**
  - The member's absolute neutrophil count (ANC) is greater than 500 cells/mm^3; **AND**
  - The member's hemoglobin level is greater than 8 g/dL; **AND**
- For the treatment of AA:
  - If requesting the 4 mg dose, the provider must attest that the member has been assessed for dose reduction and cannot reduce to 2 mg dose.

REQUIRED MEDICAL INFORMATION

- For continuation: Lymphocyte counts, liver enzymes (AST, ALT), neutrophil counts (ANC), and hemoglobin levels, documented within the six months preceding the coverage request.
- Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

- For RA requests: must be prescribed by or in consultation with a rheumatologist.
- For AA requests: must be prescribed by or in consultation with a dermatologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

- Refer to formulary
- For AA requests:
  - Initial authorization to be entered with a quantity exception allowing one 4 mg tablet per day.
  - Continuation authorizations may be entered with a quantity exception allowing one 4 mg tablet per day only if the provider attests patient cannot reduce to 2 mg dose above.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve clinical PA by HSN, quantity exceptions by GSN.

OLUTASIDENIB (REZLIDHIA)

Updated: May 25, 2023

Length of Authorization:	5 years
Initiative:	PAR: Rezlidhia: (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) with a susceptible Isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA approved test."

FDA-RECOMMENDED DOSE

150 mg by mouth twice daily (1 hour before or 2 hours after meals).

HOW SUPPLIED

150 mg capsules in 30-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **For AML:**
  - The member has a diagnosis of acute myeloid leukemia (AML); **AND**
  - The member has a susceptible IDH1 mutation; **AND**
  - The member must have relapsed or refractory disease.
- **Note**: acceptable IDH1 mutations are R132H, R132C, R132G, R132S, and R132L. Alternative IDH1 mutations require submission of additional evidence showing susceptibility to olutasidenib.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Documentation of specific IDH1 mutation.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

OMAVELOXOLONE (SKYCLARYS)

Updated: May 2, 2023

Length of Authorization:	12 months
Initiative:	PAR: Skyclarys: (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of Friedreich's ataxia.

FDA-RECOMMENDED DOSE

150 mg (3 capsules) taken orally once daily

HOW SUPPLIED

50 mg capsules in a 90-count bottle.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of Friedreich's ataxia; **AND**
- The member has documentation of a mutation in the FXN gene

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Mutations in the FXN gene.

AGE RESTRICTIONS

Between 16 and 40 years of age.

PRESCRIBER RESTRICTIONSSPARS

Must be prescribed by or in consultation with a neurologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

OMNIPOD (5-PACK) POD

Updated: July 27, 2023

Length of Authorization:	Initial: 3 months Continuation: 12 months
Initiative:	PAR: Diabetic Supplies (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

The Omnipod 5, Omnipod DASH, and Omnipod Classic Insulin Management Systems are intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.

FDA-RECOMMENDED DOSE

- The Pod provides up to three days of insulin before it is removed and replaced with a new Pod.
- Use with U-100 Insulin. System has been tested with NovoLog, Humalog, Apidra, Admelog, Fiasp, and Lyumjev.

HOW SUPPLIED

- The Omnipod DASH System is made up of two primary components: the disposable insulin infusion pump (Pod) and an associated wireless remote controller referred to as the Personal Diabetes Manager (PDM).
- The Pod is a body-wearable insulin pump that affixes to the user on the back of the arm, the lower back or abdomen, the thigh area, or any site that has a layer of fatty tissue available. It is held in place by an adhesive pad.
- Pods are available in packs of five.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- For **diabetes**, the member:
  - Must have completed a comprehensive diabetes education program; **AND**
  - Has been on a regimen of at least three injections daily with frequent self-adjustments for at least six months prior to the initiation of the pump; **AND**
  - Has documented the frequency of glucose self-testing on average at least four times per day during the two months prior to initiation of the insulin pump; **AND**
  - The member meets **one** of the following criteria on a multiple daily injection regimen:
    - Glycosylated hemoglobin level (HbA1c) > 7.0 percent; **OR**
    - History of recurring hypoglycemia; **OR**
    - Wide fluctuations in blood glucose before mealtime; **OR**
    - "Dawn" phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; **OR**
    - History of severe glycemic excursions
- For **gestational diabetes** (without pre-existing type 1 or 2 diabetes), the member:
  - Requires insulin injections greater than or equal to 3 times per day; **AND**
  - Cannot be controlled by the use of intermittent dosing

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

FOR DIABETES

- Documentation of the frequency of glucose self-testing during the two months prior to initiation of the insulin pump.
- Documentation of HbA1c or blood glucose levels demonstrating history of recurring hypoglycemia, wide fluctuations in blood glucose before mealtime, “Dawn” phenomenon with fasting blood sugars frequently exceeding 200 mg/dL, or history of severe glycemic excursions as applicable.

FOR GESTATIONAL DIABETES

Documentation of number of insulin injections per day

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 3 months
- Continuation: 12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

ONUREG® (AZACITIDINE)

Updated: April 12, 2023

Length of Authorization:	5 years
Initiative:	PAR: Onureg (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For continued treatment of adult patients with acute myeloid leukemia (AML) who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (Cri) following intensive induction chemotherapy and are not able to complete intensive curative therapy.

FDA-RECOMMENDED STARTING DOSE

300 mg orally once daily on days 1 through 14 of each 28-day cycle.

HOW SUPPLIED

200 and 300 mg tablets in 7 count blister packs

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member must have a diagnosis of AML; **AND**
- The member has achieved first CR or Cri following intensive induction chemotherapy; **AND**
- The member is not able to complete intensive curative therapy.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

55 years of age and older.

PRESCRIBER RESTRICTIONS

Prescribed by an oncologist or hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary quantity limits.

OPERATION NOTES AND OTHER INFORMATION

Approve by HICL.

OPZELURA™ (RUXOLITINIB)

Updated: September 26, 2023

Length of Authorization:	initial: 8 weeks Continuation: 12 months
Initiative:	PAR: Opzelura (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of mild to moderate atopic dermatitis (AD) in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
- For the topical treatment of nonsegmental vitiligo (NSV) in adult and pediatric patients 12 years of age and older.

FDA-RECOMMENDED STARTING DOSE

- AD: Apply a thin layer twice daily to affected areas up to 20% of BSA. Do not use more than 60 grams per week or 100 grams per 2 weeks. If signs and symptoms do not improve after eight weeks, patients should be re-examined by their healthcare provider.
- NSV: Apply a thin layer twice daily to affected areas of up to 10% body surface area. Satisfactory patient response may require treatment for more than 24 weeks. If the patient does not find the repigmentation meaningful by 24 weeks, the patient should be re-evaluated by the healthcare provider.

HOW SUPPLIED

1.5% cream in a 60-gram tube.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

For AD:

- The member has a diagnosis of mild or moderate atopic dermatitis, **AND**
- The member has tried and failed, or is contraindicated to, at least two generic topical corticosteroids **AND**
- The member will not be using ruxolitinib with a biologic therapy, **AND**
- The member has tried and failed, or is contraindicated to, pimecrolimus, tacrolimus, and crisaborole.

For NSV:

- The member has a diagnosis of immune mediated NSV, **AND**
- The member has BSA involvement of less than 10% of their body, **AND**
- The member has tried and failed, or is contraindicated to, two of the following:
  - Topical corticosteroids
  - Calcineurin inhibitors
  - Phototherapy

FOR CONTINUATION COVERAGE REQUESTS

For AD

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

For NSV

- The member has met one of the following clinical scenarios:
  - The member has experienced a substantial reduction in size of targeted lesions as assessed by the member's dermatologist, *OR*
  - The member has experienced meaningful re-pigmentation at targeted lesions as assessed by the member's dermatologist.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

12 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a dermatologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

For AD

- Initial: 8 weeks.
- Continuation: 12 months.

For NSV

- Initial: 12 weeks
- Continuation: 12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES/OTHER INFORMATION

Approve by GSN.

ORENCIA® (ABATACEPT)

Updated: December 18, 2023

Length of Authorization:	12 months
Initiative:	PAR: Orencia (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA).
- For the treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (JIA)
- For the treatment of patients 2 years of age and older with active psoriatic arthritis (PsA)
- IV only: for the prophylaxis of acute graft versus host disease (aGvHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor.

FDA-RECOMMENDED DOSE

RA, PsA (Subcutaneous)	JIA (Subcutaneous) and Pediatric PsA (Subcutaneous)
125 mg once weekly with or without loading intravenous infusion	10–25 kg: 50 mg once weekly
	25–50 kg: 87.5 mg once weekly
	50 kg or more: 125 mg once weekly

HOW SUPPLIED

- 250 mg/15 mL vial for intravenous infusion
- 50 mg/0.4 mL, 87.5 mg/0.7 mL, and 125 mg/1 mL prefilled glass syringe for subcutaneous administration in packs of 4 syringes
- 125 mg/1 mL ClickJect prefilled autoinjector for subcutaneous administration in packs of 4 autoinjectors

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

For All Indications:

- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

For treatment of RA:

- The member has a diagnosis of moderately to severely active RA; **AND**
- The member has had a previous trial of, or contraindication to, at least one of the following:
  - Methotrexate
  - Leflunomide
  - Hydroxychloroquine
  - Sulfasalazine; **AND**

- The member has had a previous trial of, or contraindication to, **two** or more of the following preferred agents:
  - Adalimumab
  - Enbrel®
  - Xeljanz®

For treatment of PJIA:

- The member has a diagnosis of moderately to severely active JIA; **AND**
- The member has had a previous trial of or contraindication to at least one of the following:
  - Methotrexate
  - Leflunomide
  - Hydroxychloroquine
  - Sulfasalazine; **AND**
- The member has had a previous trial of or contraindication to **two** of the following preferred agents:
  - Adalimumab
  - Enbrel®
  - Xeljanz®

For treatment of PsA:

- The member has a diagnosis of active PsA; **AND**
- The member has had a previous trial of or contraindication to at least one of the following:
  - Methotrexate
  - Leflunomide
  - Cyclosporine
  - Sulfasalazine; **AND**
- The member has had a previous trial of or contraindication to at least **two** or more of the following preferred agents:
  - Adalimumab
  - Cosentyx
  - Enbrel®
  - Tremfya®
  - Stelara®
  - Xeljanz®

FOR CONTINUATION

- The member continues to have a beneficial response to therapy, as assessed by the member's provider; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

REQUIRED MEDICAL INFORMATION

- Claims or medical records demonstrating use of previous therapies
- For PJIA and pedatric PsA diagnoses: current weight.

AGE RESTRICTIONS

- RA: 18 years of age and older.
- JIA PsA: 2 years of age and older

PRESCRIBER RESTRICTIONS

- PsA: Must be prescribed by or in consultation with a rheumatologist or dermatologist.
- All other indications: Must be prescribed by or in consultation with a rheumatologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION (MONTHS)

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

- If the member is currently established on the IV formulation and is transitioning to the subcutaneous product, review the request as a continuation.
- Vials are excluded from pharmacy benefit coverage
- Approve by HSN

ORGOVYX™ (RELUGOLIX)

Updated: May 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Orgovyx (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with advanced prostate cancer.

FDA-RECOMMENDED DOSE

Loading dose of 360 mg on the first day and continue treatment with a 120 mg dose taken orally once daily at approximately the same time each day.

HOW SUPPLIED

120 mg tablets.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member must have a diagnosis of advanced prostate cancer; **AND**
- The member's cancer is castration sensitive; **AND**
- The member intends to use this agent as a single agent for androgen deprivation therapy

For Renewal Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's oncologist provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years.

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

N/A

ORIAHNN® (ELAGOLIX, ESTRADIOL, AND NORETHINDRONE ACETATE)

Updated: November 15, 2023

Length of Authorization:	Initial: approve for 24 months. Renewal: approve for the remainder of treatment course (maximum 24 months)
Initiative:	PAR: Oriahnn (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of heavy menstrual bleeding (HMB) associated with uterine leiomyomas (fibroids) in premenopausal women.

FDA-RECOMMENDED DOSE

- One capsule of elagolix 300 mg-1 mg estradiol 1 mg-0.5 mg norethindrone 0.5 mg every morning, and one capsule of elagolix 300 mg every evening.
- Max duration of therapy: 24 months.

HOW SUPPLIED

Weekly blister packs: Morning and evening capsule; 14 total capsules. 4 blister packs per carton.

UTILIZATION CRITERIA

For initial coverage requests:

- The member has a confirmed diagnosis of HMB associated with fibroids; **AND**
- The member has tried and failed, or has contraindications to, an adequate trial of progestin-containing contraceptive preparation (combination hormonal contraceptive preparation, progestin-only contraceptive preparation); **AND**
- The member has not had a cumulative lifetime exposure to GnRH antagonists (e.g., relugolix, elagolix) of greater than 24 months.

For continuation coverage requests:

- The member has had a beneficial response to therapy, as attested to by the member's specialist provider; **AND**
- The member has not had a cumulative lifetime exposure to GnRH antagonists (e.g., relugolix, elagolix) of greater than 24 months.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an obstetrician-gynecologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 24 months.
- Continuation: approve for the remainder of treatment course (maximum 24 months).

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

ORILISSA® (ELAGOLIX)

Updated: November 14, 2023

Length of Authorization:	Varies, see below
Initiative:	PAR: Orilissa (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the management of moderate to severe pain associated with endometriosis

FDA-RECOMMENDED DOSE

- 150 mg orally once daily for up to 24 months in patients with no coexisting conditions
- 150 mg orally once daily or for up to 6 months in patients with coexisting moderate hepatic impairment (Child-Pugh Class B)
- 200 mg orally twice daily for up to 6 months in patients with coexisting dyspareunia

HOW SUPPLIED

- 150 mg tablets in weekly blister packs containing #7; four blister packs per carton (28 tablets total);
- 200 mg tablets in weekly blister packs containing #14; four blister packs per carton (56 tablets total).

UTILIZATION CRITERIA

For All Initial Coverage Requests:

- The member has a confirmed diagnosis of endometriosis; **AND**
- The member has tried and failed, or has contraindications to, an adequate trial of progestin-containing contraceptive preparation (combination hormonal contraceptive preparation, progestin-only contraceptive preparation); **AND**
- The member does not have advanced hepatic dysfunction (Child-Pugh Class C); **AND**
- The member has not had a cumulative lifetime exposure to GnRH antagonists (i.e., relugolix, elagolix) of greater than 24 months.

For Continuation Requests:

- The member has had a beneficial response to therapy, as attested to by the member's specialist provider; **AND**
- The member has not received more than 6 months of therapy on a 200 mg twice-daily dose, 6 months of therapy on a 150 mg daily-dose with Child-Pugh Class B hepatic function, or 24 months of therapy on a 150 mg once-daily dose with no coexisting conditions; **AND**
- The member does not have advanced hepatic dysfunction (Child-Pugh Class C).

REQUIRED MEDICAL INFORMATION

- Hepatic function (Child-Pugh Score); **AND**
- Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an obstetrician-gynecologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- 24 months for members with no coexisting conditions requesting a 150 mg once-daily dose.
- 6 months for members with Child-Pugh Class B hepatic impairment requesting a 150 mg once-daily dose.
- 6 months for members with coexisting dyspareunia requesting a 200 mg twice-daily dose.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

ORKAMBI® (LUMACAFTOR/IVACAFTOR)

Updated: October 30, 2023

Length of Authorization:	1 year (initial), 5 years (continuation)
Initiative:	PAR: Orkambi (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of cystic fibrosis (CF) in patients 1 year of age and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene.

FDA-RECOMMENDED DOSE

Age	Dose	Total Daily Dose
1 through 2 years of age and weighting 7 to less than 9 kg	One lumacaftor 75 mg/ivacaftor 94 mg packet of granules every 12 hours with fat-containing food.	Lumacaftor 150 mg/ivacaftor 186 mg
1 through 2 years of age and weighting 9 to less than 14 kg	One lumacaftor 100 mg/ivacaftor 125 mg packet of granules every 12 hours with fat-containing food.	Lumacaftor 200 mg/ivacaftor 250 mg
1 through 2 years of age and weighting 14 kg or greater	One lumacaftor 150 mg/ivacaftor 188 mg packet of granules every 12 hours with fat-containing food.	Lumacaftor 300 mg/ivacaftor 376 mg
2 through 5 years of age and weighing less than 14 kg	One lumacaftor 100 mg/ivacaftor 125 mg packet of granules every 12 hours with fat-containing food	lumacaftor 200 mg/ivacaftor 250 mg
2 through 5 years of age and weighing 14 kg or greater	One lumacaftor 150 mg/ivacaftor 188 mg packet of granules every 12 hours with fat-containing food	lumacaftor 300 mg/ivacaftor 376 mg
6 through 11 years of age	Take two lumacaftor 100 mg/ivacaftor 125 mg tablets every 12 hours with fat-containing food	lumacaftor 400 mg/ivacaftor 500 mg
12 years of age and older	Take two lumacaftor 200 mg/ivacaftor 125 mg tablets every 12 hours with fat-containing food	lumacaftor 800 mg/ivacaftor 500 mg

HOW SUPPLIED

- 75 mg ivacaftor – 94 mg lumacaftor granules
- 125 mg ivacaftor – 200 mg lumacaftor tablets
- 125 mg ivacaftor – 100 mg lumacaftor tablets or granules
- 188 mg ivacaftor – 150 lumacaftor mg granules

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member is homozygous (mutation is present on both alleles) for the F508del mutation in the CFTR gene as confirmed by an FDA-cleared CF mutation test; **AND**
- The member's baseline percent predicted forced expiratory volume in 1 second ($ppFEV_1$) is at least 40% or greater (as documented by lab report or chart notes); **AND**
- The member does not have either of the following:
  - ALT or AST > 5x ULN.
  - ALT or AST > 3x ULN with bilirubin > 2x ULN.

FOR CONTINUATION COVERAGE REQUESTS

- The member continues to have a beneficial response to therapy as assessed and documented by the member's specialist provider, and as supported by one of the following:
  - Maintenance or improvement in $ppFEV_1$; **OR**
  - Maintenance or improvement in BMI (body mass index); **OR**
  - Reduction in pulmonary exacerbations; **AND**
- The member does not have either of the following:
  - ALT or AST > 5x ULN.
  - ALT or AST > 3x ULN with bilirubin > 2x ULN.

REQUIRED MEDICAL INFORMATION

- Genomic testing showing required mutation(s).
- $ppFEV_1$ with date (required for initial and optional for continuation if other criteria met).
- AST/ALT levels.
- Bilirubin levels if applicable.

AGE RESTRICTIONS

1 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a pulmonologist or cystic fibrosis specialist.

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 1 year
- Continuation: 5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

If approved, term any active PA for Kalydeco®, Trikafta®, and/or Symdeko®.

ORLADEYO™ (BEROTRALSTAT)

Updated: May 26, 2023

Length of Authorization: 12 months
Initiative: PAR: Orladeyo (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in adults and pediatric patients 12 years of age and older.

FDA-RECOMMENDED DOSE

150 mg once daily.

HOW SUPPLIED

110 mg and 150 mg capsules in 28-day cartons.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member must have confirmatory diagnosis of HAE due to C1 inhibitor deficiency (HAE-1 or HAE-2), including confirmation of low C4 levels and low functional C1 inhibitor (C1-INH) activity; **AND**
- The member is not receiving concurrent prophylactic medications for HAE (e.g., lanadelumab, C1-INH); **AND**
- The prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy; **AND**
- The prescriber attests that the member is not concurrently taking any medications that may exacerbate HAE (e.g., ACE inhibitors, estrogens).

FOR CONTINUATION COVERAGE REQUESTS

- The member continues to have a beneficial response to therapy as assessed and documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

For initial coverage requests, confirmatory diagnosis of HAE, including C1-INH and C4 levels with date drawn.

AGE RESTRICTIONS

12 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an immunologist, allergist, or hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

ORSERDU™ (ELACESTRANT)

Updated March 7, 2023

Length of Authorization:	1 year
Initiative:	PAR: Orserdu: 2462 (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of postmenopausal women or adult men, with ER positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

FDA-RECOMMENDED STARTING DOSE

345 mg tablet taken orally, once daily, with food.

HOW SUPPLIED

345 mg and 86 mg tablets in 30 count bottles.

COVERAGE CRITERIA

For initial coverage requests:

- The member must have advanced or metastatic ER+/HER2- breast cancer; **AND**
- The member must have a confirmed ESR1 mutation; **AND**
- The member must be a male or postmenopausal female; **AND**
- The member must have one of the following:
  - Visceral crisis; **OR**
  - Progression on at least one prior line of endocrine therapy (one line must contain a CDK4/6 inhibitor)

For continuation coverage requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION.

- Tumor status (HR/HER2).
- ESR1 mutation status.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by HSN.

OTESECONAZOLE (VIVJOA)

Updated: September 20, 2023

Length of Authorization:	Three months
Initiative:	PAR: Vivjoa (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential.

FDA-RECOMMENDED DOSE

- Oteseconazole-only regimen: 600 mg capsule on Day 1, 450 mg on Day 2, then 150 mg weekly for 11 weeks beginning on Day 14 of post-initiation treatment.
- Fluconazole/Oteseconazole regimen:
  - On Day 1, Day 4, and Day 7: Administer fluconazole 150 mg orally, then
  - On Days 14-20: Administer oteseconazole 150 mg once daily for 7 days, then
  - Beginning on Day 28: Administer oteseconazole 150 mg once weekly (every 7 days) for 11 weeks (weeks 4-14).

HOW SUPPLIED

150 mg tablets in 18-count blister packs.

COVERAGE CRITERIA

For all coverage requests:

- The member has a confirmed diagnosis of RVVC with three or more acute VVC episodes within the previous 12 months; **AND**
- The member is not of reproductive potential, such as being post-menopausal, has a history of tubal ligation or hysterectomy, or has other medical conditions or history that would permanently prevent pregnancy; **AND**
- The member meets one of the following scenarios:
  - The member's VVC is confirmed to be resistant to fluconazole; **OR**
  - The member has tried and failed, or has contraindications to, a complete 6-month course of fluconazole for the prevention and treatment of RVVC.

REQUIRED MEDICAL INFORMATION

Documentation of antifungal culture sensitivities, if applicable.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

Must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

Three months.

QUANTITY RESTRICTIONS

Coverage is limited to 18 tablets per authorization.

OPERATIONAL INSTRUCTIONS/ ADDITIONAL INFORMATION

Approve by GSN.

OTEZLA® (APREMILAST)

Updated: December 18, , 2023

Length of Authorization:	12 months
Initiative:	PAR: Otezla (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients with active psoriatic arthritis (PsA)
- For the treatment of adult patients with moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- For the treatment of adult patients with oral ulcers associated with Behçet's Disease

FDA-RECOMMENDED DOSE

- **All indications require a five-day initial dose titration as follows to avoid the associated GI symptoms:**

Day 1	Day 2		Day 3		Day 4		Day 5	
AM	**AM**	**PM**	**AM**	**PM**	**AM**	**PM**	**AM**	**PM**
10 mg	10 mg	10 mg	10 mg	20 mg	20 mg	20 mg	20 mg	30 mg

- Maintenance dose begins day 6 onward with 30 mg twice daily

HOW SUPPLIED

- Two-week Starter Pack containing (4) 10 mg, (4) 20 mg, and (19) 30 mg tablets
- 28-day Starter Pack containing (4) 10 mg, (4) 20 mg, and (47) 30 mg tablets
- 30 mg tablets in 60-count bottles and 28-count cartons

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

For All Indications:

- The member's treatment plan does not include concurrent use of biologic therapy; **AND**
- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

For PsA:

- The member must have a diagnosis of active psoriatic arthritis; **AND**
- The member has had a previous trial of or contraindication to at least **one** of the following:
  - Methotrexate
  - Sulfasalazine
  - Cyclosporine
  - Leflunomide; **AND**
- The member has had a previous trial of or contraindication to at least **two** of the following preferred agents:
  - Adalimumab
  - Cosentyx
  - Enbrel
  - Tremfya
  - Stelara
  - Xeljanz

For PsO:

- The member must have a diagnosis of active moderate-to-severe plaque psoriasis
- The member has psoriatic lesions that involve greater than or equal to 10% of body surface area (BSA), or that affect the palms, soles, head, neck, or genital area, leading to disability/impact on quality of life
- The member must have documented failure, intolerance, or contraindication to at least **one** of the following:
  - PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B)
  - Topical corticosteroids
  - Calcipotriene
  - Acitretin
  - Methotrexate
  - Cyclosporine; **AND**
- The member has had a previous trial of or contraindication to at least **two** of the following preferred agents:
  - Adalimumab
  - Cosentyx
  - Enbrel
  - Tremfya
  - Stelara

For oral ulcers associated with Behçet's Disease:

- The member must have a diagnosis of chronic oral ulcers associated with Behçet's Disease; **AND**
- The member must have documented failure, intolerance, or contraindication to **all** of the following:
  - Intralesional/Topical corticosteroids
  - Oral Colchicine
  - Systemic corticosteroids

FOR CONTINUATION COVERAGE REQUESTS

- The member continues to have a beneficial response to therapy as assessed and documented by the member's specialist provider; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

REQUIRED MEDICAL INFORMATION

- Claims or medical records demonstrating use of previous therapies.
- For members treated for PsO, current BSA coverage of lesions.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a rheumatologist or dermatologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HSN

OXBRYTA™ (VOXELOTOR)

Updated: May 30, 2023

Length of Authorization:	12 months
Initiative:	PAR: Oxbryta (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of sickle cell disease in adults and pediatric patients 4 years of age and older

FDA-RECOMMENDED STARTING DOSE

- For patients aged 4 years to less than 12 years: 600 mg once daily (10 kg to less than 20 kg), 900 mg once daily (20 kg to less than 40 kg), or 1500 mg orally once daily (40kg or greater)
- For patients aged 12 years and older: 1500 mg orally once daily

HOW SUPPLIED

- 300 mg tablets in 60-count and 90-count bottles.
- 500 mg tablets in 90-count bottles
- 300 mg tablets for oral suspension in 60-count and 90-count bottles.

COVERAGE CRITERIA

For all coverage requests:

- The member has a confirmed diagnosis of sickle cell disease; **AND**
- The member has a baseline hemoglobin of less than or equal to 10.5 g/dL; **AND**
- The member is not receiving, or plans to receive, regular transfusions.

For oral suspension tablet requests of 1500 mg total daily dose:

- The member meets the criteria for all coverage requests; **AND**
- The member is less than 12 years of age and over 40 kg; **AND**
- The member cannot swallow tablets per provider attestation.

For continuation coverage requests:

- The member continues to have a beneficial response to treatment per provider attestation

REQUIRED MEDICAL INFORMATION

- For initial requests, baseline hemoglobin level.
- For members 4 to less than 12 years of age, current weight (kg).

AGE RESTRICTIONS

4 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a hepatologist, hematologist, or sickle cell disease specialist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

- For members 12 years of age and older: Refer to formulary.
- For members 4 to less than 12 years of age:
  - 2x 300 mg tablets or tablets for suspension (600 mg total) per day for 10 kg to less than 20 kg.
  - 3x 300 mg tablets or tablets for suspension (900 mg total) per day for 20 kg to less than 40 kg.
  - 5x 300 mg tablets for suspension (1500 mg total) per day for over 40 kg and provider attestation that member cannot swallow tablets.
  - 3x 500 mg tablets (1500 mg total) per day for over 40 kg and the member can swallow tablets.

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve by GSN.
- Members requesting 600 mg daily of the tablets for suspension should receive the 90-count bottle for a 45-day supply.
- 300 mg tablets (not for suspension) are not approvable for 1500 mg dose.

OXERVATE™ (CENEGERMIN)

Updated: June 27, 2023

Length of Authorization:	Eight weeks; coverage beyond an initial eight-week course requires additional plan approval
Initiative:	PAR: Oxervate (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of neurotrophic keratitis (NK)

FDA-RECOMMENDED DOSE

One drop (20 µg/mL) in the affected eye(s) six times daily (at 2-hour intervals) for eight weeks

HOW SUPPLIED

Ophthalmic solution in weekly kits containing seven multi-dose vials in an insulated pack, eight vial adapters, 45 pipettes, 45 sterile disinfectant wipes, and one dosing card

UTILIZATION CRITERIA

FOR ALL COVERAGE REQUESTS:

- The member must have a confirmed diagnosis of stage 2 (e.g., persistent corneal epithelial defect) or stage 3 (e.g., ulcer) NK; **AND**
- The member has previously tried and failed one or more conventional non-surgical treatments for NK, such as artificial tears, gels or ointments, and therapeutic contact lenses; **AND**
- The member does **not** have corneal ulceration involving the posterior third of the corneal stroma, corneal melting, or perforation.

REQUIRED MEDICAL INFORMATION

Documentation of diagnosis and previous treatment trials with outcomes.

AGE RESTRICTIONS

2 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an ophthalmologist. (MD or DO, not an optometrist)

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

Eight weeks; coverage beyond an initial eight-week course requires additional plan approval.

QUANTITY RESTRICTIONS

Approval is limited to a maximum of 14 vials per 14 days.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

PALFORZIA® PEANUT ALLERGEN POWDER-DNFP

Updated: November 3, 2023

Length of Authorization:	2 years
Initiative:	PAR: Palforzia (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

Approved to reduce the incidence and severity of allergic reactions, including anaphylaxis after accidental exposure to peanuts with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 4–17 years. Up-dosing and maintenance may be continued in patients ≥ 4 years of age.

FDA-RECOMMENDED DOSE

See package inserts for up-dosing and maintenance treatment schedule.

HOW SUPPLIED

0.5 mg, 1 mg, 10 mg, 20 mg, and 100 mg capsule powder and 300 mg sachet powder. Initial dose escalation supplied as a single card consisting of five blisters containing a total of 13 capsules.

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member must have an active prescription for injectable epinephrine; **AND**
- The member must have a diagnosis of peanut allergy as substantiated by a positive skin prick test **or** peanut-specific immunoglobulin E within the past 24 months.

FOR CONTINUATION COVERAGE REQUESTS

- The member must have an active prescription for injectable epinephrine, AND
- If member is ≤ 10 years of age:
  - The member has had a positive clinical response to therapy, as documented by the member's specialist provider; **AND**
  - The member must have documentation of persistent peanut allergy by positive skin prick test **OR** peanut-specific immunoglobulin E within the past 24 months.
- If member is > 10 years of age:
  - The member has had a positive clinical response to therapy, as documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Allergy testing results for initial requests and continuation requests up through age 10.

AGE RESTRICTIONS

- Initial requests allowed for ages 4–17
- Continuation requests allowed for ages ≥ 4

PRESCRIBER RESTRICTIONS

Must be prescribed by an allergist or immunologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

2 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HSN

PALOVAROTENE (SOHONOS)

Updated: November 30, 2023

Length of Authorization:	6 months
Initiative:	PAR: Sohonos (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the reduction in volume of new heterotopic ossification (HO) in adults and pediatric patients with fibrodysplasia ossificans progressiva (FOP).

FDA-RECOMMENDED DOSE

- Patients > 14 years of age (daily dose):
  - Daily: 5 mg.
  - Flare-up dosing week 1–4: 20 mg.
  - Flare-up dosing week 5–12: 10 mg.
- Patients < 14 years of age weight-based (daily dose):
  - 10–19.9 kg: 2.5 mg.
  - 20–39.9 kg: 3 mg.
  - 40–59.9 kg: 4 mg.
  - ≥ 60 kg: 5 mg.
- Flare week 1-4 (daily dose):
  - 10–19.9 kg: 10 mg.
  - 20–39.9 kg: 12.5 mg.
  - 40–59.9 kg: 15 mg.
  - ≥ 60 kg: 20 mg.
- Flare week 5–12 (daily dose):
  - 10–19.9 kg: 5 mg.
  - 20–39.9 kg: 6 mg.
  - 40–59.9 kg: 7.5 mg.
  - ≥ 60 kg: 10 mg.
- Week 5–12 flare dosing may be extended in 4-week intervals and continued until symptoms resolve. If marked worsening of original symptoms or another flare occurs during flare-up treatment, may restart 12-week flare-up dosing (all ages).

HOW SUPPLIED

Blister strip containing 14 capsules in a child resistant carton.

UTILIZATION CRITERIA

- For initial coverage requests:
  - The member has a diagnosis of FOP, including ACVR1 R206H mutation confirmed by genetic testing; **AND**
  - The member is 8 years of age and older if female, or 10 years of age and older if male; **AND**
  - The member weighs > 10 kg; **AND**
  - The member (if of child-bearing potential) is not pregnant and attests to appropriate contraception methods used at least 1 month before treatment, during treatment, and 1 month after the last dose.

- For continuation coverage requests:
  - The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

For initial review, medical records demonstrating ACVR1 R206H mutation, weight, age, and pregnancy status (if applicable).

AGE RESTRICTIONS

- 8 years of age and older for females.
- 10 years of age and older for males.

PRESCRIBER RESTRICTIONS

Prescribed by or in consultation with a physician who specializes in rare connective tissue diseases.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

6 months.

QUANTITY RESTRICTIONS

- Refer to formulary.
- When calculating restriction, add 10 kg to the member's current weight to allow for growth during their approval cycle.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

PALYNZIQ® (PEGVALIASE-PQPZ)

Updated: August 21, 2023

Length of Authorization:	6 months (initial), 12 months (renewal)
Initiative:	PAR: Palynziq (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

To reduce blood phenylalanine (Phe) concentrations in adult patients with phenylketonuria (PKU) who have uncontrolled Phe concentrations greater than 600 µmol/L on existing management

FDA-RECOMMENDED STARTING DOSE

2.5 mg once weekly for four weeks, and then titrated upwards over five weeks per tolerability to eventually achieve a 20 mg once-daily subcutaneous dose

HOW SUPPLIED

2.5 mg/0.5 mL, 10 mg/0.5 mL, and 20 mg/mL single-dose prefilled syringes.

COVERAGE CRITERIA

For All Initial Coverage Requests:

- The member has a confirmed diagnosis of PKU; **AND**
- The member has an initial phenylalanine level > 600 µmol/L measured in the last 30 days; **AND**
- The member has tried and failed, or is otherwise contraindicated to, a trial of sapropterin; **AND**
- The member is not currently receiving, or plans to receive, concurrent sapropterin.

For Continuation Coverage Requests:

- The member has had a documented 20% reduction in Phe levels from baseline (pre-treatment) or to under 600 µmol/L AND
- The member is neither currently receiving nor plans to receive concurrent sapropterin.

REQUIRED MEDICAL INFORMATION

Chart notes or medical records (within past 30 days) containing phenylalanine levels. Claims or chart notes demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

6 months (initial), 12 months (renewal)

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES

Approve by GSN.

PANCREATIC ENZYME REPLACEMENT THERAPY (CREON®, ZENPEP®, VIOKACE™, PANCREAZE®, PERTZYE®)

Updated: December 22, 2023

Length of Authorization:	12 months
Initiative:	PAR: Pancreatic Enzymes (IE 2462 / NCPDP 75 – GSN; IE 2194 / NCPDP 60 – GSN)

FDA-APPROVED INDICATION(S)

- **Creon:** for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions
- **Viokace:** in combination with a proton pump inhibitor, is indicated in adults for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy
- **Pancreaze/Pertzye/ZenPep:** for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions

FDA-RECOMMENDED DOSE

Various, refer to package inserts

HOW SUPPLIED

Various, refer to package inserts

UTILIZATION CRITERIA

FOR INITIAL REVIEW

The member meets one of the following clinical scenarios:

- The member has a diagnosis of severe chronic pancreatitis; **OR**
- The member has a had a total pancreatectomy; **OR**
- The member has a diagnosis of cystic fibrosis (CF); **OR**
- The member has a diagnosis of pancreatic cancer; **OR**
- The member has a diagnosis of exocrine pancreatic insufficiency (EPI), with documentation of baseline pancreatic fecal elastase < 100 mcg/g stool; **OR**
- The member has a diagnosis of exocrine pancreatic insufficiency (EPI), with documentation of baseline pancreatic fecal elastase 100–200 mcg/g stool, **AND**
  - The prescribing provider attests that additional clinical testing/review has been done to confirm EPI diagnosis ;

FOR CONTINUATION REVIEW

Member has experienced a positive clinical response as attested to by the member's specialist provider

REQUIRED MEDICAL INFORMATION

Initial coverage requests: pancreatic fecal elastase (not required unless stated in scenario above).

AGE RESTRICTIONS

PA requirement only applies to members 50 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a gastroenterologist, pulmonologist, or oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

OTHER INFORMATION

Approve by GSN

PCSK9 INHIBITORS: REPATHA® (EVOLOCUMAB), PRALUENT® (ALIROCUMAB)

Updated: December 22, 2023

Length of Authorization:	5 years
Initiative:	PAR: PCSK-9 Inhibitors (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- To reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease
- As an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia, including Heterozygous Familial Hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C)
- As an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C

FDA-RECOMMENDED DOSE

- **Evolocumab (Repatha):** 420 mg SQ once monthly, or 140 mg SQ every two weeks. May increase to 420 mg once every 2 weeks if clinically meaningful response is not achieved in 12 weeks
- **Alirocumab (Praluent):** 300 mg SQ once monthly, or 75 mg SQ every two weeks. The dosage may be adjusted 150 mg every 2 weeks

HOW SUPPLIED

See package inserts

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member must have one of the following diagnoses:
  - Established ASCVD (see OPERATIONAL NOTES AND OTHER INFORMATION); **OR**
  - Primary hyperlipidemia, as established by **one** of the following:
    - Dutch Lipid Network clinical criteria, score greater than 5
    - Simon-Broome Criteria (definite HeFH)
    - Genetic confirmation of mutant alleles at the LDL receptor, ApoB, PCSK9 or ARH adaptor protein gene locus
    - An untreated LDL-C ≥ 190 mg/dL; **AND**
- The member must have had an inadequate response (i.e., LDL-C greater than 70 mg/dL while on at least 8 weeks of therapy) to maximally tolerated atorvastatin or rosuvastatin therapy, unless otherwise contraindicated or intolerant to both atorvastatin and rosuvastatin (see OPERATIONAL NOTES AND OTHER INFORMATION), **AND**
- For Praluent requests:
  - The member must try and fail, or be contraindicated to, Repatha.

FOR CONTINUATION OF COVERAGE

Member must have clinical benefit as attested to by the member's prescribing provider.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

- Evolocumab (Repatha): 10 years of age and older.
- Alirocumab (Praluent): 18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by, or in consultation with a cardiologist, lipid specialist, or endocrinologist

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve by HSN
- Examples of ASCVD include the following:
  - History of myocardial infarction or other acute coronary syndrome
  - Coronary or other revascularization procedure
  - Transient ischemic attack, or ischemic stroke
  - Atherosclerotic peripheral arterial disease
  - Atherosclerotic disease such as coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, or carotid plaque with 50% or more stenosis).
- Statin intolerance requires the following:
  - Attestation of severe and intolerable adverse effects that have occurred with every trial of statin, and other potential causes were ruled out (low vitamin D levels, sudden increase in intense or prolonged physical activity, drug interactions with statins, or other metabolic or inflammatory causes);

PDE5 INHIBITORS (SILDENAFIL, VARDENAFIL, TADALAFIL, AVANAFIL)

Updated: November 3, 2023

Length of Authorization:	5 years
Initiative:	PAR: PDE-5 Inhibitors: ED (IE 2462 / NCPDP 75, IE 2193 / NCPDP 60 – GSN) PAR: PDE-5 Inhibitors: BPH and PAH (IE 2462 / 75, IE 2641, 15110, 7001 / 76, IE 2193 / 60 – GSN) PAR: PDE-5 Inhibitors: Reynaud's (IE 2462 / 75, IE 2641, 15110, 7001 /76, IE 2193 / 60, IE 2192 / 61-GSN)

POLICY AND PRODUCT INFORMATION

- Coverage for phosphodiesterase-5 (PDE5) inhibitors requires a diagnosis of pulmonary arterial hypertension (PAH), benign prostatic hyperplasia (BPH), or erectile dysfunction (ED), with limitations per requested agent
- For PDE5 inhibitors indicated for the treatment of ED, limited coverage is allowed without prior authorization for male members over of 35 years of age.

FDA-APPROVED INDICATION(S)

For the treatment of erectile dysfunction (avanafil, sildenafil, tadalafil, vardenafil), BPH (tadalafil), and PAH (sildenafil, tadalafil).

FDA-RECOMMENDED DOSE

For the Treatment of ED

- Avanafil (Stendra): 50 to 200 mg orally once daily, as needed
- Sildenafil (Viagra): 25 to 100 mg orally once daily, as needed
- Tadalafil (Cialis): 2.5 to 20 mg orally once daily, as needed
- Vardenafil (Levitra, Staxyn): 5 to 20 mg orally once daily, as needed

For the Treatment of BPH

- Tadalafil (Cialis): 5 mg orally once daily

For the Treatment of PAH

- Sildenafil (Revatio): 5 to 20 mg orally three times daily
- Tadalafil (Adcirca, Alyq, Tadliq): 40 mg once daily

For the treatment of Reynaud's (off-label)

- Sildenafil: Initial 20 mg orally once or twice daily; may increase to 20 mg three times daily as needed. Doses up to 50 mg three times daily have been reported.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS:

- **For the treatment of erectile dysfunction:**
  - The member has a diagnosis of erectile dysfunction; **AND**
  - The member has undergone a complete medical evaluation to identify the underlying medical cause of the erectile dysfunction

- **For the treatment of benign prostatic hyperplasia:**
  - The request is for tadalafil 2.5 mg or 5 mg once daily; **AND**
  - The member has a diagnosis of BPH; **AND**
  - The member has tried and failed an alpha-blocker (e.g., alfuzosin, doxazosin, tamsulosin, terazosin, silodosin) or 5-alpha reductase inhibitor (e.g., dutasteride, finasteride).
- **For the treatment of PAH**
  - The request is for sildenafil or tadalafil; **AND**
  - The member has a diagnosis of WHO Group I, pulmonary arterial hypertension (PAH); **AND**
  - If the request is for tadalafil suspension (Tadliq), the member must meet the following:
    - Modifications to the conventional dosage form (e.g., crushing, chewing, dissolving) are not possible or feasible, per the member's provider; **AND**
    - The member has documentation of one or more of the following clinical conditions:
      - Documented difficulty in swallowing or dysphagia; **OR**
      - Requires tube feeding; **OR**
      - Requires a dosage unobtainable with the conventional dosage form
- **For the treatment of Reynaud's**
  - The request is for sildenafil; **AND**
  - The member has a diagnosis of Reynaud's syndrome.

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

- **ED and BPH**: 18 years of age and older
- **PAH**: N/A

PRESCRIBER RESTRICTIONS

- **ED and BPH**: N/A
- **PAH**: Must be prescribed by a pulmonologist, cardiologist, or PAH specialist

REVIEWER REQUIREMENTS

All coverage requirements must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY/PARTIAL-FILL RESTRICTIONS

- ED: Refer to formulary.
- PAH: Override the formulary max of 72 per year quantity limit to permit appropriate dosing based on indication. Follow formulary quantity per day.
- BPH: Override tadalafil 5 mg formulary quantity per day to permit 1 per day dosing. Also override the formulary max of 72 per year quantity limit to permit appropriate dosing based on FDA indication.
- Reynaud's: Override the formulary max of 72 per year QL to permit appropriate dosing based on indication. QPD 3 for all strengths; 20 mg strength may be overridden to QPD 6 if specifically requested.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

JAYPIRCA (PIRTOBRUTINIB)

Updated February 1, 2024

Length of Authorization:	5 years
Initiative:	PAR: Jaypirca: 2462 (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor.

FDA-RECOMMENDED DOSE

200 mg once daily.

HOW SUPPLIED

50 mg tablets in 30-count bottles; 100 mg tablets in 60-count bottles.

UTILIZATION CRITERIA

For initial coverage requests:

- The member has a diagnosis of mantle cell lymphoma or CLL/SLL; **AND**
- The member has received at least two prior lines of therapy for their indication; **AND**
- The member has received therapy with a BTK inhibitor previously (e.g., ibrutinib, acalabrutinib, or zanubrutinib).

For continuation coverage requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies as applicable to place in therapy.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by HSN.

PEMAZYRE™ (PEMIGATINIB)

Updated: May 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Pemazyre (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.
- For the treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with fibroblast growth factor receptor 1 (FGFR1) rearrangement.

FDA-RECOMMENDED STARTING DOSE

- Cholangiocarcinoma: 13.5 mg orally once daily for days 1–14 of a 21-day cycle.
- MLN: 13.5 mg orally once daily on a continuous basis.

HOW SUPPLIED

4.5 mg, 9 mg, and 13.5 mg tablets in 14-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **For Choangiocarcinoma:**
  - The member has a documented diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma; **AND**
  - The member has a documented FGFR2 fusion or other rearrangement, as detected by an FDA-approved test; **AND**
  - The member has received at least one prior systemic cancer therapy.
- **For Myeloid/Lymphoid Neoplasms:**
  - The member must have a diagnosis of a myeloid/lymphoid neoplasms with eosinophilia; **AND**
  - The member must have evidence of FGFR1 rearrangement.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's oncologist.

REQUIRED MEDICAL INFORMATION

FGFR test results

AGE RESTRICTIONS

18 years of age or older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

PERFLUOROHEXYLOCTANE (MIEBO)

Updated July 26, 2023

Length of Authorization:	Initial: 1 year Continuation: 5 years
Initiative:	PAR: MEIBO (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of the signs and symptoms of dry eye disease (DED).

FDA-RECOMMENDED DOSE

Instill 1 drop into affected eye(s) 4 times daily.

HOW SUPPLIED

100% eye drop in 3 mL multi-dose container.

UTILIZATION CRITERIA

For initial coverage requests:

- The member has a diagnosis of dry eye, dry eye disease, or dry eye syndrome; **AND**
- The member will not be using cyclosporine ophthalmic emulsion 0.05%, cyclosporine ophthalmic solution 0.09%, lifitegrast ophthalmic solution, hydroxypropyl cellulose insert, or varenicline tartrate nasal spray, concomitantly with perfluorohexyloctane (Miebo); **AND**
- The member has tried and failed a minimum 1-month trial of cyclosporine ophthalmic emulsion.

For continuation coverage requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider; **AND**
- The member will not be using cyclosporine ophthalmic emulsion 0.05%, cyclosporine ophthalmic solution 0.09%, lifitegrast ophthalmic solution, hydroxypropyl cellulose insert, or varenicline tartrate nasal spray, concomitantly with perfluorohexyloctane (Miebo).

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an ophthalmologist or optometrist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 1 year.
- Continuation: 5 years.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

PIQRAY® (ALPELISIB)

Updated April 11, 2023

Length of Authorization:	5 years
Initiative:	PAR: Piqray (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

Used in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced, or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

FDA-RECOMMENDED DOSE

300 mg (two 150 mg film-coated tablets) taken orally, once daily, with food

HOW SUPPLIED

- 50 mg, 150 mg, and 200 mg film-coated tablets
- Supplied in blister packs by dose:
  - 300 mg daily dose (14 days): 28 x 150 mg tablets
  - 250 mg daily dose (14 days): 14 x 200 mg tablets and 14 x 50 mg tablets
  - 200 mg daily dose (28 days): 28 x 200 mg tablets

UTILIZATION CRITERIA

For Initial Coverage:

- The member is a post-menopausal woman, a premenopausal woman treated with ovarian ablation or suppression, or a male; **AND**
- The member has a diagnosis of HR-positive, HER2-negative, PIK3CA-mutated, advanced, or metastatic breast cancer; **AND**
- The member has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, tamoxifen, toremifene); **AND**
- The provider attests that the member will be receiving alpelisib in combination with fulvestrant; **AND**
- The provider attests that that they have screened the member for diabetes prior to use of alpelisib.

For Continuation of Coverage:

- The member has had a positive response to therapy, as documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- PIK3CA mutation status documentation
- Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

POLLEN IMMUNOTHERAPY (GRASTEK®, ORALAIR®, AND RAGWITEK®)

Updated: October 22, 2023

Length of Authorization:	7 months
Initiative:	PAR: Pollen Immunotherapy (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

Grastek® (Timothy grass pollen allergen extract):

- Allergen extract indicated as immunotherapy for the treatment of **grass pollen**-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in-vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens.
- Grastek® is approved for use in persons **5 through 65** years of age.

Oralair® anthoxanthum odoratum pollen, dactylis glomerata pollen, lolium perenne pollen, phleum pratense pollen, and poa pratensis pollen):

- Allergen extract indicated as immunotherapy for the treatment of **grass pollen**-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in-vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in this product.
- Oralair® is approved for use in persons **5 through 65** years of age.

Ragwitek® (ambrosia artemisiifolia pollen):

- Allergen extract indicated as immunotherapy for the treatment of **short ragweed** pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or in-vitro testing for pollen-specific IgE antibodies for short ragweed pollen.
- Ragwitek® is approved for use in adults 5 **through 65** years of age.

FDA-RECOMMENDED DOSE

See package inserts

HOW SUPPLIED

See package inserts

UTILIZATION CRITERIA

FOR ALL COVERAGE REQUESTS

- The treatment will be started at least 4 months prior to pollen season; **AND**
- The member's first dose must be administered at a healthcare facility where monitoring for severe allergic reaction will take place for at least 30 minutes after administration; **AND**
- The member must have an active prescription for a self-injectable epinephrine rescue product as attested by the prescribing provider; **AND**
- The member has tried and failed two, or has a contraindication to all, of the following:
  - Oral antihistamine
  - Intranasal antihistamine
  - Intranasal corticosteroid
  - Leukotriene inhibitor; **AND**

- The member must not have any of the following conditions:
  - Compromised lung function
  - Unstable angina
  - Recent myocardial infarction
  - Significant arrhythmia
  - Uncontrolled hypertension
  - Severe, unstable, or uncontrolled asthma
  - History of eosinophilic esophagitis; **AND**
- The member must meet the following criteria specific to the requested product:
  - For Grastek®, the member must have a positive skin test or positive IgE specific antibodies to Timothy grass
  - For Oralair®, the member must have a positive skin test or positive IgE specific antibodies to sweet vernal, orchard, perennial rye, Timothy grass, or mixed grass pollens
  - For Ragwitek®, the member must have a positive skin test or positive IgE specific antibodies to ragweed pollens.

REQUIRED MEDICAL INFORMATION

- Medical records or chart notes confirming diagnosis; **AND**
- Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

5 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an allergy specialist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

7 months

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to Formulary

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve by GSN.
- This drug must be started at least 4 months prior to the pollen season. The PA starting date should be between October 1st and January 31st.

POMALYST® (POMALIDOMIDE)

Updated: May 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Pomalyst (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of multiple myeloma (MM), in combination with dexamethasone, in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.
- For the treatment of Kaposi sarcoma in adult patients with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) and Kaposi sarcoma (KS) in adult patients who are HIV-negative.

FDA-RECOMMENDED STARTING DOSE

- MM: 4 mg orally once daily on days 1–21 of repeated 28-day cycles.
- KS: 5 mg once daily on days 1-21 of repeated 28-day cycles.

HOW SUPPLIED

1 mg, 2 mg, 3 mg, and 4 mg capsules in 21-count and 100-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests

- **For Multiple Myeloma (MM):**
  - The member has a diagnosis of multiple myeloma (MM); **AND**
  - The member has previously been treated with two therapies, including lenalidomide and a proteasome inhibitor; **OR**
  - The member will be using being pomalidomide to manage POEMS syndrome
- **For Primary CNS Lymphoma:**
  - The member has a diagnosis of primary CNS lymphoma; **AND**
  - The member is using pomalidomide as induction therapy and is unable to use methotrexate; **OR**
  - The member has relapsed or refractory disease
- **For Kaposi Sarcoma (KS):**
  - The member has a diagnosis of Kaposi sarcoma (KS) and meets one of the following clinical scenarios:
    - The member is HIV negative; **OR**
    - The member is HIV positive and has failed highly active antiretroviral therapy (HAART).
- **For Systemic Light Chain Amyloidosis:**
  - The member has a diagnosis of relapsed or refractory systemic light chain amyloidosis; **AND**
  - The member will be using pomalidomide in combination with dexamethasone.

For Continuation Coverage Requests

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist prescriber.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approve by HICL.

PONVORY™ (PONESIMOD)

Updated: September 22, 2023

Length of Authorization:	Five years
Initiative:	PAR: Ponvory (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATIONS

For the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults

FDA-RECOMMENDED DOSE

14-day titration, then 20 mg taken orally once daily starting on Day 15

HOW SUPPLIED

- 14 tablet starter pack (blister pack): 2 mg (x2), 3 mg (x2), 4 mg (x2), 5 mg (x1), 6 mg (x1), 7 mg (x1), 8 mg (x1), 9 mg (x1), and 10 mg tablets (x3)
- 20 mg tablets in a 30-count bottle

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member must have a diagnosis of a relapsing form of multiple sclerosis (MS); **AND**
- The member does not have any of the following without the presence of a functioning pacemaker:
  - Mobitz type II second-degree, third-degree atrioventricular (AV) block
  - Sick sinus syndrome
  - Sino-atrial block; **AND**
- The member has not experienced any of the following in the past six months:
  - Myocardial infarction
  - Unstable angina
  - Stroke
  - Transient ischemic attack (TIA)
  - Decompensated heart failure requiring hospitalization
  - Class III or IV heart failure; **AND**
- The member must have tried and failed one of the following or have a contraindication to all the following products, if requested for a shared indication: Avonex, Betaseron, fingolimod, Gilenya, glatiramer acetate, Glatopa, Kesimpta, Mayzent, Plegridy, or dimethyl fumarate.

FOR CONTINUATION COVERAGE REQUESTS

The member has had a positive clinical response to therapy, as documented by the member's neurology provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

Five years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HSN.

PROTON PUMP INHIBITORS

Updated: July 27, 2023

Length of Authorization:	Five years
Initiative:	PAR: PPIs (IE 2462 / NCPDP 75, IE 2194 / NCPDP 60 – GSN)

POLICY OVERVIEW

- The University of Michigan Prescription Drug Plan covers select federal legend proton-pump inhibitor (PPI) products when used to treat certain medical conditions or when prescribed at doses not otherwise available in over the counter (OTC) products (Table 1). The plan covers select federal legend PPI products when prescribed for members under 11 years of age without a prior authorization.
- **Table 1. Covered PPI Products by Generic Sequence Number (GSN):**

GSN	Generic Name	Strength	Dosage Form	Under 11 years age without PA	Hypersecretion Syndrome, Advanced Cancers	Difficulties in Swallowing
69882	esomeprazole	2.5 mg	suspdr pkt	Yes		With PA
69884	esomeprazole	5 mg	suspdr pkt	Yes		With PA
63668	esomeprazole	10 mg	suspdr pkt	Yes		With PA
62245	esomeprazole	20 mg	suspdr pkt	Yes		With PA
62246	esomeprazole	40 mg	suspdr pkt	Yes		With PA
30107	lansoprazole	30 mg	capsule dr		With PA	
51654	lansoprazole	30 mg	tab rap dr	Yes		With PA
64774	omeprazole	2.5 mg	suspdr pkt	Yes		With PA
64775	omeprazole	10 mg	suspdr pkt	Yes		With PA
43137	omeprazole	40 mg	capsule dr		With PA	
60472	omeprazole/ sodium bicarb	40 mg–1.1 g	capsule		With PA	
27462	pantoprazole	40 mg	tablet dr		With PA	
63700	pantoprazole	40 mg	granpkt dr	Yes		With PA
70816	rabeprazole	5 mg	cap dr spr	Yes		With PA
70817	rabeprazole	10 mg	cap dr spr	Yes		With PA
40941	rabeprazole	20 mg	tablet dr		With PA	

COVERAGE CRITERIA

- For hypersecretory syndromes:
  - The requested product is one of lansoprazole, omeprazole, rabeprazole, pantoprazole, omeprazole, or sodium bicarbonate*; **AND**
  - The member has a documented diagnosis of erosive esophagitis, peptic ulcer disease, or Barrett's esophagus; **OR**
  - The member has a diagnosis of a hypersecretion syndrome (e.g., Zollinger-Ellison Syndrome) confirmed with one of the following diagnostic tests:
    - Fasting serum gastrin
    - Secretin stimulation test
    - Calcium infusion study
- For advanced cancers:
  - The requested product is one of lansoprazole, omeprazole, rabeprazole, pantoprazole, omeprazole, or sodium bicarbonate*; **AND**
  - The member has a diagnosis of an advanced, metastatic, or recurrent cancer
- For difficulties in swallowing:
  - The requested product is one of lansoprazole, omeprazole, rabeprazole, pantoprazole, or esomeprazole*; **AND**
  - The member has undergone bariatric surgery, requires tube-feeding, or has a documented difficulty in swallowing; **AND**
  - The member is unable to sprinkle the contents of over-the-counter (OTC) capsule products on food

*Refer to Table 1 for a list of applicable GSNs.

EXCLUSION CRITERIA

The member is able to satisfy their medical need to reduce gastric pH levels via OTC products

REQUIRED MEDICAL INFORMATION

Documentation of diagnosis of erosive esophagitis, peptic ulcer disease or Barrett's esophagus

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

Five years

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to Formulary

OPERATIONAL INSTRUCTIONS AND ADDITIONAL INFORMATION

- In general, PPI products are considered a plan exclusion if used for the treatment of gastroesophageal reflux disease (GERD) at doses available in OTC formulations.
  - If OTC formulation, admin deny if using for GERD.
  - If Rx formulation, deny clinically if using for GERD.
- Approve by GSN

PREVYMIS™ (LETERMOVIR)

Updated: May 25, 2024

Length of Authorization:	98 days (initial), with an optional extension of up-to 168 days post-transplant
Initiative:	PAR: Prevymis (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)

FDA-RECOMMENDED DOSE

Dosed 480 mg (orally or IV) once daily for 100 days post-transplant

HOW SUPPLIED

240 and 480 mg tablets in 7-count blister packs; 240 and 480 mg single-use vials

UTILIZATION CRITERIA

For initial coverage requests (days 0–98 post-transplant):

- The member must have received an allogeneic HSCT; **AND**
- The member must be CMV-seropositive (R+); **AND**
- The medication will be initiated between day 0–28 post-transplant

For continuation coverage requests (days 99–200 post-transplant):

- The member is considered "high risk" by meeting one or more of the following criteria:
  - Human leukocyte antigen (HLA)-related (sibling) donor with at least one mismatch at one of the following three HLA-gene loci: HLA-A, -B or -DR
  - Haploidentical donor
  - Unrelated donor with at least one mismatch at one of the following four HLA –gene loci: HLA-A, -B, -C and -DRB1
  - Use of umbilical cord blood as stem cell source
  - Use of ex vivo T-cell-depleted grafts
  - Grade 2 or greater graft-versus-host disease (GVHD), requiring the use of systemic corticosteroids (defined as the use of ≥ 1 mg/kg/day of prednisone or equivalent dose of another corticosteroid)

REQUIRED MEDICAL INFORMATION

- CMV-seropositive status of the member
- Date of allogeneic HCST

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist, hematologist, or infectious disease specialist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

98 days (initial), with an optional extension of up-to 200 days post-transplant

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve by GSN.
- The IV (vial) formulation is excluded from coverage.

PROMACTA® (ELTROMBOPAG OLAMINE)

Updated: November 30, 2023

Length of Authorization:	Initial approval for 4 months; continuation approvals for 12 months
Initiative:	PAR: Promacta (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of thrombocytopenia in patients 1 year and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy
- For the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy
- For the treatment of severe aplastic anemia in patients who have had an insufficient response to immunosuppressive therapy
- In combination with standard immunosuppressive therapy (IST) for the first-line treatment of adult and pediatric patients 2 years and older with severe aplastic anemia.

FDA-RECOMMENDED STARTING DOSE

- Persistent or Chronic ITP: 50 mg once daily in adults and 25 mg in pediatric patients 1-5 years of age (initial), not to exceed 75 mg per day.
- Chronic Hep C-associated Thrombocytopenia: 25 mg once daily (initial), not to exceed 100 mg daily.
- Refractory Severe Aplastic Anemia: 50 mg once daily (initial), not to exceed 150 mg per day.
- First-line Severe Aplastic Anemia: Initiate at 2.5 mg/kg once daily in pediatric patients 2-5 years of age, 75 mg daily in patients 6-11 years of age, or 150 mg daily for patients 12+ years of age.

HOW SUPPLIED

- 12.5 mg, 25 mg, 50 mg, and 75 mg oral tablets in 30-count bottles
- 12.5 mg and 25 mg suspension packets.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- **For Persistent or Chronic ITP:**
  - The member has a confirmed diagnosis of chronic immune thrombocytopenic purpura; **AND**
  - The member has an initial platelet count less than 30,000/µL, **AND**
  - One or more of the following applies:
    - The member has had an insufficient response to four weeks of standard prednisone therapy or high dose dexamethasone (HDD); **OR**
    - The member has had an insufficient response to immunoglobulins; **OR**
    - The member has had a splenectomy.

- **For Severe Aplastic Anemia:**
  - The member has a confirmed diagnosis of severe aplastic anemia; **AND**
  - The member has an initial platelet count less than 30,000/µL; **AND**
  - One of the following applies:
    - The member has tried and failed at least one prior immunosuppressive therapy; **OR**
    - The requested medication will be used in combination with standard immunosuppressive therapy

FOR CONTINUATION COVERAGE REQUESTS

- **Chronic ITP:**
  - Increase in platelet count to ≥ 50,000/mm^3 or increase that is sufficient to avoid clinically important bleeding after at least 4 weeks of max dose
- **Severe Aplastic Anemia:**
  - Platelet count increase of at least 20,000/µL above baseline, or stable platelet counts with transfusion independence; **OR**
  - Hemoglobin increase by greater than 1.5 g/dL or reduction in ≥ 4 units of RBC transfusions for 8 consecutive weeks; **OR**
  - ANC increase of 100% or an ANC increase greater than 500/µL.

REQUIRED MEDICAL INFORMATION

- Complete blood count with differential
- Baseline serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), and bilirubin levels
- Treatment plan with planned concurrent therapies

AGE RESTRICTIONS

One years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

- Initial: 4 months
- Renewal: 12 months

QUANTITY RESTRICTIONS

- Refer to formulary
- All requests must be reviewed for consistency with member diagnosis and the FDA-approved dosing schedule, as provided in this document and the package insert.

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve by HICL.
- The plan does not cover eltrombopag for the treatment of thrombocytopenia in patients with HCV, as treatment with interferon-based regimens does not meet current practice guidelines for the treatment of HCV.

PULMONARY HYPERTENSION AGENTS (LETAIRIS®, TRACLEER®, VENTAVIS®, TYVASO® AND TYVASO DPI, OPSUMIT®, UPTRAVI®, ORENITRAM®, ADEMPAS®)

Updated: November 30, 2023

Length of Authorization:	5 years
Initiative:	• PAR: Letairis (IE 2462 / NCPDP 75 – HICL) • PAR: Tracleer (IE 2462 / NCPDP 75 – HICL) • PAR: Ventavis (IE 2462 / NCPDP 75 – HICL) • PAR: Tyvaso and Tyvaso DPI (IE 2462 / NCPDP 75 – HICL) *This is the initiative being used for Orenitram as well • PAR: Opsumit (IE 2462 / NCPDP 75 – HICL) • PAR: Uptravi (IE 2462 / NCPDP 75 – HICL) • PAR: Adempas (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

Ambrisentan (Letairis®)

- For the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1):
  - To improve exercise ability and delay clinical worsening.
  - In combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability.

Bosentan (Tracleer®)

- For the treatment of PAH (WHO Group 1) in adults to improve exercise ability and to decrease clinical worsening.
- For the treatment of PAH (WHO Group 1) in pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability.

Iloprost (Ventavis®)

- For the treatment of PAH (WHO Group 1) to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class), and lack of deterioration.

Inhaled treprostinil (Tyvaso® and Tyvaso DPI)

- For the treatment of PAH (WHO Group 1) to improve exercise ability.
- For the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD) WHO Group 3 to improve exercise ability.

Macitentan (Opsumit®)

- For the treatment of PAH (WHO Group I) to reduce the risks of disease progression and hospitalization for PAH.

Selexipag (Uptravi®)

- For the treatment of PAH (WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH.

Treprostinil (Orenitram®)

- For the treatment of PAH (WHO Group 1) to delay disease progression and to improve exercise capacity.

Riociguat (Adempas®)

- For the treatment of adults with PAH (WHO Group 1), to improve exercise capacity, WHO functional class, and to delay clinical worsening.
- For the treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH), (WHO Group 4) after surgical treatment, or inoperable CTEPH, to improve exercise capacity and WHO functional class.

FDA-RECOMMENDED DOSE

Various, refer to specific package inserts.

HOW SUPPLIED

Various, refer to specific package inserts.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- **For PAH:**
  - The member must have a diagnosis of pulmonary arterial hypertension (WHO Group 1); **AND**
  - The member must have a WHO functional classification of at least II (II-IV); **AND**
- **For PH-ILD** (Pathway for Tyvaso® and Tyvaso DPI only):
  - The member must have a diagnosis of pulmonary hypertension associated with interstitial lung disease (WHO Group 3).
- **For CTEPH** (Pathway for Adempas® only):
  - The member must have a diagnosis of chronic thromboembolic pulmonary hypertension (WHO Group 4).
  - The member must have tried and failed, or is not a candidate for, pulmonary endarterectomy.

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

- Bosentan (Tracleer®): 3 years of age and older.
- All others: 18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a cardiologist or pulmonologist (or other provider specialty if provider is certified by applicable REMS programs).

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Please note that PDE5 inhibitors used for PAH are governed by a PDE5 specific policy.

PYRUKYND® (MITAPIVAT)

Updated: May 30, 2023

Length of Authorization:	6 months
Initiative:	PAR: Pyrukynd (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency.

FDA-RECOMMENDED DOSE

Starting dose is 5 mg orally twice daily. Titrate every four weeks based on hemoglobin (Hgb) response to 20 mg twice daily, and then to the maximum recommended dose of 50 mg twice daily.

HOW SUPPLIED

- 5 mg, 20 mg, or 50 mg tablets in 56-count packages.
- Taper packs:
  - 5 mg pack: one blister wallet containing 7 tablets
  - 5 mg and 20 mg pack: two blister wallets – one 5 mg and one 20 mg, each containing 7 tablets
  - 20 mg and 50 mg pack: two blister wallets – one 20 mg and one 50 mg, each containing 7 tablets

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of pyruvate kinase deficiency; **AND**
- The member has documentation of at least two mutant alleles in the PKLR gene, of which at least one is a missense mutation; **AND**
- The member is not homozygous for R479H mutation or had two non-missense variants, without the presence of another missense variant in the PKLR gene; **AND**
- The member has documentation of a current hemoglobin ≤ 10 mg/dL.

For Continuation Coverage Requests:

- The member must have documentation of hemoglobin improvement over baseline.

REQUIRED MEDICAL INFORMATION

- Initial: mutation status and current hemoglobin levels
- Continuation: current hemoglobin levels.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

6 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by HICL.

QBREXZA™ (GLYCOPYRRONIUM)

Updated: August 2, 2023

Length of Authorization:	6 months (initial); 12 months (continuation)
Initiative:	PAR: Qbrexza (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

A topical anticholinergic agent indicated to treat primary axillary hyperhidrosis in adults and pediatric patients, ages 9 years and older.

FDA-RECOMMENDED DOSE

Apply once daily to each axilla using a single pre-moistened cloth.

HOW SUPPLIED

A carton containing 30 individually wrapped pre-moistened cloths.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member is diagnosed with primary axillary hyperhidrosis of at least 6 months duration; **AND**
- The member is experiencing secondary issues such as acrocyanosis, maceration with bacterial or fungal infections, recurrent secondary infections, or persistent eczematous dermatitis; **AND**
- The member has failed an adequate trial of maximum strength (20%) topical aluminum chloride or aluminum chloride is contraindicated; **AND**
- The member has failed an adequate trial of subcutaneous onabotulinumtoxinA (Botox®) or onabotulinumtoxinA (Botox) is contraindicated; **AND**
- Glycopyrronium (Qbrexza®) will not be used concurrently with onabotulinumtoxinA (Botox®).

FOR CONTINUATION COVERAGE REQUESTS

- The member has had a positive clinical response to therapy, as documented by the member's provider; **AND**
- The member will not use glycopyrronium (Qbrexza®) concurrently with onabotulinumtoxinA (Botox®).

REQUIRED MEDICAL INFORMATION

Chart notes or documentation of current and historic treatment plan

AGE RESTRICTIONS

9 years of age and older

REVIEWER REQUIREMENTS

COVERAGE DURATION

- Initial: 6 months.
- Continuation: 12 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

QINLOCK™ (RIPRETINIB)

Updated: May 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Qinlock (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib.

FDA-RECOMMENDED DOSE

150 mg orally once daily.

HOW SUPPLIED

50 mg tablets in 90-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a documented diagnosis of advanced gastrointestinal stromal tumor (GIST); **AND**
- The member has received three prior lines of therapy containing imatinib (Gleevec), sunitinib (Sutent), and regorafenib (Stivarga), unless contraindicated; **OR**
- The member has metastatic or unresectable tumor with activating mutations of KIT; **AND**
- The member has been previously treated with BRAF-targeted therapy.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's oncologist.

REQUIRED MEDICAL INFORMATION

Documentation of contraindication to prior lines of therapy, if applicable.

AGE RESTRICTIONS

18 years of age or older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years.

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary quantity limit.

OPERATIONAL NOTES

Approve by GSN.

QUIZARTINIB (VANFLYTA)

Updated: November 22, 2023

Length of Authorization:	5 years
Initiative:	PAR: Vanflyta (IE 2462 / NCPDP 75 – HSN)

FDA-APPROVED INDICATION(S)

In combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive as detected by an FDA-approved test.

FDA-RECOMMENDED DOSE

- Induction (up to 2 cycles with cytarabine and anthracycline): 35.4 mg orally once daily (days 8 to 21 of each cycle)
- Consolidation (up to 4 cycles with high dose cytarabine): 35.4 mg orally once daily (days 6 to 19 of each cycle)
- Maintenance (up to 36 cycles of monotherapy):
  - If QTc interval is ≤ 450 ms, then 26.5 mg orally once daily on days 1 through 14 of the first cycle
  - If QTc interval remains ≤ 450 ms, then increase to 53 mg once daily on day 15 of the first cycle, maintain 26.5 mg once daily if at any point in therapy QTc interval was > 500 ms.

HOW SUPPLIED

17.7 mg or 26.5 mg tablets in 14 and 28-count bottles.

UTILIZATION CRITERIA

- For initial coverage requests:
  - The member has a diagnosis of AML; **AND**
  - The member has documentation of FLT3-ITD status; **AND**
  - The member is treatment naïve for their AML; **AND**
  - The member has not received Hematopoietic Stem Cell Transplantation (HSCT)
- For continuation coverage requests:
  - The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Documentation of FLT3-ITD.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HSN.

RADICAVA ORS® (EDARAVONE)

Updated: September 26, 2023

Length of Authorization:	12 months
Initiative:	PAR: Radicava (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of amyotrophic lateral sclerosis (ALS).

FDA-RECOMMENDED DOSE

105 mg (5 mL) daily for 14 days, followed by a 14-day drug free period, followed by a cycle of daily dosing 10 out of 14 days, followed by 14-day drug-free periods.

HOW SUPPLIED

35 mL and 50 mL bottles.

COVERAGE CRITERIA

FOR INITIAL REVIEW

- The member has a confirmed diagnosis of ALS; **AND**
- The member was initially diagnosed within the preceding 24 months of the coverage request; **AND**
- The member has a percent predicted forced vital capacity (%FVC) ≥ 80%; **AND**
- The member has scores of at least 2 points on all 12 items of the ALS Functional Rating Scale (ALSFRS-R) questionnaire.

FOR CONTINUATION

- The member has had a positive clinical response to therapy, as documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Date of initial ALS diagnosis.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by a neurologist experienced in the treatment of ALS.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

- Initial Approvals: Enter an override to permit a QPD of 2.5 for the first 28 days, then refer to formulary limits.
- Continuations: Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by HSN.

REBIF® (INTERFERON BETA-1A)

Updated: August 21, 2023

Length of Authorization:	5 years
Initiative:	PAR: Rebif (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

FDA-RECOMMENDED DOSE

22 mcg or 44 mcg injected subcutaneously three times per week.

HOW SUPPLIED

- Titration pack of six 8.8 mcg syringes or auto-injectors and six 22 mcg syringes or auto-injectors.
- Twelve 22 mcg or 44 mcg syringes or auto-injectors package.

COVERAGE CRITERIA

FOR INITIAL REVIEW

- Member must have tried and failed **one** of the following or have a contraindication to the following products if requested for a shared indication: Avonex®, Betaseron®, Gilenya®, fingolimod, glatiramer acetate, Glatopa®, Kesimpta®, Mayzent®, Plegridy®, or dimethyl fumarate.

FOR CONTINUATION

- Member has had a positive clinical response to therapy, as documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurology provider

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by HICL.

REGRANEX® (BECAPLERMIN) GEL

Updated: May 10, 2023

Length of Authorization:	3 months
Initiative:	PAR: Regranex (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply, when used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief and infection control.

FDA-RECOMMENDED DOSE

The amount to be applied depends upon the size of the ulcer area (guideline in PI).

HOW SUPPLIED

0.01% becaplermin gel in a 15-gram tube.

COVERAGE CRITERIA

FOR INITIAL AND CONTINUATION COVERAGE REQUESTS

- The member has a diagnosis of a diabetic neuropathic ulcer of the lower extremity; **AND**
- The member must have an ulcer that extends into the subcutaneous tissue or beyond; **AND**
- The member's lower extremity must possess adequate blood supply; **AND**
- The member will be using Regranex® as adjunct treatment to, NOT a replacement for, good ulcer care including initial sharp debridement, pressure relief, standard of care moist dressing changes, and prevention and treatment of infection.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

N/A

COVERAGE DURATION

3 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

Approve by GSN.

RETEVMO™ (SELPERCATINIB)

Updated: February 2, 2023

Length of Authorization:	5 years
Initiative:	PAR: Retevmo (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- Adult patients with locally advanced or metastatic RET fusion-positive non-small cell lung cancer (NSCLC).
- Patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy.
- Patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).
- Adult patients with locally advanced or metastatic *RET* fusion-positive solid tumor that has progressed on or following prior systemic therapy or who have no satisfactory alternative treatment options.

FDA-RECOMMENDED STARTING DOSE

< 50 kg: 120 mg orally twice daily; > 50 kg: 160 mg orally twice daily

HOW SUPPLIED

40 mg capsules in 60-count bottles, 80 mg capsules in 60- and 120-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests

- The member has a documented diagnosis of diagnosis of a solid tumor cancer; **AND**
- The member has documentation of diagnosis of one of the following: RET mutant or RET fusion positive disease.

For Continuation Coverage Requests

- The member continues to have a beneficial response to therapy, as assessed by the member's oncologist.

REQUIRED MEDICAL INFORMATION

- Documentation of RET mutation or fusion

AGE RESTRICTIONS

- Thyroid cancer and MTC: 12 years of age or older.
- NSCLC and other solid tumors: 18 years of age or older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years.

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

Approve by HICL.

REVLIMID® (LENALIDOMIDE)

Updated: May 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Revlimid (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of patients with multiple myeloma (MM), in combination with dexamethasone
- For the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality
- For the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib
- For the treatment of adult patients with previously treated follicular lymphoma (FL)
- For the treatment of adult patients with previously treated marginal zone lymphoma (MZL)

FDA-RECOMMENDED STARTING DOSE

- **For MM:** 25 mg orally once daily on days 1–21 of repeated 28-day cycles, or 10 mg orally once daily
- **For MDS:** 10 mg orally once daily
- **For MCL:** 25 mg orally once daily on days 1–21 of repeated 28-day cycles
- **For FL, MZL:** 20 mg orally once daily on days 1–21 of repeated 28-day cycles for up to 12 cycles of treatment

HOW SUPPLIED

- 2.5 mg, 5 mg, and 10 mg in 28-count and 100-count bottles
- 15 mg, 20 mg, and 25 mg capsules in 21-count and 100-count bottles

UTILIZATION CRITERIA

For Initial Review:

- The member has an NCCN-recognized category 2A or higher indication for treatment

For Continuation:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist prescriber

REQUIRED MEDICAL INFORMATION

None

AGE RESTRICTIONS

None

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by HICL.

REYVOW® (LASMIDITAN)

Updated: January 1, 2024

Length of Authorization:	12 months
Initiative:	PAR: Reyvow (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the acute treatment of migraine with or without aura in adults

FDA-RECOMMENDED DOSE

50 mg to 200 mg orally once daily, as needed. Not to be used for more than four migraines per month

HOW SUPPLIED

50 mg and 100 mg tablets in 8-count cartons

UTILIZATION CRITERIA

FOR INITIAL REQUESTS

- The member has a diagnosis of migraine; **AND**
- The member has tried and failed two or more generic triptan products unless otherwise contraindicated to the class*.
- ***Class contraindications may include a history of coronary artery disease, stroke, TIA, peripheral vascular disease, ischemic bowel disease, cardiac arrhythmias, and uncontrolled blood pressure.**

FOR CONTINUATION REQUESTS

The member has had a beneficial response to therapy as attested to by the prescribing provider.

AGE RESTRICTIONS

18 years of age and older

REVIEWER REQUIREMENTS

Must be reviewed by a pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HSN.

REZUROCK™ (BELUMOSUDIL)

Updated: April 28, 2023

Length of Authorization:	6 months
Initiative:	PAR: REZUROCK (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (cGvHD) after failure of at least two prior lines of systemic therapy.

FDA-RECOMMENDED DOSE

200 mg tablet taken orally once daily with food.

HOW SUPPLIED

200 mg tablets in a 30-count bottle.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of chronic graft-versus-host disease secondary to bone marrow and stem cell transplant; **AND**
- The member has tried and failed at least two prior lines of systemic therapy for their cGvHD.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

12 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a hematologist, oncologist, or other transplant specialist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

QUANTITY RESTRICTIONS

- **For 200 mg once daily**: refer to formulary.
- **For 200 mg twice daily**: dose quantity override needed for length of PA approval. The member must meet **one** of the following scenarios to qualify for a quantity override:
  - The member is on a PPI that cannot be switched to an alternate therapy; **OR**
  - The member is on a CYP3A inducer that cannot be switched to an alternate therapy.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

RHOPRESSA® (NETARSUDIL) AND ROCKLATAN™ (NETARSUDIL, LATANOPROST)

Updated: July 28, 2023

Length of Authorization:	5 years
Initiative:	PAR: Rhopressa & Rocklatan (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension

FDA-RECOMMENDED DOSE

One drop in the affected eye(s) once daily in the evening

HOW SUPPLIED

- **Rhopressa**: 0.2 mg/mL (2.5 mL/bottle) of netarsudil dimesylate. Contains benzalkonium chloride 0.015% as a preservative.
- **Rocklatan**: 0.2 mg/mL (2.5 mL/bottle) of netarsudil dimesylate and 0.05 mg/mL of latanoprost. Contains benzalkonium chloride 0.015% as a preservative.

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of open-angle glaucoma or ocular hypertension; **AND**
- The member has tried and failed two or more, or has contraindication to all, of the following generic ophthalmic products:
  - Latanoprost
  - Bimatoprost
  - Timolol
  - Levobunolol
  - Brimonidine
  - Apraclonidine
  - Dorzolamide
  - Pilocarpine

FOR CONTINUATION COVERAGE REQUEST

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an ophthalmologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to Formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN

RINVOQ® (UPADACITINIB)

Updated: April 1, 2024

Length of Authorization:	VARIES – see COVERAGE DURATION
Initiative:	PAR: Rinvoq 15 or 30 (IE 2462 / NCPDP 75 – GSN) PAR: Rinvoq: UC/CD Initial (IE 2462 / NCPDP 75 – HSN)

FDA-APPROVED INDICATION(S)

- For the treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more TNF blockers.
- For the treatment of adults with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to one or more TNF blockers.
- For the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis (AD) whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.
- For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more TNF blockers.
- For the treatment of adults with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers.
- For the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.
- For the treatment of adult patients with moderately to severely-active Crohn's disease (CD) who have had an inadequate response or intolerance to one or more TNF blockers.

FDA-RECOMMENDED DOSE

RA/PsA/AS/nr-axSpA:

- 15 mg orally once daily.

AD:

- Age 65 years of age and older: 15 mg orally once daily.
- Pediatric Patients 12 years of age and older weighing at least 40 kg and adults less than 65 years of age: initiate treatment with 15 mg orally once daily. If an adequate response is not achieved, consider increasing the dosage to 30 mg once daily.

UC:

- 45 mg once daily for 8 weeks, then maintenance treatment is 15 mg once daily. A dosage of 30 mg once daily may be considered for patients with refractory, severe, or extensive disease.

CD:

- 45 mg once daily for 12 weeks, then maintenance treatment is 15 mg once daily. A dosage of 30 mg once daily may be considered for patients with refractory, severe or extensive disease.

HOW SUPPLIED

- 15 mg and 30 mg extended-release tablets in 30-count bottles
- 45 mg extended-release tablets in 28-count bottles.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

For all indications:

- The member has tried and failed, or has contraindications to, a TNF-inhibitor (does not apply to Atopic Dermatitis diagnosis); **AND**
- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

For the treatment of RA :

- The member has a diagnosis of moderately to severely active rheumatoid arthritis; **AND**
- The member has had a previous trial of or contraindication to at least one of the following:
  - Methotrexate
  - Leflunomide
  - Hydroxychloroquine
  - Sulfasalazine; **AND**
- The member has had a previous trial of, or contraindication to, at least two of the following preferred agents:
  - Adalimumab
  - Enbrel
  - Xeljanz; **AND**

For the treatment of PsA:

- The member has a diagnosis of active psoriatic arthritis; **AND**
- The member has had a previous trial of, or contraindication to, at least one of the following:
  - Methotrexate
  - Sulfasalazine
  - Cyclosporine
  - Leflunomide; **AND**
- The member has had a previous trial of, or contraindication to, at least two of the following without adequate response:
  - Adalimumab
  - Cosentyx
  - Enbrel
  - Tremfya
  - Stelara
  - Xeljanz

For the treatment of AS:

- The member has a diagnosis of AS; **AND**
- The member has had a previous trial of at least **one**, or contraindication to **all**, of the following:
  - Nonsteroidal anti-inflammatory drugs (NSAIDs)
  - Methotrexate
  - Sulfasalazine; **AND**
- The member has had a previous trial of at least two of (or contraindication, inadequate response, or intolerance to all) of the following preferred agents:
  - Adalimumab
  - Enbrel
  - Xeljanz
  - Cosentyx

For the treatment AD:

- The member has a diagnosis of moderate to severe atopic dermatitis; **AND**
- The member has one of the following:
  - A minimum body surface area (BSA) involvement of at least 10%; **OR**
  - Eczema Area and Severity Index (EASI) score of at least 16; **OR**
  - Physician Global Assessment (PGA) score of at least 3; **AND**
- The member meets ONE of the following clinical scenarios:
  - The member has a greater than 50% of their BSA impacted; **OR**
  - The member has had a previous trial of at least one therapy from at least two of the following preferred therapy categories without adequate response:
    - Topical calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
    - Medium or high potency topical corticosteroids
    - Topical PDE-4 inhibitors (e.g., crisaborole); **AND**
- The member has had a previous trial and failure of at least **one** of the following
    - Adbry; **OR**
    - Dupixent

For the treatment of UC:

- The member has a diagnosis of moderate to severely active UC; **AND**
- The member has had a previous trial of or contraindication to at least one of the following:
  - Thiopurines (e.g., 6-mercaptopurine or azathioprine); **OR**
  - Corticosteroids; **OR**
  - The member has tried and failed one or more previous biologic therapies (e.g., infliximab, certolizumab, vedolizumab, golimumab, ustekinumab, or natalizumab)**; AND**
- The member has had a previous trial of, or contraindication to, at least two of the following preferred agents:
  - Adalimumab
  - Stelara
  - Xeljanz

For the treatment of CD:

- The member has a diagnosis of moderate to severely active CD; **AND**
- The member has had a previous trial of or contraindication to at least one of the following:
  - Thiopurines (e.g., 6-mercaptopurine or azathioprine)
  - Corticosteroids
  - Methotrexate; **OR**
  - The member has tried and failed one or more previous biologic therapies (e.g., adalimumab, infliximab, certolizumab, vedolizumab, golimumab, ustekinumab, or natalizumab); **AND**
- The member has had a previous trial or contraindication to **both** of the following:
  - Adalimumab
  - Stelara

For the treatment of nr-axSpA:

- The member has a diagnosis of active non-radiographic axial spondylarthritis; **AND**
- The member has had a previous trial of at least **one**, or contraindication to **all**, of the following:
  - Nonsteroidal anti-inflammatory drugs (NSAIDs)
  - Methotrexate
  - Sulfasalazine; **AND**
- The member has had a previous trial of, or contraindication to Cosentyx **and** Cimzia without adequate response

FOR CONTINUATION COVERAGE REQUESTS

- The member has had a positive clinical response to therapy, as documented by the member's specialist provider; **AND**
- The member's liver enzymes are below three times the upper limit of normal (per lab specified range); **AND**
- The member's lymphocyte count is greater than 500 cells/mm^3; **AND**
- The member's absolute neutrophil count (ANC) is greater than 500 cells/mm^3; **AND**
- The member's hemoglobin level is greater than 8 g/dL; **AND**
- If the member is using upadacitinib for atopic dermatitis, they must experience or maintain one of the following:
  - A reduction in BSA involvement of a least 20% from baseline; **OR**
  - A decrease in EASI score of at least 50% from baseline; **OR**
  - A PGA score of 0 or 1.
- If the member is using upadacitinib for UC, they must have achieved either clinical response or clinical remission by week 8 (clinical response or remission for UC must be substantiated by endoscopic improvement **or** clinically important differences in baseline and reassessment scores on a validated disease assessment instrument.); **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib).

REQUIRED MEDICAL INFORMATION

- For all continuation: lymphocyte counts, liver enzymes (AST, ALT), neutrophil counts (ANC), and hemoglobin levels, documented within the six months preceding the coverage request.
- For UC first continuation: documentation of clinical response or remission as described above.
- Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

- PsA/RA/UC/AS/nr-axSpA/CD: 18 years of age and older.
- AD: 12 years of age and older.

PRESCRIBER RESTRICTIONS

- RA/AS/nr-axSpA/: must be prescribed by or in consultation with a rheumatologist.
- PsA: must be prescribed by or in consultation with a dermatologist or rheumatologist.
- AD: must be prescribed by or in consultation with a dermatologist or allergist.
- UC/CD: must be prescribed by or in consultation with a gastroenterologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

- RA/AS/PsA/AD/CD/nr-axSpA: 12 months
  - Use PAR: Rinvoq 15 or 30
- UC/CD:
  - 3 months initial (approve by HSN)
    - Use PAR: Rinvoq: UC/CD Initial
  - 12 months continuation (approve by GSN for 15 mg or 30 mg tablets only)
    - Use PAR: Rinvoq 15 or 30

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

- For RA/AS/PsA/AD/nr-axSpA: Approve by GSN.
- For UC/CD: Approve by HSN for initial and GSN for continuation.
  - 45 mg tablets are allowed for the initial 3-month approval **only**.
  - 15 and 30 mg tablets are the only strengths allowed for continuation requests.
- 45 mg tablets are only approvable for the UC/CD indications.

RIVFLOZA® (NEDOSIRAN)

Updated: April 23, 2024

Length of Authorization:	12 Months
Initiative:	PAR: Rivfloza (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- To lower urinary oxalate levels in children 9 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function.

FDA-RECOMMENDED DOSE

- Weight-based dose administered subcutaneously once monthly.

Age	Body Weight	Dosing Regimen
12+ yoa	≥ 50 kg	160 mg once monthly (Pre-filled Syringe, 1 mL)
	< 50 kg	128 mg once monthly (Pre-filled Syringe, 0.8 mL)
9 – 11 yoa	≥ 50 kg	160 mg once monthly (Pre-filled Syringe, 1 mL)
	< 50 kg	3.3 mg/kg once monthly, not to exceed 128 mg (Vial, nearest 0.1 mL)

HOW SUPPLIED

128 mg and 160 mg single-dose pre-filled syringes and 80 mg single-dose vials in cartons containing one unit each.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of PH1 confirmed by genetic testing of the AGXT mutation; **AND**
- The member has an eGFR ≥30 mL/min; **AND**
- The member has a documented 3-month trial of, or contraindication to, high-dose vitamin B6 (pyridoxine); **AND**
- The member must not use nedosiran (Rivfloza) in combination with lumasiran (Oxulmo).

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider; **AND**
- The member has an eGFR ≥30 mL/min; **AND**
- The member must not use nedosiran (Rivfloza) in combination with lumasiran (Oxulmo).

REQUIRED MEDICAL INFORMATION

- Chart notes or medical records documenting weight and eGFR.
- Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

9 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by, or in consultation with, a nephrologist or physician.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY/PARTIAL-FILL RESTRICTIONS

Approve a quantity exception in line with FDA labeled dosing for age and submitted weight.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

ROFLUMILAST CREAM (ZORYVE®)

Updated: January 10, 2024

Length of Authorization:	12 months
Initiative:	PAR: Zoryve (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- Cream: For topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.
- Foam: For the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

FDA-RECOMMENDED DOSE

Apply a thin layer of cream to affected areas once daily.

HOW SUPPLIED

0.3% cream and 0.3% foam in 60-gram tubes.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- Plaque psoriasis:
  - The requested product is the 0.3% **cream**; **AND**
  - The member must have tried and failed three, or have contraindication to all, of the following:
    - Topical corticosteroid
    - Tazarotene
    - Calcipotriene
    - Topical calcineurin inhibitor
- Seborrheic dermatitis:
  - The requested product is the 0.3% **foam**; **AND**
  - The member must have tried and failed three, or have contraindication to all, of the following:
    - Topical antifungal
    - Topical corticosteroid
    - Topical calcineurin inhibitor

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

- Cream: 12 years of age and older.
- Foam: 9 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a dermatologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

ROZLYTREK® (ENTRECTINIB)

Updated: February 1, 2024

Length of Authorization:	5 years
Initiative:	PAR: Rozlytrek (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive
- Adult and pediatric patients older than 1 month of age with solid tumors that:
  - Have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, as detected by an FDA-approved test without a known acquired resistance mutation,
  - Are metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy.

FDA-RECOMMENDED DOSE

- 600 mg orally once daily
- Pediatric dosing for NTRK fusion positive tumors is by BSA (see package insert)

HOW SUPPLIED

- 100 mg capsules in 30-count bottles
- 200 mg capsules in 90-count bottles
- 50 mg pellet packet in 42-count carton.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **For NSCLC:**
  - Member must have a diagnosis of metastatic, ROS-1 positive NSCLC
- **For NTRK Tumors:**
  - The member must be diagnosed with a solid tumor that has a NTRK gene fusion without known acquired resistance mutation(s)**.**
- For all indications:
  - If requesting pellet packs, the provider must attest that capsules cannot be used.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Documentation of tumor status (i.e., ROS-1 NSCLC, or NTRK gene fusion without known acquired resistance mutations)

AGE RESTRICTIONS

- **NSCLC:** 18 years of age and older
- **NTRK Fusion:** N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY/PARTIAL-FILL RESTRICTIONS

- Refer to formulary.
- Quantity overrides to permit up to five 100 mg capsules per day can be approved in the following scenarios:
  - The member requires a dose reduction that cannot be achieved with the 200 mg capsules (i.e., 300 mg or 500 mg per day).
  - The member is a pediatric patient with a BSA of 1.11 to 1.50 m^2, necessitating the 500 mg dose.

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve by GSN.
- Capsules are currently flat priced, necessitating the need to limit the use of 100 mg capsules in settings that the 200 mg capsules are possible.
- Pellets are similarly more expensive per mg than the 200mg capsules, necessitating restriction to members who cannot use the capsules.

RUBRACA® (RUCAPARIB)

Updated: October 11, 2023

Length of Authorization:	5 years
Initiative:	PAR: Rubraca (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the maintenance treatment of adult patients with deleterious BRCA mutation (germline or somatic)-associated with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy
- For the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.

FDA-RECOMMENDED DOSE

600 mg (two 300 mg tablets) taken orally twice daily

HOW SUPPLIED

200, 250, and 300 mg tablets in 60-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **For ovarian, fallopian tube, or peritoneal cancers treatment:**
  - The member has a diagnosis of ovarian, fallopian tube, or peritoneal cancer; **AND**
  - The member has been treated with one or more lines of therapy for their indication; **AND**
  - The requested medication will be used as single agent therapy.
- **For prostate cancer:**
  - The member has a diagnosis of metastatic castration-resistant prostate cancer (mCRPC); **AND**
  - The member has documentation of BRCA1 or BRCA2 mutated disease; **AND**
  - The member has been treated previously with both an androgen receptor-directed therapy and taxane-based chemotherapy; **AND**
  - The member is either receiving a gonadotropin-releasing hormone (GnRH) analog concurrently OR has had a bilateral orchiectomy.
- **For uterine neoplasms:**
  - The member must have a diagnosis of a BRCA altered uterine leiomyosarcoma (uLMS); **AND**
  - The member will be using rucaparib after trial and failure of at least one other therapy for uLMS.

- **For Pancreatic Adenocarcinoma:**
  - The member has a diagnosis of pancreatic adenocarcinoma; **AND**
  - The member has documentation of BRCA1 or BRCA2 or PALB2 mutated disease; **AND**
  - The member meets one of the following clinical scenarios:
    - The member has an ECOG score of 0-1 with good biliary drainage and adequate nutritional intake; **OR**
    - The member has an ECOG score of 2 with no disease progression after at least 4-6 months of chemotherapy.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by HSN.

RUCONEST® (C1 ESTERASE INHIBITOR, RECOMBINANT)

Updated: May 26, 2023

Length of Authorization:	60 days
Initiative:	PAR: Ruconest (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE)

FDA-RECOMMENDED DOSE

50 U per kg (max of 4200 U) administered as IV injection over approximately 5 minutes. An additional dose may be administered if symptoms persist (max. 2 doses in 24 hours).

Body Weight	Ruconest Dose for IV Injection	Volume (mL) of Reconstituted Solution (150 U/mL) to be Administered
< 84 kg	50 U per kg	Body weight in kg divided by 3
≥ 84 kg	4200 U (2 vials)	28 mL

HOW SUPPLIED

Single-use 2100 U/25 mL glass vials containing 2100 U lyophilized powder for reconstitution

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member must have confirmatory diagnosis of HAE due to C1 inhibitor deficiency (HAE-1 or HAE-2), including confirmation of low C4 levels and low functional C1 inhibitor (C1-INH) activity; **AND**
- The member is not using therapy in combination with other approved treatments for acute HAE attacks (e.g., icatibant, ecallantide); **AND**
- The prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from acute attack therapy with icatibant, **AND**
- The prescriber attests that the member is not concurrently taking any medications that may exacerbate HAE (e.g., ACE inhibitors, estrogens), **AND**
- The member has received adequate training on self-administration from their healthcare provider; **AND**
- ONE of the following is true:
  - The member is between 13 and 18 years of age; **OR**
  - The member is older than 18 years of age and has tried and failed acute treatment with icatibant acetate (Firazyr).

For Continuation:

- The member has had a positive clinical response to therapy, as documented by the member's specialty provider; **AND**
- Confirmation that the quantity on hand for the member is not greater than four vials.

REQUIRED MEDICAL INFORMATION

For initial reviews, confirmatory diagnosis of HAE, including C1-INH and C4 levels with date drawn.

AGE RESTRICTIONS

13 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an allergist, immunologist, or hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

60 days

QUANTITY RESTRICTIONS

- Refer to formulary
- Limit to one fill per approval.

OPERATION NOTES AND OTHER INFORMATION

- Approve by GSN.
- This medication is covered on the medical benefit for in office administration. It is covered on the pharmacy benefit for those patients who have been trained on self-administration and for whom there is no other acute treatment option.

RUKOBIA® (FOSTEMSAVIR)

Updated: May 8, 2023

Length of Authorization:	5 years
Initiative:	PAR: Rukobia (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

FDA-RECOMMENDED DOSE

600 mg extended-release tablet twice daily.

HOW SUPPLIED

600 mg extended-release tablets in 60-count bottles.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQEUESTS

- The member has a documented diagnosis of HIV-1; **AND**
- The member has documented resistance, intolerability, and/or contraindication to ARV agents in at least 3 classes; **AND**
- The member must be failing the current regimen with confirmed plasma HIV-1 RNA ≥400 copies/mL.

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's prescribing provider.

REQUIRED MEDICAL INFORMATION

HIV-1 RNA plasma level.

AGE RESTRICTIONS

18 years of age or older.

PRESCRIBER RESTRICTIONS

Must be prescribed by either an infectious disease or HIV specialist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary quantity limit.

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by GSN

RYDAPT® (MIDOSTAURIN)

Updated: April 25, 2023

Length of Authorization:	5 years
Initiative:	PAR: Rydapt (IE 2462 / NCPDP 75 – GSN; IE 2641, 15110 / NCPDP 76 – HICL))

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with:

- Newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutation-positive as detected by an FDA-approved test, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation.
- Aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).

FDA-RECOMMENDED DOSE

- **AML:** 50 mg orally twice daily with food on Days 8 to 21 of each cycle of induction with cytarabine and daunorubicin and on Days 8 to 21 of each cycle of consolidation with high-dose cytarabine.
- **ASM, SM-AHN, and MCL:** 100 mg orally twice daily with food.

HOW SUPPLIED

25 mg capsules in 56-count and 112-count cartons.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **For AML:**
  - The member must have a diagnosis of AML; **AND**
  - The member must have FLT3 mutated disease.
- **For ASM, SM-AHN, or MCL:**
  - The requested product must be intended to be used as single agent therapy; **AND**
  - The member has one of the following diagnoses:
    - Aggressive systemic mastocytosis (ASM); **OR**
    - Systemic mastocytosis with associated hematologic neoplasm (SM-AHN) with KIT816V mutation; **OR**
    - Mast cell leukemia (MCL).

For myeloid/lymphoid neoplasms with eosinophilia:

- The member must have a diagnosis of a myeloid/lymphoid neoplasm with eosinophilia; **AND**
- The member must have FGFR1 or FLT3 rearrangements.

For Continuation coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Documentation of mutation status

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist.

REVIEWER REQUIREMENTS

Must be reviewed by a pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

- **For AML:** Refer to formulary.
  - Internal note: enter PA with a metric quantity and days' supply of 112 capsules per 28 days' supply
- For ASM, SM-AHN, MCL, or myeloid/lymphoid neoplasm with eosinophilia:
  - Internal note: enter PA with a metric quantity and days' supply of 224 capsules per 28 days' supply

OPERATIONAL AND OTHER INFORMATION

Approve by GSN

SCEMBLIX® (ASCIMINIB)

Updated: April 11, 2023

Length of Authorization:	5 years
Initiative:	Par: Scemblix (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs).
- For the treatment of Ph+ CML in CP with the T315I mutation.

FDA-RECOMMENDED DOSE

- Ph+ CML in CP: 80 mg orally once daily or 40 mg twice daily.
- Ph+ CML in CP with the T315I mutation: 200 mg orally twice daily.

HOW SUPPLIED

20 mg and 40 mg tablets in 60-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of CML in chronic phase; **AND**
- The member meets one of the following clinical scenarios:
  - The member has been previously treated with at least two prior TKIs for CML; **OR**
  - The member has documentation of T315I mutation

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

- Initial Review:
  - T315I mutation if applicable.
  - Claims or medical records demonstrating use of previous therapies if applicable.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by a hematologist or oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

For T315I mutation positive requests: a quantity override may be entered to permit GSN 082784 to process at an MDD of 10.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

SIGNIFOR® (PASIREOTIDE)

Updated: November 20, 2023

Length of Authorization:	5 years
Initiative:	PAR: Signifor (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

FDA-RECOMMENDED DOSE

The recommended initial dose is either 0.6 mg or 0.9 mg subcutaneously twice a day. The recommended dosage range is 0.3 mg to 0.9 mg twice a day. Titrate dose based on response and tolerability.

HOW SUPPLIED

0.3 mg/1 mL, 0.6 mg/1 mL, and 0.9 mg/1 mL ampules (boxes of 60 ampules).

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member must have a diagnosis of Cushing's disease; AND
- The member must either not have had success with pituitary surgery, or is not a candidate for surgery; AND
- The member must have tried one of the following without adequate control of cortisol levels:
  - Ketoconazole
  - Cabergoline
  - Metyrapone

FOR CONTINUATION COVERAGE REQUESTS

The member has had a positive clinical response to therapy, as documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- Medical records or chart notes supporting diagnosis.
- Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an endocrinologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHERINFORMATION

Approve by HSN.

SILIQ® (BRODALUMAB)

Updated: December 18 , 2023

Length of Authorization:	12 months
Initiative:	PAR: Siliq (IE 2462 / NCPDP 75 –HICL) PAR: Loading Dose (IE 15110, 2641, 7001 / NCPDP 76 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.

FDA-RECOMMENDED DOSE

210 mg administered by subcutaneous injection at weeks 0, 1, and 2 followed by 210 mg every 2 weeks.

HOW SUPPLIED

Carton of two 210 mg/1.5 mL single-dose prefilled syringes

UTILIZATION CRITERIA

For Initial Coverage Requests:

- Plaque Psoriasis:
  - The member has a diagnosis of moderate-to-severe plaque psoriasis; **AND**
  - The member has psoriatic lesions that involve greater than or equal to 10% of body surface area (BSA), or that affect the palms, soles, head, neck, or genital area, leading to disability/impact on quality of life; **AND**
  - The member has had a previous trial of or contraindication to at least one of the following:
    - PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B)
    - Topical corticosteroids
    - Calcipotriene
    - Acitretin
    - Methotrexate
    - Cyclosporine; AND
  - The member has had a previous trial of or contraindication to at least **three** of the following preferred agents:
    - Adalimumab
    - Cosentyx
    - Enbrel
    - Tremfya
    - Stelara; **AND**
  - The member has been counseled on the risk of suicidal ideation and behavior associated with this medication in clinical trials; **AND**
  - The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

REQUIRED MEDICAL INFORMATION

For Initial Coverage Requests:

- Current BSA coverage of lesions
- Claims or medical records demonstrating use of previous therapies

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a dermatologist or rheumatologist

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Internal note:

- Loading dose:
  - Enter second PA with a metric quantity and days' supply of 4.5 mL (#3 210 mg/1.5 mL syringes) per 21 days
  - Use initiative PAR: Loading Dose
  - Select CTI reason code: 2nd **or** for Existing PA Approved. No approval letter is sent with second PA
- Maintenance dose: refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HSN

SIMPONI® (GOLIMUMAB)

Updated: December 18, 2023

Length of Authorization:	12 months
Initiative:	PAR: Simponi (IE 2462 / NCPDP 75 – GSN) PAR: Loading Dose (IE 15110, 2641, 7001 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

- In combination with methotrexate, for the treatment of adult patients with moderately to severely active rheumatoid arthritis.
- For the treatment of adult patients with active psoriatic arthritis.
- For the treatment of adult patients with active ankylosing spondylitis.
- For adult patients with moderately to severely active ulcerative colitis who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for:
  - Inducing and maintaining clinical response
  - Improving endoscopic appearance of the mucosa during induction
  - Inducing clinical remission
  - Achieving and sustaining clinical remission in induction responders

FDA-RECOMMENDED DOSE

Table 1: approved golimumab regimens per indication.

Indication	Induction	Maintenance
RA, PsA, and AS	N/A	50 mg Q4W
UC	200 mg subcutaneous injection at Week 0, followed by 100 mg at Week 2	100 mg Q4W (starts at week 6)

HOW SUPPLIED

- 50 mg/0.5 mL single-dose prefilled syringe or prefilled SmartJect® autoinjector.
- 100 mg/mL single-dose prefilled syringe or prefilled SmartJect® autoinjector.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

For all Conditions:

- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

For Rheumatoid Arthritis:

- The member has a diagnosis of moderate to severe Rheumatoid Arthritis; **AND**
- The member will be using methotrexate in combination with golimumab; **AND**
- The member has tried and failed, or is contraindicated to, at least **one** of the following:
  - Methotrexate monotherapy
  - Hydroxychloroquine
  - Sulfasalazine
  - Leflunomide; **AND**
- The member has had a previous trial of or contraindication to at least **two** of the following preferred agents:
  - Adalimumab
  - Enbrel
  - Xeljanz

For PsA:

- The member has a diagnosis of active psoriatic arthritis; **AND**
- The member has had a previous trial of or contraindication to at least **one** of the following:
  - Methotrexate
  - Sulfasalazine
  - Cyclosporine
  - Leflunomide; **AND**
- The member has had a previous trial of or contraindication to at least **two** of the following preferred agents:
  - Adalimumab
  - Cosentyx
  - Enbrel
  - Tremfya
  - Stelara
  - Xeljanz

For Ankylosing Spondylitis:

- The member has a diagnosis of Ankylosing Spondylitis; **AND**
- The member has had a previous trial of at least **one**, or contraindication to **all**, of the following:
  - Nonsteroidal anti-inflammatory drugs (NSAIDs)
  - Methotrexate
  - Sulfasalazine; **AND**
- The member has had a previous trial of, or contraindication to, at least two of the following preferred agents without adequate response:
  - Adalimumab
  - Enbrel
  - Xeljanz
  - Cosentyx

For Ulcerative Colitis:

- The member has a diagnosis of moderate to severely active Ulcerative Colitis; **AND**
- The member has had a previous trial of or contraindication to at least one of the following:
  - Thiopurines (i.e., 6-mercaptopurine or azathioprine)
  - Corticosteroids**; OR**
  - The member has tried and failed one or more previous biologic therapies (e.g., infliximab, certolizumab, vedolizumab, golimumab, ustekinumab, or natalizumab); **AND**
- The member has had a previous trial of or contraindication to at least **two** of the following preferred agents:
  - Adalimumab
  - Stelara
  - Xeljanz

FOR CONTINUATION COVERAGE REQUESTS

- The member continues to have a beneficial response to therapy, as assessed by the member's provider; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

- For UC, must be prescribed by Gastroenterologist.
- For RA and AS, must be prescribed by a Rheumatologist.
- For PsA must be prescribed by either a Rheumatologist or a Dermatologist.

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

- **For UC**—loading dose:
  - Enter second PA with a metric quantity and days' supply of #3 (three 100 mg syringes/autoinjectors) per 28 days per 1 month.
  - Use initiative PAR: Loading Dose.
  - Select CTI reason code: 2nd **or** for Existing PA Approved. No approval letter is sent with second PA.
  - Continuation approvals should defer to formulary quantity limit.

All other indications:

- Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

- Approvals should be entered by GSN.
- UC indication is only approvable for the 100 mg formulations.
- RA/AS/PsA indications are only approvable for the 50 mg formulations.

SIROLIMUS TOPICAL GEL 0.2% (HYFTOR®)

Updated: September 7, 2023

Length of Authorization:	Initial: 3 months. Continuation: 1 year.
Initiative:	PAR: Hyftor (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older.

FDA-RECOMMENDED DOSE

- Apply to the skin of the face affected with angiofibroma twice daily.
- The maximum daily dosage is:
  - 6–11 years of age: 600 mg (2 cm)
  - 12 years of age and older: 800 mg (2.5 cm)

HOW SUPPLIED

Topical gel, 0.2% (2 mg of sirolimus per 1 g) in 10 g tubes

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of facial angiofibroma associated with tuberous sclerosis; **AND**
- The member is not a candidate for procedural removal of the facial angiofibroma.

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

6 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a dermatologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 3 months.
- Continuation: 1 year.

QUANTITY RESTRICTIONS

- If the member is 6–11 years of age, refer to the formulary.
- If the member is 12 years of age or older, authorize QPD of 1 gram per day.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

SIVEXTRO® (TEDIZOLID)

Updated: May 30, 2023

Length of Authorization:	60 days
Initiative:	PAR: Sivextro (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), and Enterococcus faecalis in adults and pediatric patients 12 years and older.

FDA-RECOMMENDED DOSE

200 mg orally once daily for six (6) days

HOW SUPPLIED

30-count bottles and 6-count blister packs

UTILIZATION CRITERIA

For all coverage requests:

- The member has a diagnosis of acute bacterial skin and skin structure infections (ABSSSI) caused by isolates susceptible to tedizolid.

REQUIRED MEDICAL INFORMATION

Confirmation of isolate susceptibility

AGE RESTRICTIONS

12 years of age and older

PRESCRIBER RESTRICTIONS

Prescribed by or in consultation with an infectious disease specialist

COVERAGE DURATION

60 days

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

SKYRIZI® (RISANKIZUMAB-RZAA)

Updated: December 18, 2023

Length of Authorization:	12 months
Initiative:	PAR: Skyrizi (IE 2462/NCPDP 75 – GSN) PAR: Loading Dose (IE 15110, 2641, 7001 / NCPDP 76 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of moderate-to-severe plaque psoriasis (PsO) in adults who are candidates for systemic therapy or phototherapy.
- For the treatment of active psoriatic arthritis in adults.
- For the treatment of moderately to severely active Crohn's disease in adults.

FDA-RECOMMENDED STARTING DOSE

- PsO and PsA: 150 mg (two 75 mg injections) administered by subcutaneous injection at week 0, week 4, and every 12 weeks thereafter
- Crohn's: 600 mg administered by intravenous infusion over a period of at least one hour at week 0, week 4, and week 8, followed by 180 mg or 360 mg administered by subcutaneous injection at week 12, and every 8 weeks thereafter.

HOW SUPPLIED

- 75 mg/0.83 mL prefilled syringe (available as one carton of two syringes)
- 150 mg/mL single dose pen or prefilled syringe (carton of one).
- 180 mg/1.2mL (150 mg/mL) single dose prefilled cartridge with on-body injector
- 360 mg/2.4 mL (150 mg/mL) single dose prefilled cartridge with on-body injector
- 600 mg/10 mL (60 mg/mL) single dose vial for IV infusion (not covered on pharmacy benefit)

COVERAGE CRITERIA

For Initial Coverage Requests:

- **For all indications:**
  - The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib),
- **Plaque Psoriasis:**
  - The member's diagnosis is moderate to severe PsO; **AND**
  - The member has psoriatic lesions that involve greater than or equal to 10% of body surface area (BSA) or affect the palms, soles, head, neck, or genital area, leading to disability or impact on quality of life; **AND**
  - The member has had a previous trial of, or contraindication to, at least **one** of the following:
    - Methotrexate
    - Cyclosporine
    - Acitretin
    - Calcipotriene
    - Topical corticosteroids
    - PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B); **AND**
  - The member has had a previous trial of, or contraindication to, at least two of the following without adequate response:
    - Adalimumab
    - Cosentyx
    - Enbrel
    - Tremfya
    - Stelara
- **Psoriatic Arthritis:**
  - The member has a diagnosis of active psoriatic arthritis; **AND**
  - The member has had a previous trial of or contraindication to at least **one** of the following:
    - Methotrexate
    - Sulfasalazine
    - Cyclosporine
    - Leflunomide; **AND**
  - The member has had a previous trial of, or contraindication to, at least two of the following without adequate response:
    - Adalimumab
    - Cosentyx
    - Enbrel
    - Tremfya
    - Stelara
    - Xeljanz

- **Crohn's Disease (CD):**
  - The member has a diagnosis of moderate to severely active CD; **AND**
  - The member has had a previous trial of or contraindication to at least one of the following:
    - Thiopurines (e.g., 6-mercaptopurine or azathioprine)
    - Corticosteroids
    - Methotrexate; **OR**
    - The member has tried and failed one or more previous biologic therapies (e.g., risankizumab, infliximab, certolizumab, vedolizumab, golimumab, ustekinumab, or natalizumab); **AND**
  - The member has had a previous trial of, or contraindication to, both of the following preferred agents:
    - Adalimumab
    - Stelara

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib).

REQUIRED MEDICAL INFORMATION

For Initial Coverage Requests:

- For members treated for PsO: current BSA coverage of lesions.
- Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age or older.

PRESCRIBER RESTRICTIONS

- PsO/PsA: must be prescribed by or in consultation with a rheumatologist or dermatologist.
- Crohn's: must be prescribed by or in consultation with a gastroenterologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

- PsO/PsA:
  - When approving the loading dose, allow for 150 mg per 28 days for the first two months of treatment, followed by 150 mg every 12 weeks.
  - For the maintenance dose, refer to formulary.
- Crohn's: Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve by GSN
- Internal Note:
  - Loading dose for PsO/PsA
  - Approve loading dose for 1 month with a metric quantity and days' supply of #1/28 DS. (intent = 150 mg [two 75 mg injections] at week 0, week 4, and every 12 weeks thereafter).
  - Use initiative PAR: Loading Dose
  - Select CTI reason code: 2nd **or** for Existing PA Approved. No approval letter is sent with second PA.

SODIUM-GLUCOSE TRANSPORT PROTEIN 2 (SGLT2) INHIBITORS

Updated: November 22, 2023

Length of Authorization:	5 years
Initiative:	STP: DPP4/SGLT2 Inhibitors (IE 31121 / NCPDP 608 – HICL)

POLICY AND PRODUCT INFORMATION

- In general, SGLT2 inhibitors indicated for the management of type II diabetes mellitus (T2DM) in adults are covered for adults with T2DM who have tried and failed metformin monotherapy. Non-preferred products may also require trial and failure of preferred SGLT2 inhibitors. Products with an indication for heart failure (HF), chronic kidney disease (CKD), or cardiovascular (CV) risk reduction require confirmation of disease.
- **This policy applies to the following products:**
  - Non-preferred (Tier 3):
    - Canagliflozin (Invokana)
    - Canagliflozin/Metformin (Invokamet, Invokamet XR)
    - Ertugliflozin (Steglatro)
    - Ertugliflozin/Metformin (Segluromet)
    - Ertugliflozin/Sitagliptin (Steglujan)
    - Dapagliflozin/Saxagliptin Hcl (Qtern)
    - Sotagliflozin (Inpefa)
  - Preferred (Tier 2):
    - Dapagliflozin (Farxiga)
    - Dapagliflozin/Metformin (Xigduo XR)
    - Empagliflozin (Jardiance)
    - Empagliflozin/Linagliptin (Glyxambi)
    - Empagliflozin/Linagliptin/Metformin (Trijardy XR)
    - Empagliflozin/Metformin (Synjardy, Synjardy XR)

FDA-APPROVED INDICATION(S)

Various – refer to package inserts.

FDA-RECOMMENDED DOSE

Various – refer to package inserts.

HOW SUPPLIED

Various – refer to package inserts.

UTILIZATION CRITERIA

For all coverage requests:

- For the treatment of TD2M
  - The member has a diagnosis of TD2M; **AND**
  - The requested product is NOT sotagliflozin (Inpefa); AND
  - If the requested product contains one of canagliflozin (Invokana, Invokamet), ertugliflozin (Steglatro, Segluromet, Steglujan), or combination dapagliflozin/saxagliptin (Qtern), the member has tried and failed the following:
    - Farxiga or Xigduo; **AND**
    - Glyxambi, Trijardy, Jardiance, or Synjardy.
- For the treatment of heart failure with or without diabetes
  - The requested product is one of the following: empagliflozin (Jardiance), dapagliflozin (Farxiga), or sotagliflozin (Inpefa); **AND**
  - The member has a diagnosis of heart failure.
- For the treatment of CKD:
  - The requested product is one of dapagliflozin (Farxiga); **AND**
  - The member has a diagnosis of CKD.
- For the treatment of CV risk reduction in adults with T2DM, CKD, and other CV risk factors:
  - The requested product is sotagliflozin (Inpefa); **AND**
  - Sotagliflozin (Inpefa) is being used for risk reduction of cardiovascular mortality, hospitalization for heart failure, and urgent heart failure visits; **AND**
  - The member has a diagnosis of type 2 diabetes, chronic kidney disease, or other cardiovascular risk factors.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

Refer to formulary.

PRESCRIBER RESTRICTIONS

N/A

COVERAGE DURATION

Five years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HSN.

SOMATULINE® DEPOT (LANREOTIDE ACETATE)

Updated: June 13, 2022

Length of Authorization:	12 months
Initiative:	PAR: Somatuline Depot (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the long-term treatment of acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option.
- For the treatment of adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.
- For the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

FDA-RECOMMENDED DOSE

90 mg given via the deep subcutaneous route, at 4-week intervals for 3 months.

HOW SUPPLIED

60 mg/0.2 mL, 90 mg/0.3 mL, and 120 mg/0.5 mL sterile, single-dose, prefilled syringe

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member must have a diagnosis of acromegaly, **AND**
  - The member has tried surgery, radiation therapy, or medical treatment and had an inadequate response or other treatment have been considered and deemed inappropriate or contraindicated, **AND**
  - The member's growth hormone and/or serum insulin-like growth factor 1 (IGF-1) levels will be monitored after 3 months of initial therapy and monitored periodically thereafter. **OR**
- The member has a diagnosis of either GEP-NET or carcinoid syndrome, **OR**
- The member has a diagnosis of a somatostatin receptor positive tumor or other hormone-secreting tumor fulfilling NCCN 2A or higher guidelines.

FOR CONTINUATION COVERAGE REQUESTS

The member has had a positive clinical response to therapy, as documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an endocrinologist or oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HSN.

SOMAVERT® (PEGVISOMANT)

Updated: October 23,, 2023

Length of Authorization:	12 months
Initiative:	PAR: Somavert (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of acromegaly in patients who have had an inadequate response to surgery or radiation therapy, or for whom these therapies are not appropriate. The goal of treatment is to normalize serum insulin-like growth factor-I (IGF-I) levels.

FDA-RECOMMENDED DOSE

- On day after physician loading dose, patients begin 10 mg subcutaneous injections daily.
- Doses are titrated in 5 mg increments until serum IGF-1 concentrations are within normal range. The recommended dosage range is between 10 mg to 30 mg given subcutaneously once daily and the maximum daily dosage is 30 mg once daily.

HOW SUPPLIED

- One day package: 10, 15, 20, 25, 30 mg single-dose vials with one sterile water prefilled syringe and needle per carton.
- 30-day package: Outer carton with 30 sterile water prefilled syringes, 30 needles, and three intermediate cartons each containing ten single-dose vials of 10, 15, 20, 25, or 30 mg.

COVERAGE CRITERIA

For Initial Coverage Requests

- The member must have a diagnosis of acromegaly; **AND**
  - The member has tried surgery, radiation therapy, or medical treatment and had an inadequate response or other treatment have been considered and deemed inappropriate or contraindicated; **AND**
  - The member's monitoring plan will include both serum insulin-like growth factor 1 (IGF-1) levels at 6-month intervals after normalized, and liver function testing as recommended by the manufacturer; **AND**
  - The member's serum insulin-like growth factor 1 (IGF-1) levels are above the age and gender adjusted normal range.

For Continuation Coverage Requests

- The member has had a positive clinical response to therapy, as documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- Medical records or chart notes confirming diagnosis.
- Claims or medical records demonstrating use of previous therapies.
- Documentation of IGF-1 levels at 6-month intervals for initial requests.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an endocrinologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by HSN

SOTYKTU™ (DEUCRAVACITINIB)

Updated: December 18, 2023

Length of Authorization:	12 months
Initiative:	PAR: Sotyktu (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

FDA-RECOMMENDED DOSE

6 mg orally once daily.

HOW SUPPLIED

6 mg tablets in 30-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member must have a diagnosis of active moderate-to-severe plaque psoriasis; **AND**
- The member has psoriatic lesions that involve greater than or equal to 10% of body surface area (BSA), or that affect the palms, soles, head, neck, or genital area, leading to disability/impact on quality of life; **AND**
- The member must have documented failure, intolerance, or contraindication to at least one of the following:
  - PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B)
  - Topical corticosteroids
  - Calcipotriene
  - Acitretin
  - Methotrexate
  - Cyclosporine; **AND**
- The member has had a previous trial of, or contraindication to, at least two of the following preferred agents:
  - Adalimumab
  - Cosentyx
  - Enbrel
  - Tremfya
  - Stelara; **AND**
- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, pr potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

REQUIRED MEDICAL INFORMATION

- Claims or medical records demonstrating use of previous therapies.
- For members treated for PsO, current BSA coverage of lesions.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a dermatologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

SOVALDI® (SOFOSBUVIR)

Updated: October 26, 2023

Length of Authorization:	• 16 weeks: Adults with previous glecaprevir/pibrentasvir failure or sofosbuvir/velpatasvir/voxilaprevir failure • 12 weeks: Children 3 to 5 years of age with genotype 2, adults with genotypes 2 or 4 • 24 weeks: Children 3 to 5 years of age with genotype 3, adults with genotypes 1 or 3
Initiative:	PAR: Sovaldi (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- Treatment of adult patients with genotype 1, 2, 3, or 4 chronic HCV infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral regimen.
- Treatment of pediatric patients 3 years of age or older with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis in combination with ribavirin.

FDA-RECOMMENDED DOSE

- Dosing for an adult patient: one 400 mg tablet by mouth once daily.
- Dosing of pediatric patients 3 years of age and older is based on weight. Refer to table below.

Body Weight (kg)	Sovaldi Daily Dose
≥ 35	400 mg per day
17 to < 35	200 mg per day
< 17	150 mg per day

- Duration of treatment varies based on clinical factors; please see package insert for details.

HOW SUPPLIED

- 400 mg and 200 mg oral tablets in 28-count bottles.
- 150 mg and 200 mg oral pellets contained in unit-dose packets in 28-count cartons.

UTILIZATION CRITERIA

FOR INITIAL REVIEW

- The member has a documented diagnosis of chronic HCV; **AND**
- The member's treatment plan includes concomitant therapy with ribavirin; **AND**
  - The member meets one of the following clinical scenarios:
    - The member has tried and failed either glecaprevir or pibrentasvir, and/or sofosbuvir, velpatasvir, or voxilaprevir; **OR**
    - The member is a child aged 3 through 5 with genotype 2 or 3 HCV infection.

REQUIRED MEDICAL INFORMATION

For members aged 3 through 5: Genotype status

AGE RESTRICTIONS

3 years of age or older

PRESCRIBER RESTRICTIONS

Must be prescribed by a hepatologist or infectious disease specialist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

- 16 weeks: Adults with previous glecaprevir/pibrentasvir failure or sofosbuvir/velpatasvir/voxilaprevir failure
- 12 weeks: Children 3 to 5 years old with genotype 2, adults with genotypes 2 or 4
- 24 weeks: Children 3 to 5 years old with genotype 3, adults with genotype 1 or 3

QUANTITY RESTRICTIONS

Refer to formulary quantity limit

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

- All approvals should be entered by GSN
- Per AASLD/IDSA guidelines sofosbuvir is recommended in the following:
  - In patient with previous glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir treatment failure, sofosbuvir (in combination with ribavirin and glecaprevir/pibrentasvir) is recommended for adult patients of all genotypes with compensated cirrhosis or without cirrhosis.
  - Children 3 through 5 years of age with genotype 2 or 3 who are treatment-I or treatment-experienced without cirrhosis or with compensated cirrhosis, sofosbuvir in combination with ribavirin is the only FDA-approved DAA.

SPARSENTAN (FILSPARI)

Updated: April 24, 2023

Length of Authorization:	12 months
Initiative:	PAR: Filspari: 2462 (IE 2462 / NCPDP 75 – HICL

FDA-APPROVED INDICATION(S)

To reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.

FDA-RECOMMENDED DOSE

200 mg orally once daily. After 14 days, increase to the recommended dose of 400 mg once daily, as tolerated.

HOW SUPPLIED

200 mg and 400 mg tablets in 30-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of primary IgAN; **AND**
- The diagnosis has been confirmed by biopsy; **AND**
- The member's urine protein-to-creatinine ratio (UPCR) is ≥1.5 g/g; **AND**
- The member's estimated glomerular filtration rate (eGFR) is ≥ 30 mL/min/1.73 m^2; **AND**
- The member has tried and failed a maximally tolerated stable dose of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB)

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider and demonstrated by a reduction in UPCR; **AND**
- The member's estimated glomerular filtration rate (eGFR) is ≥ 30 mL/min/1.73 m^2

REQUIRED MEDICAL INFORMATION

For Initial Coverage Requests:

- Chart notes or medical records supporting diagnosis, biopsy results, UPCR, eGFR.
- Claims or medical records demonstrating use of previous therapies.

For Continuation Coverage Requests:

- Chart notes or medical records demonstrating UPCR and eGFR.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a nephrologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by HSN.

SPRAVATO® (ESKETAMINE)

Updated: November 17, 2023

Length of Authorization:	TRD: 12 months MDD with acute suicidal ideation or behavior: 1 month (4 weeks)
Initiative:	PAR: Spravato (IE 2462 / NCPDP 75 – HICL) PAR: Loading Dose (IE 15110, 2641, 7001 / NCPDP 76 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of treatment-resistant depression (TRD) in adults, in conjunction with an oral antidepressant (AD).
- For the treatment of depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior, in conjunction with an oral antidepressant (AD).

FDA-RECOMMENDED DOSE

- For TRD:
  - Induction phase (weeks 1 to 4): 56 mg or 84 mg twice per week
  - Maintenance phase (week 5 and thereafter): Up to 56 mg or 84 mg once weekly
- For depressive symptoms in adults with MDD with acute suicidal ideation or behavior: 84 mg twice per week for four weeks.

HOW SUPPLIED

Nasal spray devices that deliver a total of 28 mg esketamine per device

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- For TRD
  - The member has a diagnosis of depression and is under the care and supervision of a psychiatrist; **AND**
  - The member has tried and failed two separate trials of antidepressant monotherapy with adjunctive second-generation antipsychotic and/or lithium.
- For MDD with acute suicidal ideation or behavior:
  - The member has a diagnosis of MDD and is under the care and supervision of a psychiatrist; **AND**
  - The member has acute suicidal ideation or behavior.

FOR CONTINUATION COVERAGE REQUESTS

The member continues to benefit from treatment, as attested to by the member's treating psychiatrist.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age or older

PRESCRIBER RESTRICTIONS

Must be prescribed by a psychiatrist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- TRD: 12 months
- MDD with acute suicidal ideation or behavior: 1 month (4 weeks)

QUANTITY RESTRICTIONS

- For TRD, enter two authorizations if approved:
  - Loading dose: Allow for 84 mg twice weekly for the first four weeks.
  - Maintenance dose: Refer to formulary Quantity Limits.
- For MDD with suicidality: Allow for a maximum of 84 mg twice weekly for four weeks.
- Internal note:
  - Approve loading dose for 1 month with a metric quantity and days' supply of #16/28 DS for 56 mg twice weekly **AND** #24/28 DS for 84 mg twice weekly. (Approve loading dose for each strength, regardless of what has been requested, to allow for flexibility in dosing based on tolerability for the first month).
  - Use initiative PAR: Loading Dose
  - Select CTI reason code: 2nd O/R for Existing PA Approved. No approval letter is sent with the loading dose Pas.

OPERATION NOTES AND OTHER INFORMATION

Approve by HICL.

SPRITAM® (LEVETIRACETAM TABLET, FOR SUSPENSION)

Updated: November 27, 2023

Length of Authorization:	12 months
Initiative:	PAR: Spritam (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- Indicated for the treatment of partial onset seizures in patients with epilepsy 4 years of age and older weighing more than 20 kg.
- Indicated as adjunctive therapy in the treatment of myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy.
- Indicated as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy.

FDA-RECOMMENDED DOSE

- Refer to package insert for specific dosing information. In general, for patients weighing 40 kg or more: Initiate with a dose of 500 mg twice daily. The dose may be increased every 2 weeks by increments of 500 mg twice daily to a maximum recommended daily dose of 1500 mg twice daily.
- For pediatric patients 4+ years of age and weighing 20 kg to 40 kg: Initiate with 250 mg twice daily. Increase the dose every 2 weeks by increments 250 mg twice daily to a maximum recommended dose of 750 mg twice daily.

HOW SUPPLIED

250, 500, 750, 1000 mg tablets for suspension in 60-count cartons.

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member must have a diagnosis of partial onset seizures with epilepsy, myoclonic seizures with juvenile myoclonic epilepsy, or primary generalized tonic-clonic seizures with idiopathic generalized epilepsy; **AND**
- The member is not able to use a solid dosage form of levetiracetam; **AND**
- The member has a documented reason they cannot take levetiracetam oral solution (e.g., due to being on a ketogenic diet).

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

4 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist.

REVIEWER REQUIREMENTS

All coverage requests must by reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTION AND OTHER INFORMATION

Approve by HICL.

SPRYCEL® (DASATINIB)

Updated December 22, 2023

Length of Authorization:	5 years
Initiative:	PAR: Sprycel (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of the following:
  - Newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase
  - Adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib
  - Adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy
  - Pediatric patients 1 year of age and older with Ph+ CML in chronic phase; **AND**
  - Pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy.

FDA-RECOMMENDED DOSE

- Chronic phase CML in adults: 100 mg once daily
- Accelerated phase CML, myeloid or lymphoid blast phase CML, or Ph+ **all** in adults: 140 mg once daily
- Chronic phase CML and ALL in pediatrics: starting dose based on body weight

HOW SUPPLIED

20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg tablets in 30-count and 60-count bottles

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has one or more of the following diagnoses:
  - Ph+ CML
  - BCR-ABL1 positive CML
  - Melanoma, Cutaneous
  - Ph+ B-ALL
  - Ph+ T-ALL with ABL-class translocation
  - Recurrent conventional or chondroid chordoma
  - Metastatic and widespread chondrosarcoma
  - High grade (grade II or III), clear cell, or extracompartmental chondrosarcoma in systemic recurrence
  - Myeloid/lymphoid neoplasms with eosinophilia and ABL1 rearrangement
  - Gastrointestinal stromal tumors (GIST) with all of the following:
    - Unresectable, recurrent/progressive, or metastatic disease with generalized (widespread, systemic) progression;
    - PDGFRA exon 18 mutations that are insensitive to imatinib; **AND**
    - Prior treatment with imatinib or avapritinib

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Medical records confirming above genetic requirements

AGE RESTRICTIONS

1 year of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an oncologist or hematologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approve by HSN

STELARA® (USTEKINUMAB)

Updated: December 18, 2023

Length of Authorization:	Initial (4months); Continuation (12 months)
Initiative:	PAR: Stelara: Other (IE 2462 / NCPDP 75 – GSN) PAR Stelara: UC and CD (IE 2462 / NCPDP 75 – GSN; IE 7001, 15110 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of patients 6 years of age or older with moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy.
- For the treatment of patients 6 years of age or older with active psoriatic arthritis
- For the treatment of adult patients with moderately to severely active Crohn's disease.
- For the treatment of adult patients with moderately to severely active ulcerative colitis.

FDA-RECOMMENDED DOSE

- PsO (adult):
  - 100 kg or less: 45 mg subcutaneous initially and 4 weeks later, followed by 45 mg every 12 weeks.
  - 100 kg or more: 90 mg subcutaneous initially and 4 weeks later, followed by 90 mg every 12 weeks.
- PsA/PsO (pediatric):
  - 60 kg or less: 0.75 mg/kg subcutaneous at weeks 0, 4 and every 12 weeks thereafter.
  - 60 to 100 kg: 45 mg at weeks 0, 4 and every 12 weeks thereafter.
  - 100 kg or more: 90 mg at weeks 0, 4 and every 12 weeks thereafter.
- PsA:
  - 45 mg subcutaneous initially and 4 weeks later, followed by 45 mg every 12 weeks.
  - Co-existing plaque psoriasis weighing more than 100 kg: 90 mg subcutaneous initially and 4 weeks later, followed by 90 mg every 12 weeks.
- CD/UC:
  - One IV loading dose (refer to package insert for dosing regimen), followed by 90 mg subcutaneous every 8 weeks thereafter.

HOW SUPPLIED

- Prefilled syringes: 45 mg/0.5 mL and 90 mg/1 mL
- Single-dose vial (subcutaneous): 45 mg/0.5 mL
- Single-dose vial (IV): 130 mg/26 mL (5 mg/mL)

COVERAGE CRITERIA

FOR INITIAL REVIEW

For all indications:

- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib).

For PsO:

- Member has ≥ 10% BSA involvement of plaque psoriasis or has plaques affecting palms, soles, head, neck, or genitalia, leading to a disability/impact on quality of life; **AND**
- The member has had a previous trial of or contraindication to one or more of the following:
  - Acitretin
  - Calcipotriene
  - Cyclosporine
  - Methotrexate
  - PUVA (Phototherapy Ultraviolet Light A)/UVB (Ultraviolet Light B)
  - Topical corticosteroids

For PsA:

- The member has a diagnosis of active psoriatic arthritis; **AND**
- The member has had a previous trial of or contraindication to at least one or more of the following:
  - Methotrexate
  - Cyclosporine
  - Leflunomide
  - Sulfasalazine.

For CD:

- The member has a diagnosis of moderate to severely active Crohn's disease; **AND**
- The member has had a previous trial of or contraindication to at least one of the following therapy options/categories without adequate response:
  - Thiopurines (e.g., 6-mercaptopurine or azathioprine)
  - Corticosteroids
  - Methotrexate; **OR**
  - The member has tried and failed one or more previous biologic therapies (e.g., adalimumab, risankizumab, infliximab, certolizumab, vedolizumab, golimumab, or natalizumab)

For UC:

- The member has a diagnosis of moderate to severely active ulcerative colitis; **AND**
- The member has had a previous trial of**, or contraindication to,** at least **one** of the following:
  - Thiopurine (i.e., 6-mercaptopurine or azathioprine)
  - Corticosteroids; **OR**
  - The member has tried and failed one or more previous biologic therapies (e.g. infliximab, certolizumab, vedolizumab, golimumab, ustekinumab, or natalizumab).

FOR CONTINUATION

For all indications:

- The member has had a positive clinical response to therapy, as documented by the member's specialist provider; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib).

If dose escalation is requested:

- Dose escalation exceeding the FDA-approved dosing regimens requires six months of continuous, on-label dosing and documentation of therapeutic failure to the FDA-approved regimens; **AND**
- Provider attestation that alternative therapies, including the concurrent use of non-biologic therapies, have been considered prior to dose escalation.

REQUIRED MEDICAL INFORMATION

- Current member weight for PsO, PsA with concurrent PsO (not required if diagnosis is PsA only).
- For members treated for PsO, current BSA coverage of lesions
- Claims or medical records demonstrating use of previous therapies

AGE RESTRICTIONS

- CD, and UC: 18 years of age and older
- PsA/PsO: 6 years of age and older

PRESCRIBER RESTRICTIONS

- CD and UC: must be prescribed by or in consultation with Gastroenterologist.
- PsA, PsO, or PsO with PsA: must be prescribed by or in consultation with a rheumatologist or a dermatologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

QUANTITY RESTRICTIONS

- PsA (NOTE: if co-existing PsO, follow PsO rules):
  - Initial: Approve for a total of 4 months.
    - Approve loading dose for 1 month with a metric quantity and days' supply of #0.5/28 DS. (Intent = one 45 mg/0.5 mL prefilled syringe or one 45 mg/0.5 mL vial per 28 days).
    - Use initiative PAR: Loading Dose
    - Select CTI reason code: 2nd O/R for Existing PA Approved. No approval letter is sent with second PA.
  - Continuation: Approve for 12 months
- PsO:
  - Initial: Approve for a total of 4 months.
    - Weight ≤ 100 kg:
      - Approve loading dose for 1 month with a metric quantity and days' supply of #0.5/28 DS. (Intent = one 45 mg/0.5 mL prefilled syringe or one 45 mg/0.5 mL vial in 28 days).
    - Weight > 100 kg:
      - Approve loading dose for 1 month with a metric quantity and days' supply of #1/28 DS. (Intent = one 90 mg/mL prefilled syringe in 28 days);
    - For Loading Dose:
      - Use initiative PAR: Loading Dose
      - Select CTI reason code: 2nd O/R for Existing PA Approved. No approval letter is sent with second PA.
  - Continuation: Approve for 12 months
- UC/CD:
  - Initial: Approve one authorization for a total of 4 months.
    - Enter PA with a metric quantity and days' supply of #1/56 DS. Intent = one 90 mg/mL per 56 days (with a start date after the end date of the previous IV loading dose).
  - Continuation: Approve for 12 months.
    - Enter PA with a metric quantity and days' supply of #1/56 DS.

OPERATIONAL NOTES AND OTHER INFORMATION

- **Internal note**: When approving, use canned fax back "Approval: Stelara QUANTITY LIMIT," and enter in the quantity and days' supply approved (e.g., 1 per 56 days, etc.).
- Approve by GSN

STIMULANTS

Updated: December 21, 2023

Length of Authorization:	5 years
Initiative:	PAR: Stimulants (IE 2462 / NCPDP 75; IE 2194 / NCPDP 60 – HICL)

POLICY AND PRODUCT INFORMATION

- This policy applies to formulary stimulant products, including the following:
  - Amphetamine isomers, salts, and prodrugs.
  - Methylphenidate isomers, salts, and prodrugs.
- Coverage of most formulary stimulant products in traditional dosage forms (e.g., tablets, capsules) requires prior authorization if the member is 26 years of age or older.
- Coverage for serdexmethylphenidate-dexmethylphenidate (Azstarys) and methylphenidate PM (Jornay PM) require prior authorization for all members regardless of age.
- Coverage of formulary stimulant products in alternative dosage forms (e.g., solutions, suspensions, patches) requires prior authorization for members over the age of 10 years.

UTILIZATION CRITERIA

For serdexmethylphenidate-dexmethylphenidate (Azstarys) and methylphenidate PM (Jornay PM) capsules:

- The member has a diagnosis of ADD/ADHD; **AND**
  - The member's symptoms are causing clinically significant impairment in social, academic, or occupational functioning; **AND**
  - The member has tried and failed at least one generic long-acting amphetamine product and at least one generic long-acting methylphenidate product.

For the treatment of ADD/ADHD:

- The member has a diagnosis of ADD/ADHD; **AND**
- The member's symptoms are causing clinically significant impairment in social, academic, or occupational functioning.

For the treatment of narcolepsy:

- The member has a diagnosis of narcolepsy or idiopathic hypersomnia, confirmed by polysomnography and multiple sleep latency testing (MSLT); **AND**
- The member has been evaluated for other causes of excessive daytime sleepiness (e.g., insufficient sleep syndrome, upper airway resistance syndrome, depression).

For the management of fatigue associated with Multiple Sclerosis:

- The member has a diagnosis of multiple sclerosis (MS); **AND**
- The member experiences fatigue secondary to their MS diagnosis.

For the management of cancer-related fatigue:

- The request is for a methylphenidate product **AND**
- The member is experiencing fatigue associated with cancer therapy (active treatment, post-treatment, or end of life).

For the management of binge eating disorder (BED):

- The member has a diagnosis of BED; **AND**
- The member's treatment plan includes combination of lisdexamfetamine with behavioral therapy such as cognitive behavioral therapy, or interpersonal psychotherapy; **AND**
- The member has tried and failed, could not tolerate, or is contraindicated to, two of the following medications for BED:
  - Sertraline
  - Citalopram
  - Fluoxetine
  - Topiramate

For alternative formulations (e.g., solutions, suspensions, patches), in addition to applicable requirements above:

- The member has a documented difficulty in swallowing or dysphagia, or requires tube feeding; **AND**
- Modifications to the conventional dosage form (e.g., crushing, chewing, dissolving) are not possible or feasible, per the member's provider.

For use of the dextroamphetamine patch (Xelstrym), in addition to applicable requirements above:

- The member has a documented difficulty in swallowing or dysphagia, or requires tube feeding; **AND**
- Modifications to the conventional dosage form (e.g., crushing, chewing, dissolving) are not possible or feasible, per the member's provider; **AND**
- The member has tried and failed or has a contraindication to the methylphenidate patch.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

N/A

COVERAGE DURATION

5 years

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary quantity limits.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

- **Internal note**: Requests for liquid formulations, chewable tablets, patches, etc., with an age limit (AL) of "Up to 10 years old" indicated in the drug lookup tool must also meet "For alternative formulations" criteria above
- Approve by HSN

STIVARGA® (REGORAFENIB)

Updated: May 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Stivarga (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- Treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild- type, an anti-EGFR therapy.
- Treatment of patients with locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate.
- Treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

FDA-RECOMMENDED DOSE

160 mg (four 40 mg tablets) once daily for the first 21 days of each 28-day cycle.

HOW SUPPLIED

40 mg tablets

UTILIZATION CRITERIA

For initial coverage requests:

- **For Osteosarcoma:**
  - The member has a diagnosis of osteosarcoma; **AND**
  - The member has tried an NCCN first line therapy for osteosarcoma.
- **For Rectal/Colon Cancer:**
  - The member has a diagnosis of advanced or metastatic colon or rectal cancer; **AND**
  - The member has progressed through all available treatment regimens besides regorafenib, trifluridine, or tipiracil.
- **For Glioblastoma:**
  - The member has a diagnosis of recurrent glioblastoma.
- **For Gastrointestinal Stromal Tumors (GIST):**
  - The member has a diagnosis of unresectable, recurrent, or metastatic GIST; **AND**
  - The member has experienced progression after imatinib **and** either sunitinib **or** dasatinib.
- **For Hepatocellular Carcinoma (HCC):**
  - The member has a diagnosis of progressive HCC; **AND**
  - The member meets one of the following clinical scenarios:
    - The member is not a transplant candidate; **OR**
    - The member is considered inoperable by performance status or comorbidity, or have local disease or local disease with minimal extrahepatic disease only; **OR**
    - The member has metastatic disease or extensive liver tumor burden.

- **For Soft Tissue Sarcomas:**
  - The member has a diagnosis of advanced or metastatic pleomorphic rhabdomyosarcoma; **OR**
  - The member has a diagnosis of a solitary fibrous tumor; **OR**
  - The member has a diagnosis of non-adipocytic sarcoma; **OR**
  - The member has a diagnosis of angiosarcoma.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

STRENSIQ® (ASFOTASE ALFA)

Updated: May 8, 2023

Length of Authorization:	6 months (initial), 12 months (continuation)
Initiative:	PAR: Strensiq (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP).

FDA-RECOMMENDED DOSE

- Perinatal/Infantile-Onset hypophosphatasia (HPP)
  - Recommended dosage regimen is 2 mg/kg administered subcutaneously three times per week, or 1 mg/kg six times per week. Injection site reactions may limit the tolerability of the six times per week regimen. The dosage may be increased to 3 mg/kg three times per week for insufficient efficacy.
- Juvenile-Onset hypophosphatasia (HPP)
  - Recommended dosage regimen is 2 mg/kg administered subcutaneously three times per week, or 1 mg/kg six times per week. Injection site reactions may limit the tolerability of the six times per week regimen.

HOW SUPPLIED

- Single-use vials: 18 mg/0.45 mL, 28 mg/0.7 mL, 40 mg/mL, 80 mg/0.8 mL in 1- and 12-count cartons.

COVERAGE UTILIZATION CRITERIA

FOR INITIAL REVIEW REQUESTS

All Indications:

- The member is not currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)]; **AND**
- The member does not have serum calcium or phosphate levels below the normal range; **AND**
- The member does not have a treatable form of rickets; **AND**
- The member meets the diagnosis specific criteria below.

For perinatal/infantile-onset HPP:

- The member must have a documented diagnosis of perinatal/infantile-onset hypophosphatasia (HPP); **AND**
- The member was 6 months of age or younger at HPP onset; **AND**
- The member meets one of the following criteria:
  - The member is positive for tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing; **OR**
  - The member meets **TWO** of the following criteria:
    - Serum alkaline phosphatase (ALP) level below that of normal range for patient age
    - Serum pyridoxal-5'-phosphate (PLP) levels elevated AND patient has not received vitamin B6 supplementation in the previous week
    - Urine phosphoethanolamine (PEA) level above that of normal range for patient age
    - Radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, widened growth plates, areas of radiolucency or sclerosis)
    - Presence of **TWO** or more of the following:

- Rachitic chest deformity
- Craniosynostosis (premature closure of skull bones)
- Delay in skeletal growth resulting in delay of motor development
- History of vitamin B6 dependent seizures
- Nephrocalcinosis or history of elevated serum calcium
- History or presence of non-traumatic postnatal fracture and delayed fracture healing

For juvenile-onset hypophosphatasia (HPP):

- The member has a diagnosis of juvenile-onset hypophosphatasia (HPP); **AND**
- The member was 18 years of age or younger at hypophosphatasia (HPP) onset; **AND**
- The member meets one of the following criteria:
  - The member is positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing; **OR**
  - The member meets two of the following criteria:
    - Serum alkaline phosphatase (ALP) level below that of normal range for patient age
    - Serum pyridoxal-5'-phosphate (PLP) levels elevated **AND** patient has not received vitamin B6 supplementation in the previous week
    - Urine phosphoethanolamine (PEA) level above that of normal range for patient age
    - Radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, osteomalacia, widened growth plates, areas of radiolucency or sclerosis)
    - Presence of two or more of the following:
      - Rachitic deformities (rachitic chest, bowed legs, knock-knees)
      - Premature loss of primary teeth prior to 5 years of age
      - Delay in skeletal growth resulting in delay of motor development
      - History or presence of non-traumatic fractures or delayed fracture healing

FOR CONTINUATION COVERAGE REQUESTS

- **First continuation:** The member, during the last 6 months of treatment, must have experienced improvement in the skeletal characteristics of hypophosphatasia (HPP) (e.g., improvement of the irregularity of the provisional zone of calcification, physeal widening, metaphyseal flaring, radiolucencies, patchy osteosclerosis, ratio of mid-diaphyseal cortex to bone thickness, gracile bones, bone formation and fractures).
- **Subsequent continuations:** The provider attests to continued member benefit from therapy.

REQUIRED MEDICAL INFORMATION

Documentation of genetic tests and labs as applicable per criteria set used above

AGE RESTRICTIONS

Age restrictions outlined in criteria above

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an endocrinologist

REVIEWER REQUIREMENTS

Must be reviewed by a pharmacist

COVERAGE DURATION

- Initial: 6 months
- Continuation: 12 months

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

SUCRAID® (SACROSIDASE)

Updated: August 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Sucraid (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

As oral replacement therapy of the genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID).

FDA-RECOMMENDED DOSE

- < 15kg: 1 mL (8,500 I.U.) (one full measuring scoop or 28 drops) per meal or snack.
- ≥ 15 kg: 2 mL (17,000 I.U.) (two full measuring scoops or 56 drops) per meal or snack.

HOW SUPPLIED

- Oral Solution is available in 118 mL (4 fluid ounces) packaged as 2 bottles per box.
- Each mL of solution contains 8,500 International Units (I.U.) of sacrosidase. A 1 mL measuring scoop is provided with each bottle.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member must have a diagnosis of congenital sucrase-isomaltase deficiency (CSID) as confirmed by:
  - The member has a molecular genetic test demonstrating pathogenic or likely pathogenic sucrase-isomaltase (SI) gene variant; **OR**
  - The member has an endoscopic biopsy of the small intestine indicating normal small bowel morphology in the presence of all of the following:
    - Decreased (or absent) sucrase activity
    - Decreased to normal isomaltase activity
    - Decreased maltase activity
    - Decreased to normal lactase activity.

FOR CONTINUATION COVERAGE REQUESTS

The member must continue to receive benefit as attested to by their prescribing provider.

REQUIRED MEDICAL INFORMATION

- Member weight (kg)
- Chart notes or medical records supporting diagnosis.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a gastroenterologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION (MONTHS)

5 years

QUANTITY RESTRICTIONS

All authorizations should be limited to the dose required by weight.

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by GSN.

SUNOSI® (SOLRIAMFETOL)

Updated: June 29, 2023

Length of Authorization:	5 years
Initiative:	PAR: Sunosi (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

To improve wakefulness in adult patients with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA)

FDA-RECOMMENDED DOSE

- For Narcolepsy: 75 mg once daily, with a maximum dose of 150 mg once daily
- For OSA: 37.5 mg once daily, with a maximum dose of 150 mg once daily

HOW SUPPLIED

75 mg functionally scored tablets and 150 mg tablets in 30-count and 100-count bottles

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of EDS; **AND**
- The member meets one of the following clinical scenarios:
  - The member has a diagnosis of narcolepsy, confirmed by both a polysomnography and a multiple sleep latency test (MSLT); **OR**
  - The member has documentation one or more confounding factors impacting MSLT accuracy and the member has documented history of narcolepsy diagnosis throughout chart notes; **OR**
  - The member has a diagnosis of OSA; **AND**
- If diagnosed with OSA, the member has and continues to utilize continuous positive airway pressure (CPAP) therapy; **AND**
- The member has tried and failed Modafinil or Armodafinil

FOR CONTINUATION OF COVERAGE REQUESTS

- The member has had a positive response to therapy, as documented by the member's specialty provider; **AND**
- If diagnosed with OSA, the member has and continues to utilize continuous positive airway pressure (CPAP) therapy.

REQUIRED MEDICAL INFORMATION

For EDS associated with narcolepsy: documentation of polysomnography and sleep latency test or chart notes as applicable per criteria above.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a neurologist or sleep specialist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

Five years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approve by HICL.

SYMDEKO® (TEZACAFTOR/IVACAFTOR)

Updated: October 30, 2023

Length of Authorization:	Initial: 1 year; Continuation: 5 years
Initiative:	PAR: Symdeko (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of cystic fibrosis (CF) in patients aged 6 years and older who are homozygous for the F508del mutation or who have at least one mutation in the CF transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor.

FDA-RECOMMENDED STARTING DOSE

Table 1. Dosing

Age	Morning (one tablet)	Evening (one tablet)
6 to < 12 years of age weighing < 30 kg	tezacaftor 50 mg/ivacaftor 75 mg	ivacaftor 75 mg
6 to < 12 years of age weighing ≥ 30 kg	tezacaftor 100 mg/ivacaftor 150 mg	ivacaftor 150 mg
≥ 12 years of age	tezacaftor 100 mg/ivacaftor 150 mg	ivacaftor 150 mg

HOW SUPPLIED

- 50 mg/75 mg TEZ/IVA tablets and 75 mg IVA tablets in a 56-count tablet carton
- 100 mg/150 mg TEZ/IVA tablets and 150 mg IVA tablets in a 56-count tablet carton

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of CF; **AND**
- The member meets either of the following clinical scenarios:
  - The member is homozygous for the *F508del* mutation; **OR**
  - The member has at least one mutation in the CFTR gene that is responsive to TEZ/IVA (Table 2).

Table 2: Known CFTR Gene Mutations Responsive to TEZ/IVA

2789+5G→A	D110E	E56K	P67L	S945L
3272-26A→G	D110H	E831X	R1070W	S977F
3849+10kbC→T	D1152H	F1052V	R117C	F508del (homozygous)
711+3A→G	D1270N	F1074L	R347H	
A1067T	D579G	K1060T	R352Q	
A455E	E193K	L206W	R74W	

- The member's baseline FEV1 (forced expiratory volume in one second) is at least 40% or higher (as documented by lab report or chart notes); **AND**
- The member does not have either of the following:
  - ALT or AST > 5x ULN.
  - ALT or AST > 3x ULN with bilirubin > 2x ULN.

FOR CONTINUATION COVERAGE REQUESTS

- Confirmation that the member continues to have a beneficial response to therapy as assessed and documented by the member's specialist provider, as defined, and supported by one of the following:
  - Maintenance or improvement in FEV1; **OR**
  - Maintenance or improvement in BMI (body mass index); **OR**
  - Reduction in pulmonary exacerbations; **AND**
  - The member does not have either of the following:
    - ALT or AST > 5x ULN.
    - ALT or AST > 3x ULN with bilirubin > 2x ULN.

REQUIRED MEDICAL INFORMATION

- Genomic testing showing required mutation(s).
- FEV1 with date (required for initial and optional for continuation if other criteria met).
- AST/ALT levels.
- Bilirubin levels if applicable.

AGE RESTRICTIONS

6 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a pulmonologist or cystic fibrosis specialist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

- Initial: 1 year
- Continuation: 5 years

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

If approved, term any active PA for Kalydeco®, Orkambi®, and/or Trikafta®.

SYMLIN®/SYMLINPEN® (PRAMLINTIDE)

Updated: May 26, 2023

Length of Authorization:	Five years
Initiative:	STP: SymlinPen (IE 31121 / NCPDP 608 – GSN)

FDA-APPROVED INDICATION(S)

As an adjunctive treatment in patients with type 1 or type 2 diabetes who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy.

FDA-RECOMMENDED DOSE

- **Type 2 diabetes:** 60 mcg subcutaneously, injecting immediately prior to each major meal. Maximum dose of 120 mcg prior to each major meal.
- **Type 1 diabetes:** 15 mcg subcutaneously, injecting immediately prior to each major meal. Maximum dose of 60 mcg prior to each major meal.

HOW SUPPLIED

- 1.5 mL disposable multidose SymlinPen 60 pen-injector containing 1000 mcg/mL pramlintide
- 2.7 mL disposable multidose SymlinPen 120 pen-injector containing 1000 mcg/mL pramlintide

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of type 1 or type 2 diabetes mellitus; **AND**
- The member is experiencing inadequate glycemic control using insulin.

FOR CONTINUATION COVERAGE REQUESTS

- The member continues to benefit from treatment, as attested to by the member's treating provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years and older

PRESCRIBER RESTRICTIONS

N/A

COVERAGE DURATION

Five years

QUANTITY/PARTIAL-FILL RESTRICTIONS

N/A

OPERATIONAL NOTES/OTHER INFORMATION

N/A

SYMTUZA® (DARUNAVIR, COBICISTAT, EMTRICITABINE, TENOFOVIR ALAFENAMIDE)

Updated: May 10, 2023

Length of Authorization:	5 years
Initiative:	PAR: Symtuza (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

A complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 40 kg who have no prior antiretroviral treatment history or who are virologically suppressed (HIV-1 RNA less than 50 copies per mL), on a stable antiretroviral regimen for at least 6 months, and have no known substitutions associated with resistance to darunavir or tenofovir.

FDA-RECOMMENDED STARTING DOSE

One tablet by mouth once daily.

HOW SUPPLIED

As a single tablet regimen of 800 mg darunavir (DRV), 150 mg cobicistat (COBI), 200 mg emtricitabine (FTC), and 10 mg tenofovir alafenamide (TAF), in 30-count bottles.

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member has a confirmed diagnosis of HIV-1; **AND**
- The member weighs at least 40kg**; AND**
- The member is perceived to be at high risk for non-adherence or has low engagement in their care, as assessed by the member's specialist provider; **AND**
- The member meets one of the following clinical scenarios:
  - The member is antiretroviral treatment naïve; **OR**
  - The member is currently virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no known substitutions associated with resistance to darunavir or tenofovir.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Patient weight (kg).

AGE RESTRICTIONS

3 years of age or older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an infectious disease specialist or HIV specialist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

18 years

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

TABRECTA™ (CAPMATINIB)

Updated: May 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Tabrecta (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.

FDA-RECOMMENDED STARTING DOSE

400 mg orally twice daily.

HOW SUPPLIED

150 mg and 200 mg tablets in 56-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a documented diagnosis metastatic non-small cell lung cancer (NSCLC); **AND**
- The member's tumor(s) have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's oncologist.

REQUIRED MEDICAL INFORMATION

Mesenchymal-epithelial transition (MET) tumor status.

AGE RESTRICTIONS

18 years of age or older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary quantity limits.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

Approve by HICL.

TAFINLAR® (DABRAFENIB)

Updated: June 27, 2023

Length of Authorization:	5 years
Initiative:	PAR: Tafinlar (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- As a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.
- In combination with trametinib, for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test.
- In combination with trametinib, for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection.
- In combination with trametinib, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test.
- In combination with trametinib, for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options.
- In combination with trametinib for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative options.
- In combination with trametinib for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy.

FDA-RECOMMENDED STARTING DOSE

- Adult and pediatric patients weighing 51 kg or greater: 150 mg orally twice daily.
- Pediatric patients weighing 8 kg to 50 kg: refer to package insert.

HOW SUPPLIED

- 50 mg and 75 mg capsules in 120-count bottles.
- 10 mg tablets for suspension in 210-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member must meet one of the following clinical scenarios:
  - The member has a malignant disease with confirmed BRAF V600E or V600 K mutation; **AND**
    - The member has a confirmed diagnosis of one of the following:
      - Melanoma
      - NSCLC
      - Head and Neck Cancers – Salivary Gland Tumors
      - Thyroid Cancer
      - Esophageal and Esophagogastric Junction Cancers
      - Ovarian Cancer, Fallopian Tube Cancer, Primary Peritoneal Cancer—Low Grade
      - CNS Cancer
      - Biliary Tract Cancer
      - Gastrointestinal Stromal Tumors

    - Pancreatic Adenocarcinoma
    - Langerhans Cell Histiocytosis (LCH)
    - Erdheim-Chester Disease (ECD); **OR**
  - The member has a diagnosis of a solid tumor; **AND**
    - The member's disease is unresectable or metastatic solid tumors; **AND**
    - The member has confirmed BRAF V600E mutation; **AND**
    - The member progressed following prior treatment and has no satisfactory alternative treatment options; **OR**
  - The member has a diagnosis of LGG; **AND**
    - The member has confirmed BRAF V600E mutation; **AND**
- If request is for tablets for suspension, then the member must meet one of the following criteria:
  - Has documented difficulty in swallowing or dysphagia
  - Requires tube feeding
  - Requires a dosage unobtainable with the conventional dosage form
  - Is under 11 years of age

For continuation coverage requests:

- The member continues to have a beneficial response to therapy, as assessed and attested to by the member's oncology provider; **AND**
- If request is for tablets for suspension, then the member must meet one of the following criteria:
  - Has documented difficulty in swallowing or dysphagia
  - Requires tube feeding
  - Requires a dosage unobtainable with the conventional dosage form
  - Is under 11 years of age

REQUIRED MEDICAL INFORMATION

- BRAF V600E or V600K mutation status
- Claims or medical records demonstrating use of previous therapies, as applicable.

AGE RESTRICTIONS

- LGG with a BRAF V600E mutation: 1 year of age and older.
- Unresectable or metastatic solid tumors with BRAF V600E: 6 years of age and older
- Other indications: 18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

- Refer to formulary
- If member meets criteria for tablets for suspension, then enter a quantity override to permit dosing based on current weight. When calculating restriction, add 10 kg to the member's current weight to allow for growth during their approval cycle

OPERATIONAL NOTES

Approve by HICL.

TAGRISSO® (OSIMERTINIB)

Updated: May 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Tagrisso (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the first-line treatment, and as adjuvant treatment following tumor resection, of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
- For the treatment of patients with metastatic EGFR T790M mutation-positive NSCLC, as detected by an FDA-approved test, whose disease has progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.

FDA-RECOMMENDED STARTING DOSE

80 mg once daily until disease progression or unacceptable toxicity.

HOW SUPPLIED

40 and 80 mg oral tablets in 30-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of NSCLC; **AND**
- The member's tumor expresses one of the following:
  - EGFR T790M mutation
  - EGFR S768I mutation
  - EGFR L861Q mutation
  - EGFR G719X mutation
  - EGFR exon 19 deletion
  - Exon 21 L858R mutation; **AND**
- If the member has T790M mutation positive disease, they must have experienced progression following therapy with erlotinib, afatinib, gefitinib or dacomitinib; **AND**
- If requesting 160 mg dose, the member must have progressive CNS disease or leptomeningeal disease.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's oncologist.
- If requesting 160 mg dose, the member must have progressive CNS disease or leptomeningeal disease.

REQUIRED MEDICAL INFORMATION

Lab results for the member's applicable tumor mutation(s) or deletion(s)

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

18 years

QUANTITY RESTRICTIONS

- Refer to formulary
- If criteria is met for the 160 mg dose, enter a quantity override to permit 2 x 80 mg tablets per day for the same duration as the clinical approval.
  - Only the 80 mg tablet (GSN 075147) may be approved for this dose.

OPERATION NOTES AND OTHER INFORMATION

Approve by HICL.

TAKHZYRO® (LANADELUMAB-FLYO)

Updated: April 6, 2023

Length of Authorization:	12 months
Initiative:	PAR: Takhzyro (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 2 years and older.

FDA-RECOMMENDED DOSE

- Ages 2–6: 150 mg subcutaneously every 4 weeks
- Ages 6–12: 150 mg subcutaneously every 2 weeks
- Ages 12+: 300 mg subcutaneously every 2 weeks
- A dosing interval of every 4 weeks is also effective and may be considered if the patient is well-controlled (e.g., attack free) for more than 6 months.

HOW SUPPLIED

- 150 mg/1 mL single-dose prefilled syringe
- 300 mg/2 mL solution in single-dose vials or pre-filled syringes

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member must have confirmatory diagnosis of HAE due to C1 inhibitor deficiency (HAE-1 or HAE-2), including confirmation of low C4 levels and low functional C1 inhibitor (C1-INH) activity; **AND**
- The member is not receiving concurrent prophylactic medications for HAE (i.e., C1-INH, berotralstat); **AND**
- The prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy; **AND**
- The prescriber attests that the member is not concurrently taking any medications that may exacerbate HAE (e.g., ACE inhibitors, estrogens).

FOR CONTINUATION COVERAGE REQUESTS

- The member continues to have a beneficial response to therapy as assessed and documented by the member's specialist provider.
- For biweekly dosing requests: A dose reduction, to every-4 week-dosing, has been considered in the last 12 months

REQUIRED MEDICAL INFORMATION

For initial reviews, confirmatory diagnosis of HAE, including C1-INH and C4 levels with date drawn.

AGE RESTRICTIONS

2 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an immunologist, allergist, or hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY RESTRICTIONS

- Initial requests and continuation requests ineligible for dose reduction:
  - 12+ years old: Approve a QPD override to allow 0.15 per day.
  - < 12 years old: Approve a QPD override to allow 0.08 per day.
- All other continuation requests: Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN (correct strength for age).

TALTZ® (IXEKIZUMAB)

Updated: December 18, 2023

Length of Authorization:	12 months
Initiative:	PAR: Taltz (IE 2462 / NCPDP 75 – HICL; IE 7001 / NCPDP 76 – HICL) PAR: Loading Dose (IE 15110, 2641, 7001 / NCPDP 76 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of patients 6 years of age and older with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.
- For the treatment of adult patients with active psoriatic arthritis (PsA).
- For the treatment of adult patients with active ankylosing spondylitis (AS).
- For the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

FDA-RECOMMENDED DOSE

- For PsO (adults): 160 mg (two 80 mg injections) at week 0, followed by 80 mg at weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks.
- For PsO (pediatrics):

Weight	Starting Dose (Week 0)	Dose Every 4 Weeks (Q4W) Thereafter
Greater than 50 kg	160 mg (two 80 mg injections)	80 mg
25 to 50 kg	80 mg	40 mg
Less than 25 kg	40 mg	20 mg

- For PsA and AS: 160 mg (two 80 mg injections) at week 0, followed by 80 mg every 4 weeks.

HOW SUPPLIED

80 mg single-dose autoinjector or prefilled syringes (PFS); in 1, 2, and 3 count cartons.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

For all indications:

- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

For PsO:

- If less than 18 years of age: the member weighs greater than 50 kg, **AND**
- The member has a documented diagnosis of moderate to severe PsO; **AND**
- The member has psoriatic lesions that involve greater than or equal to 10% of body surface area (BSA) or that affect the palms, soles, head, neck, or genital area, leading to disability/impact on quality of life, **AND**
- The member has had a previous trial of or contraindication to at least one of the following:
  - PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B)
  - Topical corticosteroids
  - Calcipotriene

- Acitretin
- Methotrexate
- Cyclosporine; **AND**

- The member has had a previous trial of or contraindication to at least **three** of the following preferred agents:
  - Adalimumab
  - Cosentyx
  - Enbrel®
  - Tremfya®
  - Stelara®

For PsA:

- The member has a documented diagnosis of moderate to severe PsA; **AND**
- The member has had a previous trial of or contraindication to at least one of the following:
  - Methotrexate
  - Sulfasalazine
  - Cyclosporine
  - Leflunomide; **AND**
- The member has had a previous trial of or contraindication to at least **two** of the following preferred agents:
  - Adalimumab
  - Cosentyx
  - Enbrel®
  - Tremfya®
  - Stelara®
  - Xeljanz®

For AS:

- The member has a diagnosis of ankylosing spondylitis; **AND**
- The member has had a previous trial of at least **one**, or contraindication to **all**, of the following:
  - Nonsteroidal anti-inflammatory drugs (NSAIDs)
  - Methotrexate
  - Sulfasalazine; **AND**
- The member has had a previous trial of, or contraindication to, at least two of the following without adequate response:
  - Adalimumab
  - Enbrel®
  - Xeljanz
  - Cosentyx

For nr-axSpA:

- The member has a diagnosis of active non-radiographic axial spondylarthritis***;*** **AND**
- The member has had a previous trial of at least **one**, or contraindication to **all**, of the following:
  - Nonsteroidal anti-inflammatory drugs (NSAIDs)
  - Methotrexate
  - Sulfasalazine; **AND**
- The member has had a previous trial of, or contraindication to Cosentyx **and** Cimzia without adequate response.

FOR CONTINUATION COVERAGE REQUESTS

- The member has had a positive clinical response to therapy, as documented by the member's specialist provider; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib),

REQUIRED MEDICAL INFORMATION

For Initial Coverage Requests:

- For members treated for PsO: current BSA coverage of lesions.
- Claims or medical records demonstrating use of previous therapies.

For All Coverage Requests:

- For pediatric members (under 18 years of age) treated for plaque psoriasis, weight is required.

AGE RESTRICTIONS

- Plaque Psoriasis: 6 years of age and older.
- All other indications: 18 years of age and older.

PRESCRIBER RESTRICTIONS

- For PsO and PsA: must be prescribed by or in consultation with a dermatologist or rheumatologist.
- For AS: must be prescribed by or in consultation with a rheumatologist.

REVIEWER REQUIREMENTS

Coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Internal Note:

- PsO Loading Doses
  - Adult:
    - Loading dose 1 (Days 1–28): enter PA with a metric quantity and days' supply of #3/28 DS (three 80 mg doses in a 4-week period).
    - Loading dose 2 (Days 29–84): enter PA with a metric quantity and days' supply of #2/28 DS (two 80 mg doses in a 4-week period). PA start date should be day after loading dose 1 PA ends.
  - Pediatric:
    - Greater than 50 kg: Enter PA with a metric quantity and days' supply of #2/28 DS per 1 month.
    - Less than or equal to 50 kg: not covered. Office administration only.
- AS and PsA Loading Doses:
  - Loading dose (days 1–28): Enter PA with a metric quantity and days' supply of #2/28 DS (two 80 mg doses in a 4-week period).

- Nr-axSpA:
  - Only one 12-month approval needed, defer to formulary QL
  - Loading doses:
    - Use initiative PAR: Loading Dose
    - Select CTI reason code: 2nd **or** for Existing PA Approved. No approval letter is sent with loading dose Pas.

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve by HSN
- If the patient has both a PsA and PsO diagnosis, approve quantity limit overrides based on PsO dosing.

TALZENNA® (TALAZOPARIB)

Updated: September 15, 2023

Length of Authorization:	5 years
Initiative:	PAR: Talzenna (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients with deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer.
- In combination with enzalutamide for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC)

FDA-RECOMMENDED DOSE

1 mg orally once daily

HOW SUPPLIED

0.1 mg, 0.25 mg, 0.35 mg, 0.5 mg, 0.75 mg, and 1 mg capsules in 30-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- For Breast Cancer:
  - The member has a documented diagnosis of advanced or metastatic breast cancer; **AND**
  - The member has documentation of germline BRCA mutation.
  - The member plans on using the medication as a single agent therapy.
- For Prostate Cancer:
  - The member has a diagnosis of metastatic castration-resistant prostate cancer (CRPC) ; **AND**
  - The member has a documentation of homologous recombination repair (HRR) mutation (i.e., BRCA1, BRCA2, ATM, ATR, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, or RAD51C) ; **AND**
  - The member will be receiving enzalutamide concomitantly; **AND**
  - The member has not had prior novel hormone therapy.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Documentation of tumor mutation status.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approve at the HSN level.

TAPINAROF CREAM (VTAMA®)

Updated: August 16, 2023

Length of Authorization:	12 months
Initiative:	PAR: Vtama (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the topical treatment of plaque psoriasis in adults.

FDA-RECOMMENDED DOSE

Apply a thin layer of cream to affected areas once daily.

HOW SUPPLIED

1% cream in 60-gram tubes

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member must have a diagnosis of plaque psoriasis, AND
- The member must have tried and failed three, or have contraindication to all of the following:
  - Topical corticosteroid
  - Tazarotene
  - Calcipotriene
  - Topical calcineurin inhibitor

FOR CONTINUATION COVERAGE REQUESTS

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Claims or chart notes demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a dermatologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

TASIGNA® (NILOTINIB)

Updated: April 25, 2023

Length of Authorization:	5 years
Initiative:	Par: Tasigna (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of adult and pediatric patients 1 year of age or older with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.
- For the treatment of adult patients with chronic phase and accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia (Ph+ CML) who are resistant or intolerant to prior therapy that included imatinib.
- For the treatment of pediatric patients 1 year of age or older with chronic phase and accelerated phase Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) who are resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy.

FDA-RECOMMENDED DOSE

- Adult patients with newly diagnosed Ph+ CML-CP: 300 mg orally twice daily.
- Adult patients with resistant or intolerant Ph+ CML-CP and CML-AP: 400 mg orally twice daily.
- Pediatric patients with newly diagnosed Ph+ CML-CP or resistant or intolerant Ph+ CML-CP and CML-AP: 230 mg/m^2 orally twice daily, rounded to the nearest 50 mg dose (to a maximum single dose of 400 mg)

HOW SUPPLIED

- 50 mg capsules in 120-count bottles.
- 150 or 200 mg capsules in cartons of 4 x 28-count blister packs (total of 112 capsules each carton). NDC for individual 28-count blister pack available.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **For all indications:**
  - The member does not have a known T315I, Y253H, E255K/V, F359V/C/I, or G250E mutation;
- **For Lymphoid, myeloid, or mixed lineage neoplasms:**
  - The member has a diagnosis of a lymphoid, myeloid or mixed lineage neoplasms with eosinophilia; **AND**
  - The member has documentation of an ABL1 rearrangement.
- **For GIST:**
  - The member has a diagnosis of gastrointestinal stromal tumors (GIST); **AND**
  - The member has unresectable, recurrent, or metastatic disease.
- **For CML:**
  - The member has a diagnosis of CML; **AND**
  - The member's disease is characterized as one of the following:
    - BCR: AB:1 positive
    - Philadelphia chromosome positive
- **For ALL:**
  - The member has a diagnosis of B-cell Acute Lymphoblastic Leukemia (B-ALL); **AND**
  - The member has Philadelphia chromosome positive disease.

- **For Melanoma:**
  - The member has a diagnosis of cutaneous melanoma; **AND**
  - The member has activating mutations of KIT; **AND**
  - The member will be using as nilotinib as a second-line to BRAF-targeted therapy.
- **For PVNS/TGCT:**
  - The member has a diagnosis of Pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT).

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Documentation of mutation or rearrangement status, if applicable.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a hematologist or oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

TAVALISSE® (FOSTAMATINIB)

Updated: May 8, 2023

Length of Authorization:	Initial: 3 months Renewal: 12 months
Initiative:	PAR: Tavalisse (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

FDA-RECOMMENDED STARTING DOSE

100 mg orally twice daily (initial); if platelet count has not increased to at least 50 × 109/L after a month, the dose may be increased to 150 mg twice daily.

HOW SUPPLIED

100 mg and 150 mg tablets in 60-count bottles.

COVERAGE CRITERIA

For All Coverage Reviews:

- The member has a confirmed diagnosis of chronic immune thrombocytopenic purpura; **AND**
- The member has an initial platelet count less than 30,000/µL; **AND**
- The member does not have alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) levels greater than three times the upper limit of normal; **AND**
- The member has tried and failed a therapeutic trial of all of the following regimens, unless otherwise contraindicated:
  - Four weeks of standard prednisone therapy or high dose dexamethasone (HDD)
  - Intravenous immunoglobulins (IVIG)
  - Eltrombopag (Promacta®)
  - Romiplostim (Nplate®)
  - Rituximab (Rituxan®)

For Continuation:

- The member has had an increase in platelet count to ≥ 50,000/mm^3 while on therapy or an increase that is sufficient to avoid clinically important bleeding after at least 4 weeks on max dose.

REQUIRED MEDICAL INFORMATION

- Documentation of platelet count.
- ALT/AST laboratory values.
- Previous medication trials documented by claims or chart notes.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

Initial: 3 months

Renewal: 12 months

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

TAVNEOS® (AVACOPAN)

Updated: February 7, 2022

Length of Authorization:	12 months
Initiative:	PAR: Tavneos (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

As an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids.

FDA-RECOMMENDED STARTING DOSE

30 mg (three 10 mg capsules) by mouth twice daily.

HOW SUPPLIED

10 mg capsules in 30-count and 180-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of ANCA-associated vasculitis, specifically, GPA or MPA; **AND**
- The member's treatment plan includes concurrent use avacopan with either cyclophosphamide or rituximab.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a nephrologist or rheumatologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

TAZVERIK® (TAZEMETOSTAT)

Updated: March 23, 2023

Length of Authorization:	5 years
Initiative:	PAR: Tazverik (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection.
- For the treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies.
- For the treatment of adult patients with R/R FL who have no satisfactory alternative treatment options.

FDA-RECOMMENDED DOSE

800 mg orally twice daily with or without food until disease progression or unacceptable toxicity.

HOW SUPPLIED

200 mg tablets in 240 count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **For Epithelioid Sarcoma:**
  - The member must have a diagnosis of metastatic or locally advanced epithelioid sarcoma not eligible for complete resection; **AND**
  - The member must have evidence of loss of INI1 expression.
- **For Follicular Lymphoma:**
  - The member must have a diagnosis of relapsed or refractory follicular lymphoma; **AND**
  - The member must meet one of the following clinical scenarios:
    - The member must have tumors positive for EZH2 mutation **and** have received at least two prior systemic therapies for this indication; **OR**
    - The member must have no other satisfactory treatment options as attested to by the prescribing provider.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- For epithelioid sarcoma: documentation of INI1 loss of expression (notation in chart notes is sufficient)
- For FL: documentation of EZH2 mutation, if applicable
- Claims or medical records demonstrating use of previous therapies, if applicable.

AGE RESTRICTIONS

- For epithelioid sarcoma: 16 years of age and older.
- For FL: 18 years of age and older.

REVIEWER REQUIREMENTS

All requests must be reviewed by a pharmacist or physician.

PRESCRIBER RESTRICTIONS

Prescribed by an oncologist or hematologist.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

TECFIDERA® (DIMETHYL FUMARATE)

Updated: September 10, 2023

Length of Authorization:	5 years
Initiative:	PAR: Tecfidera (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

FDA-RECOMMENDED DOSE

The starting dose is 120 mg twice a day orally. After 7 days, the dose should be increased to the maintenance dose of 240 mg twice a day orally.

HOW SUPPLIED

- 30-day starter pack of fourteen 140 mg capsules and twenty-three 240 mg capsules
- 120 mg supplied in a bottle of 14
- 240 mg capsules supplied in a bottle of 60

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member must have a diagnosis of relapsing form of multiple sclerosis; **AND**
- The member must have tried and failed at least one of the following disease-modifying agents for the treatment of their MS:
  - Avonex®
  - Betaseron®
  - Dimethyl fumarate (generic)
  - Gilenya®
  - Fingolimod
  - Glatiramer acetate or Glatopa®
  - Mayzent®
  - Plegridy®
  - Kesimpta®

FOR CONTINUATION COVERAGE REQUESTS

- The member has had a positive clinical response to therapy, as documented by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

N/A

COVERAGE DURATION

18 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HSN.

TENAPANOR (IBSRELA®)

Updated: November 30, 2023

Length of Authorization:	12 months
Initiative:	PAR: Ibsrela (IE 2462/NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of irritable bowel syndrome with constipation (IBS-C) in adults.

FDA-RECOMMENDED DOSAGE

50 mg orally twice daily.

HOW SUPPLIED

50 mg tablets in 60-count bottles.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member must have clinically diagnosed IBS-C with symptoms persisting for at least 3 months, **AND**
- The member has attempted lifestyle changes, including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake, **AND**
- The member must not have a known or suspected mechanical gastrointestinal obstruction or perforation, **AND**
- The member must have tried and failed two, or is contraindicated to all, of the following:
  - Lubiprostone (Amitiza)
  - Linaclotide (Linzess)
  - Plecanatide (Trulance)
- The member must not be on concurrent lubiprostone, plecanatide, or linaclotide.

FOR CONTINUATION COVERAGE REQUESTS

- The member continues to have a beneficial response to therapy, as assessed by the member's provider; **AND**
- The member must not be taking concurrent lubiprostone, plecanatide, or linaclotide.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a gastroenterologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

TEPMETKO® (TEPOTINIB)

Updated: March 24, 2023

Length of Authorization:	5 years
Initiative:	PAR: Tepmetko (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations.

FDA-RECOMMENDED DOSE

450 mg orally once daily with food

HOW SUPPLIED

225 mg tablets, available in 30-count and 60-count blister packs

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of NSCLC; **AND**
- The member's disease harbors a confirmed mesenchymal-epithelial transition (MET) exon 14 skipping alteration.

For Continuation Of Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Documentation of (MET) exon 14 skipping status

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

COVERAGE DURATION

5 years

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by GSN.

TESTOSTERONE

Updated: November 27, 2023

Length of Authorization:	12 months.
Initiative:	PAR: Testosterone (IE 2462 / NCPDP 75 – GSN)

POLICY OVERVIEW

The University of Michigan Prescription Drug Plan covers select testosterone products. In general, testosterone products are covered for members who meet pre-defined coverage criteria for the treatment of hypogonadism, female-to-male gender dysphoria, and hypoactive sexual desire disorder in post-menopausal women. This policy applies to all covered formulations of testosterone.

COVERAGE CRITERIA

INITIAL COVERAGE REQUESTS FOR INJECTABLE AND TOPICAL TESTOSTERONE PRODUCTS

For all indications:

- The member does not have a history of prostate cancer or elevated prostate-specific antigen (PSA) levels; **AND**
- The member does not have a history of cardiovascular events (e.g., myocardial infarction, transient ischemic attack, or coronary syndrome) within the previous six months.

For the treatment of hypogonadism:

- The member is male with a diagnosis of hypogonadism; **AND**
- The member has two separate subnormal pre-treatment morning serum testosterone levels
  - Subnormal testosterone levels (i.e., less than 300 ng/dL) **OR**
  - Subnormal testosterone levels corrected for sex hormone binding; **AND**
- If member is obese (body mass index ≥ 30), member has undergone an adequate trial of lifestyle modification with diet and exercise.

For the treatment of gender dysphoria:

- The member was assigned female at birth and is transitioning gender

For the treatment of hypoactive sexual desire disorder (HSDD):

- The member is a post-menopausal female; **AND**
- The member has tried and failed counseling, such as couples therapy and/or sex therapy; **AND**
- The member does not have HSDD attributable to a co-existing medical or psychiatric condition, problems with the relationship, or the effects of a medication or drug substance.

INITIAL COVERAGE REQUESTS FOR ORAL TESTOSTERONE (JATENZO® OR TLANDO)

For the treatment of primary and/or hypogonadotropic hypogonadism

- The member does not have a history of prostate cancer or elevated prostate-specific antigen (PSA) levels; **AND**
- The member does not have a history of cardiovascular events (e.g., myocardial infarction, transient ischemic attack, or coronary syndrome) within the previous six months; **AND**
- The member is male with a documented diagnosis of primary[1] or hypogonadotropic[2] hypogonadism; **AND**
- The member has two separate subnormal pre-treatment morning serum testosterone levels (i.e., less than 300 ng/dL), or subnormal testosterone levels corrected for sex hormone binding; **AND**
- If member is obese (body mass index ≥ 30), member has undergone an adequate trial of lifestyle modification with diet and exercise; **AND**
- The member has tried and failed both a topical and an injectable formulation of testosterone replacement therapy.

[1] Primary hypogonadism (congenital or acquired) is specific to testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals.

[2] Hypogonadotropic hypogonadism (congenital or acquired) is specific to gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation.

CONTINUATION REQUESTS – APPLICABLE TO ALL TESTOSTERONE FORMULATIONS

For all indications:

- The member has not had a cardiovascular event (e.g., myocardial infarction, transient ischemic attack, or coronary syndrome) within the previous six months; **AND**
  - The member's testosterone levels have remained within or below the normal limits while on therapy, as defined by the laboratories' reference values; **OR**
  - The member's testosterone regimen has been reduced following above-normal levels and have subsequently remained within or below the laboratories' normal limits.

REQUIRED MEDICAL INFORMATION

For the treatment of hypogonadism, documentation of morning testosterone levels with dates within the previous 12 months.

AGE RESTRICTIONS

12 years of age or older.

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY RESTRICTIONS

- Coverage of injectable forms of testosterone is limited to a maximum dose of 200 mg per week. Plan approval is required if the requested dosage exceeds 200 mg of delivered testosterone per week.
- Coverage of topical testosterone is limited to the lesser-of the formulary-coded maximum dose per product, or 2,000 mg of testosterone per week. Refer to individual product information for calculating the amount of testosterone provided per application. Plan approval is required if the dosage exceeds 2,000 mg of testosterone per week.
- Refer to formulary for other product-specific quantity limits.

OPERATION NOTES AND OTHER INFORMATION

- Approve by GSN.
- A one-month continuation override is permissible if a dose change occurs and time is needed to perform labs. Only one override allowed per dose change occurrence.

TEZSPIRE (TEZEPELUMAB)

Updated January 4, 2024

Length of Authorization:	1 year
Initiative:	PAR: Tezspire: 2462 (IE 2462 / NCPDP 75 – HICL

FDA-APPROVED INDICATION(S)

For the add-on maintenance treatment of adult and pediatric patients 12 years of age and older with severe asthma.

FDA-RECOMMENDED DOSE

210 mg subcutaneously once every 4 weeks.

HOW SUPPLIED

210 mg/1.91 mL solution in a single-dose prefilled syringe (for administration by a healthcare provider) or pen (for self-administration).

UTILIZATION CRITERIA

- **For initial coverage requests:**
  - The member has a confirmed diagnosis of severe asthma; **AND**
  - The member is currently utilizing a high dose inhaled corticosteroid (ICS) product plus either a long-acting beta-2 agonist (LABA) or a long-acting muscarinic antagonist (LAMA); **AND**
  - The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib).
- **For continuation coverage requests:**
  - The member has experienced a decrease in the frequency of exacerbations and improvement in symptoms, as attested to by the member's specialist provider; **AND**
  - The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib).

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of current therapies.

AGE RESTRICTIONS

12 years of age or older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an asthma specialist, allergist, or pulmonologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OTHER INFORMATION

Members transitioning from medical benefit to the pharmacy benefit should be treated as a continuation of therapy requests.

THALOMID® (THALIDOMIDE)

Updated: May 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Thalomid (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of newly diagnosed multiple myeloma (MM), in combination with dexamethasone.
- For the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL).
- As maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

FDA-RECOMMENDED STARTING DOSE

- For MM: 200 mg orally once daily.
- For ENL: 100 to 400 mg orally once daily.

HOW SUPPLIED

50 mg, 100 mg, 150 mg, and 200 mg capsules in 28-count blister packs.

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of one of the following:
  - Erythema nodosum leprosum (ENL),
  - Multiple myeloma
  - Castleman Disease
  - The Rosai-Dorfman Disease; **AND**
    - The member plans on using the medication as a single agent
  - Langerhans Cell Histiocytosis; **AND**
    - The member plans on using the medication as a single agent
  - Kaposi Sarcoma; **AND**
    - The member has disease that has progressed or not responded to first-line and alternate first-line systemic therapy.
  - Myelofibrosis-associated anemia; **AND**
    - The member uses this medication in combination with a prednisone taper; **AND**
    - The member has one of the following:
      - Serum EPO ≥500 mU/mL
      - Serum EPO <500 mU/mL and no response or loss of response to erythropoiesis stimulating agents

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's oncologist.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

12 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

THIOLA® (TIOPRONIN)

Updated: July 31, 2023

Length of Authorization: 6 months initial, 12 months continuation
Initiative: PAR: Thiola (IE 2462 / NCPDP 75 – GSN; (IE 2641, 15110 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

For use in combination with high fluid intake, alkali, and diet modification, for the prevention of cystine stone formation in adults and pediatric patients 20 kg and greater with severe homozygous cystinuria, who are not responsive to these measures alone.

FDA-RECOMMENDED STARTING DOSE

- Adults: Initially 800 mg/day, divided in three doses.
- Pediatrics (≥ 20 kg): 15 mg/kg/day, divided in three doses. Titrated per efficacy and tolerability to reduce urinary cysteine level to < 250mg/L.

HOW SUPPLIED

- Thiola®: 100 mg instant-release tablets in 100-count bottles
- Thiola® EC: 100 mg and 300 mg delayed-release tablets in 300-count and 90-count bottles, respectively.

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of severe homozygous cystinuria; **AND**
- The member has a 24-hour urine collection with urinary cystine > 400 mg/day (1.7 mmol/day); **AND**
- The member has tried and failed all of the following, unless contraindicated:
  - High fluid intake, with urine output of at least 3 L/day
  - Urinary alkalization with potassium citrate or bicarbonate
  - Sodium and protein dietary restrictions
  - D-penicillamine

FOR CONTINUATION COVERAGE REQUESTS

Confirmation that the member continues to have a beneficial response to therapy as assessed and documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- Documentation of 24-hour urinary cystine levels
- Current weight (kg) if under 18 years of age

AGE RESTRICTIONS

2 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a nephrologist or urologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

6 months initial, 12 months continuation

QUANTITY/PARTIAL-FILL RESTRICTIONS

Internal note: enter PA with a metric quantity and days' supply sufficient for the on-label dosing requested.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

N/A

TIBSOVO® (IVOSIDENIB)

Updated: April 25, 2023

Length of Authorization:	5 years
Initiative:	PAR: Tibsovo (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) who have a specific genetic isocitrate dehydrogenase-1 (IDH1) mutation.
- For the treatment of newly diagnosed acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test in adult patients who are ≥ 75 years of age or who have comorbidities that preclude use of intensive induction chemotherapy.
- For the treatment of adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test

FDA-RECOMMENDED DOSE

500 mg orally once daily.

HOW SUPPLIED

250 mg tablets in 60-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- For Initial AML requests:
  - The member has a diagnosis of acute myeloid leukemia (AML); **AND**
  - The member has a susceptible IDH1 mutation; **AND**
  - The member must meet one of the following clinical scenarios:
    - The member has relapsed or refractory AML; **OR**
    - The member is aged 60 years of age or older with comorbidities that preclude use of intensive induction chemotherapy; **OR**
    - The member is aged 60 years of age or older and post-remission therapy following response to previous lower intensity therapy with the same regimen.

For Osteosarcoma:

- The member has a diagnosis of chondrosarcoma; **AND**
- The member has confirmation of a susceptible IDH1 mutation.

For Cholangiocarcinoma Requests:

- The member has a diagnosis of cholangiocarcinoma; **AND**
- The member has confirmation of a susceptible IDH1 mutation.

For CNS Cancer:

- The member has a diagnosis of oligodendroglioma; **AND**
- The member has a documentation of a susceptible IDH1 mutation; **AND**
- The member has documentation of 1p19q co-deletion.

Note: acceptable IDH1 mutations are R132H, R132C, R132G, R132S, and R132L. Alternative IDH1 mutations require submission of additional evidence showing susceptibility to ivosidenib.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Documentation of specific mutation or deletion statuses, as applicable.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

18 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

TOPICAL RETINOIDS (ADAPALENE 0.3% GEL, TAZAROTENE, AND TOPICAL TRETINOIN)

Updated: April 24, 2023

Length of Authorization:	5 years
Initiative:	• PAR: Topical Retinoids: (IE 2462 / NCPDP 75 – HICL, IE 2193, 2194 / NCPDP 60 – HICL) • STP: Tazorac (IE 31121 / NCPDP 608, 2194 / NCPDP 60 – HICL) • PAR: Adapalene (IE 2462 / NCPDP 75 – GSN)

POLICY INFORMATION

- Treatment of wrinkles is not a covered benefit.
- Tazarotene and Tretinoin: Prior authorization is required for members 40 years of age and older.
- Adapalene 0.3% gel: Prior authorization is required for all members.

FDA-APPROVED INDICATION(S)

- Adapalene 0.3% and Tretinoin: treatment of acne vulgaris.
- Tazarotene 0.05% and 0.1% are indicated for the topical treatment of patients with plaque psoriasis of up to 20% body surface area involvement.
- Tazarotene 0.1% is also indicated for the topical treatment of patients with facial acne vulgaris of mild to moderate severity.

FDA-RECOMMENDED DOSE

Apply once daily.

HOW SUPPLIED

- Adapalene 0.3% Gel
- Tazarotene 0.05% and 0.1% Gel
- Tretinoin:
  - Cream: 0.025%, 0.05% and 0.1%
  - Gel: 0.01%, 0.025% and 0.05%
  - Lotion: 0.05% (brand only)
  - Microsphere gel: 0.1% and 0.04%

COVERAGE CRITERIA

For Initial Coverage Requests:

- **Adapalene 0.3% Gel:**
  - The member must have a diagnosis of acne vulgaris; **AND**
  - The member has tried and failed over the counter (OTC) adapalene 0.1% for at least 12 weeks without satisfactory results.
- **Tazarotene:**
  - The member must have a diagnosis of plaque psoriasis or acne vulgaris; **AND**
  - The member has tried and failed generic tazarotene 0.1% cream.
- **Tretinoin topical:**
  - The member must have a diagnosis of acne vulgaris; **AND**
  - The member has tried and failed generic tretinoin 0.025%, 0.05%, or 0.1% cream (for microsphere gel and 0.05% gel only).

For Continuation Coverage Requests:

- The member must have a diagnosis of acne vulgaris (or psoriasis for tazarotene only); **AND**
- The member has had a positive clinical response to therapy, as documented by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

N/A

COVERAGE DURATION

5 years.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

- Adapalene: approve by GSN.
- Tazarotene and tretinoin: approve by HSN.
- When used for wrinkles, topical retinoids are not a covered benefit.
- Adapelene 0.1% is a plan exclusion (available OTC).

TOUJEO®, TOUJEO® MAX (INSULIN GLARGINE 300 UNITS/ML)

Updated: May 18, 2023

Length of Authorization:	5 years
Initiative:	PAR: Toujeo (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

Indicated to improve glycemic control in adults and pediatric patients 6 years of age and older with diabetes mellitus.

FDA-RECOMMENDED DOSE

Dose individualized

HOW SUPPLIED

- Toujeo® (300 units/mL): 1.5 mL pen
- Toujeo® Max (300 unit/mL): 3 mL pen

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member must have a diagnosis of diabetes mellitus; **AND**
- The member requires 100 units or more of insulin glargine per dose.

For Continuation Coverage Requests:

- The member has had a positive clinical response to therapy, as documented by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

6 years of age and older

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

N/A

COVERAGE DURATION

18 years

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary quantity limits.

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

N/A

TREMFYA® (GUSELKUMAB)

Updated: December 18, 2023

Length of Authorization:	12 months.
Initiative:	PAR: Tremfya (IE 2462 / NCPDP 75 – GSN) PAR: Loading Dose (IE 15110, 2641, 7001 / NCPDP 76 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients with
  - Moderate-to-severe plaque psoriasis (PSO) who are candidates for systemic therapy or phototherapy
  - Active psoriatic arthritis

FDA-RECOMMENDED DOSE

Dosed 100 mg subcutaneously at week 0, 4, and every 8 weeks thereafter.

HOW SUPPLIED

Supplied as a single-dose 100 mg/mL prefilled syringe and injector system.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- For All Indications:
  - The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)
- For PsO:
  - The member has a diagnosis of moderate-to-severe plaque psoriasis (PsO); **AND**
  - The member has psoriatic lesions that involve greater than or equal to 10% of body surface area (BSA) or that affect the palms, soles, head, neck, or genital area, leading to disability/impact on quality of life; **AND**
  - The member has had a previous trial of or contraindication to at least one of the following:
    - PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B)
    - Topical corticosteroids
    - Calcipotriene
    - Acitretin
    - Methotrexate
    - Cyclosporine
- For PsA:
  - The member has a diagnosis of active Psoriatic Arthritis (PsA); **AND**
  - The member has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs):
    - Methotrexate
    - Leflunomide
    - Cyclosporine
    - Sulfasalazine.

FOR CONTINUATION COVERAGE REQUEST

- The member must have a beneficial response to therapy as assessed and documented by the member's specialist provider; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

REQUIRED MEDICAL INFORMATION

For Initial Coverage Requests:

- For members treated for PsO: current BSA coverage of lesions.
- Claims or medical records demonstrating use of previous therapies

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a rheumatologist or dermatologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATIONS

Duration of approval: 12 months.

QUANTITY LIMITS

- Loading dose:
  - Enter second PA per 1 month with a metric quantity and days' supply of #1/28 DS (one 100 mg pen or injector for a 28-day supply, with a fill count of 1).
  - Use initiative PAR: Loading Dose
  - Select CTI reason code: 2nd **or** for Existing PA Approved. No approval letter is sent with second PA.
- For continuation requests: Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN

TRIKAFTA® (ELEXACAFTOR/TEZACAFTOR/IVACAFTOR)

Updated: October 31, 2023

Length of Authorization:	12 months (initial), 5 years (continuation)
Initiative:	PAR: Trikafta (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of cystic fibrosis (CF) in patients aged 2 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on in vitro data.

FDA-RECOMMENDED DOSE

- Taken orally twice daily approximately 12 hours apart. The morning dose consists of two tablets (each containing elexacaftor 100 mg, tezacaftor 50 mg, and ivacaftor 75 mg). The evening dose consists of one tablet (containing ivacaftor 150 mg).
- Refer to package insert for pediatric weight-based dosing.

HOW SUPPLIED

- Elexacaftor 50 mg, tezacaftor 25 mg, and ivacaftor 37.5 mg tablets
  - 84-count tablet carton (4 wallets, each wallet containing 14 tablets of elexacaftor, tezacaftor, and ivacaftor and 7 tablets of ivacaftor)
- Elexacaftor 100 mg, tezacaftor 50 mg, and ivacaftor 75 mg tablets
  - 84-count tablet carton (4 wallets, each wallet containing 14 tablets of elexacaftor, tezacaftor, and ivacaftor and 7 tablets of ivacaftor)
- Elexacaftor 80 mg, tezacaftor 40 mg, and ivacaftor 60 mg oral granules.
  - 56-count packet carton (4 wallets, each containing 7 packets of elexacaftor, tezacaftor, and ivacaftor and 7 packets of ivacaftor)
- Elexacaftor 100 mg, tezacaftor 50 mg, and ivacaftor 75 mg oral granules
  - 56-count packet carton (4 wallets, each containing 7 packets of elexacaftor, tezacaftor, and ivacaftor and 7 packets of ivacaftor)

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a documented diagnosis of CF; **AND**
- The member has at least one mutation in the CFTR gene that is responsive to elexacaftor/tezacaftor/ivacaftor (see package insert clinical pharmacology section for list of acceptable mutations); **AND**
- The member's baseline percent predicted forced expiratory volume in 1 second (ppFEV1) is at least 40% or greater (as documented by lab report or chart notes); **AND**
- The member does not have either of the following:
  - ALT or AST > 5x ULN.
  - ALT or AST > 3x ULN with bilirubin > 2x ULN.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy as assessed and documented by the member's specialist provider, and as supported by one of the following:
  - Maintenance or improvement in ppFEV1; **OR**

- Maintenance or improvement in BMI (body mass index); **OR**
- Reduction in pulmonary exacerbations; **AND**

- The member does not have either of the following:
  - ALT or AST > 5x ULN.
  - ALT or AST > 3x ULN with bilirubin > 2x ULN.

REQUIRED MEDICAL INFORMATION

- Genomic testing showing required mutation(s).
- ppFEV1 with date (required for initial and optional for continuation if other criteria met).
- AST/ALT levels.
- Bilirubin levels if applicable.

AGE RESTRICTIONS

2 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a pulmonologist or cystic fibrosis specialist.

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 1 year
- Continuation: 5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

If approved, term any active PA for Kalydeco®, Orkambi®, and/or Symdeko®.

TROFENETIDE (DAYBUE)

Updated: May 3, 2023

Length of Authorization:	Initial: 3 months. Continuation: 6 months.
Initiative:	PAR: Daybue: (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older.

FDA-RECOMMENDED DOSE

Patient Weight	Trofinetide Dosage	Trofinetide Volume
9–11 kg	5,000 mg twice daily	25 mL twice daily
12–19 kg	6,000 mg twice daily	30 mL twice daily
20–34 kg	8,000 mg twice daily	40 mL twice daily
35–49 kg	10,000 mg twice daily	50 mL twice daily
≥ 50 kg	12,000 mg twice daily	60 mL twice daily

HOW SUPPLIED

200 mg/mL oral solution supplied in 450 mL bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of classic or typical Rett syndrome; **AND**
- The member is a biological female; **AND**
- The member has documentation of the MECP2 mutation.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Documented MECP2 mutation

AGE RESTRICTIONS

5-20 years of age.

PRESCRIBER RESTRICTIONS

Must be prescribed by a neurologist or a pediatric geneticist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 3 months.
- Continuation: 6 months.

QUANTITY RESTRICTIONS

- For 9–11 kg, refer to formulary.
- For all weights above 11 kg, enter a quantity exception override to permit dosing in accordance with FDA label.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

TRULANCE® (PLECANATIDE)

Updated: November 30, 2023

Length of Authorization:	12 months
Initiative:	PAR: Trulance (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of Chronic Idiopathic Constipation (CIC) in adults and Irritable Bowel Syndrome with Constipation (IBS-C) in adults

FDA-RECOMMENDED DOSAGE

CIC and IBS-C: 3 mg once daily

HOW SUPPLIED

3 mg tablets in 30-count bottles and blister packs.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member must meet one of the following:
  - Have clinically diagnosed CIC with symptoms persisting for at least 3 months; **OR**
  - Have clinically diagnosed IBS-C with symptoms persisting for at least 3 months; **AND**
- The member has attempted lifestyle changes, including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; **AND**
- The member must not have a known or suspected mechanical gastrointestinal obstruction or perforation; **AND**
- The member must not be on concurrent tenapanor, lubiprostone, linaclotide, or prucalopride.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider; **AND**
- The member must not be taking concurrent tenapanor, lubiprostone, linaclotide, or prucalopride.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a gastroenterologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

TRUQAP®(CAPIVASERTIB)

Updated: March 25, 2024

Length of Authorization:	5 years
Initiative:	PAR: Truqap (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- Used in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alteration as detected by an FDA-approved test following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.

FDA-RECOMMENDED DOSAGE

400 mg orally twice daily for 4 days, followed by 3 days off.

HOW SUPPLIED

160 mg or 200 mg tablets in 64-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of HR-positive, HER2-negative, advanced, or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN alterations; **AND**
- The member must have disease progression following one line of endocrine therapy or recurrence on or within 12 months of completing adjuvant therapy; **AND**
- The member must have a clinical reason for not using alpelisib supported with documentation and rationale; **AND**
- The member must not have experienced disease progression on or following other PI3K/AKT/PTEN inhibitors; **AND**
- The provider attests that the member will be receiving capivasertib in combination with fulvestrant.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- PIK3CA/AKT1/PTEN alteration status documentation.
- Claims or medical records demonstrating use of previous therapies.
- Clinical rationale or documentation for why alpelisib (Piqray) is inappropriate for use in member

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

TUKYSA® (TUCATINIB)

Updated: March 24, 2023

Length of Authorization:	5 years
Initiative:	PAR: Tukysa (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- In combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.
- In combination with trastuzumab for the treatment of adult patients with RAS wild-type, HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

FDA-RECOMMENDED DOSE

300 mg orally twice daily (in combination with trastuzumab and capecitabine for breast cancer; in combination with trastuzumab for colorectal cancer).

HOW SUPPLIED

50 mg in 60-count bottles and 150 mg in 60- and 120-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **For breast cancer:**
  - The member has a documented diagnosis of HER2-positive breast cancer; **AND**
  - The member meets one of the following:
    - The member has received at least one prior anti-HER2 therapy (e.g., trastuzumab, pertuzumab, or ado-trastuzumab); **OR**
    - The member has brain metastases and will be receiving concomitant capecitabine and trastuzumab.
- **For colorectal cancer:**
  - The member has a documented diagnosis of RAS wild-type, HER2-positive unresectable or metastatic colorectal cancer.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's oncologist.

REQUIRED MEDICAL INFORMATION

- HER2 tumor status
- RAS-wild type confirmation, as applicable.
- Chart notes or medical records supporting diagnosis.
- Claims or medical records demonstrating use of previous therapies, as applicable.

AGE RESTRICTIONS

18 years of age or older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by HICL.

TURALIO® (PEXIDARTINIB)

Updated: January 17, 2024

Length of Authorization:	5 years
Initiative:	PAR: Turalio (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

FDA-RECOMMENDED DOSE

250 mg taken orally twice daily with a low-fat meal (approximately 11 to 14 grams of total fat).400 mg orally twice daily.

HOW SUPPLIED

125 mg capsules in 28-count and 120-count bottles.

UTILIZATION CRITERIA

For initial coverage requests:

- For TGCT:
  - The member must be diagnosed with diffuse or recurrent TGCT; **AND**
  - The member has severe impairment not amenable to improvement with surgery.
- For histiocytic neoplasm:
  - The member must be diagnosed with Erdheim-Chester Disease, Rosai-Dorfman Disease, or Langerhans Cell Histiocytosis; **AND**
  - The member has documented colony stimulating factor 1 receptor (CSF1R) mutation.

For continuation coverage requests:

- Member has had a positive clinical response to therapy, as documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

For histiocytic neoplasm: Documentation of CSF1R mutation.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or rheumatologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

TYKERB® (LAPATINIB)

Updated December 21, 2023

Length of Authorization:	5 years
Initiative:	PAR: Tykerb (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- In combination with the following:
  - Capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress human epidermal growth factor receptor 2 (HER2) and who have received prior therapy, including an anthracycline, a taxane, and trastuzumab.
  - Letrozole for the treatment of postmenopausal women with hormone receptor-positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated.

FDA-RECOMMENDED DOSE

- HER2-Positive Metastatic Breast Cancer: 1,250 mg given orally once daily on days 1–21 continuously in combination with capecitabine 2,000 mg/m^2/day (administered orally in 2 doses approximately 12 hours apart) on days 1–14 in a repeating 21-day cycle.
- Hormone Receptor-Positive, HER2-Positive Metastatic Breast Cancer: 1,500 mg given orally once daily continuously in combination with letrozole 2.5 mg once daily.

HOW SUPPLIED

250 mg tablets in 150-count bottles.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- Chordomas:
  - The member has a diagnosis of conventional or chondroid chordoma; **AND**
  - The member's condition is described as recurrent; **AND**
  - The member has EGFR-positive disease.
- Breast cancer:
  - The member has a diagnosis of breast cancer; **AND**
  - The member meets one of the following clinical scenarios:
    - The member has hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-positive disease; **AND**
      - The member's condition is described as recurrent unresectable (local or regional) or stage IV (M1); **AND**
      - The member meets one of the following descriptions:
        - Postmenopausal female
        - Premenopausal female treated with ovarian ablation/suppression
        - Male undergoing concomitant suppression of testicular steroidogenesis.
    - The member has HER2-positive disease; **AND**
      - The member's condition is described as recurrent unresectable (local or regional) or stage IV (M1); **AND**
      - The member is using lapatinib as third-line therapy or beyond; **AND**

        - The member will be using lapatinib in combination with either trastuzumab (without cytotoxic therapy) or capecitabine.
    - The member has brain metastases related to their HER2 positive breast cancer; **AND**
        - The member will be using lapatinib in combination with capecitabine.
- CNS Cancer:
    - The member has a diagnosis of intracranial or spinal ependymoma (excluding subependymoma); **AND**
    - The member's condition is described as recurrent; **AND**
    - The member will be using lapatinib in combination with temozolomide; **AND**
    - The member has received previous radiation therapy; **AND**
    - The member has, or has had, one of the following:
        - Gross total or subtotal resection with negative cerebrospinal fluid (CSF) cytology; **OR**
        - Subtotal resection and evidence of metastasis (brain, spine, or CSF); **OR**
        - Unresectable disease.
- Colon or Rectal Cancer:
    - The member has a diagnosis of unresectable, advanced or metastatic, colon or rectal cancer (HER2-amplified and RAS and BRAF wild type); **AND**
    - The member has not previously been treated with a HER2 inhibitor; **AND**
    - The member will be using lapatinib in combination with trastuzumab; **AND**
    - The member has previously been treated with an NCCN-recommended prior regimen or is not appropriate for intensive chemotherapy.

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies as applicable to place in therapy

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

18 years.

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by HSN

TYRVAYA™ (VARENICLINE TARTRATE)

Updated: July 31, 2023

Length of Authorization:	Initial: 1 year Renewal: 5 years
Initiative:	Par: Tyrvaya (IE 2462 / NCPDP 75 – GSN)

POLICY AND PRODUCT INFORMATION

- The prescription drug plan covers varenicline tartrate nasal spray after a trial and failure of cyclosporine ophthalmic emulsion 0.05%.
- Concomitant use of varenicline tartrate with another prescription dry eye treatment is not covered and detailed in the utilization criteria.

FDA-APPROVED INDICATION(S)

For the treatment of the signs and symptoms of dry eye disease.

FDA-RECOMMENDED DOSE

One spray (0.03 mg varenicline per 0.05 mL spray) in each nostril twice daily.

HOW SUPPLIED

Two 60-spray (4.2 mL) nasal spray bottles per carton.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of dry eye, dry eye disease, or dry eye syndrome; **AND**
- The member will not be using cyclosporine ophthalmic emulsion 0.05%, cyclosporine ophthalmic solution 0.09%, lifitegrast ophthalmic solution, or hydroxypropyl cellulose insert concomitantly with Tyrvaya™ (varenicline tartrate); **AND**
- The member meets one of the following scenarios:
  - The member has tried and failed a minimum 1-month trial of cyclosporine ophthalmic emulsion; **OR**
  - The member is expected to have mechanical difficulty administering eye drops due to another condition (e.g., Parkinson's disease, arthritis, etc.).

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies as applicable

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an ophthalmologist or optometrist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 1 year
- Continuation: 5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

VALTOCO® (DIAZEPAM NASAL SPRAY)

Updated: May 9, 2023

Length of Authorization:	Five years
Initiative:	PAR: Valtoco (IE 2462 / NCPDP 75 – HICL

FDA-APPROVED INDICATION(S)

For the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 6 years of age and older.

FDA-RECOMMENDED DOSE

- Recommended dosing is between 5–20 mg per dose and depends on the patient's specific age and weight.
- **Initial dose:** 5 mg and 10 mg doses are administered as a single spray into one nostril. Administration of 15 mg and 20 mg doses requires two nasal spray devices, one spray into each nostril.
- **Second dose:** A second dose, when required, may be administered at least 4 hours after the initial dose. If administered, use a new blister pack.
- Should be used to treat no more than one episode every five days and no more than five episodes per month.

HOW SUPPLIED

- 5 mg carton: 2 individual blister packs, each containing one 5 mg nasal spray device
- 10 mg carton: 2 individual blister packs, each containing one 10 mg nasal spray device
- 15 mg carton: 2 individual blister packs, each containing two 7.5 mg nasal spray devices
- 20 mg carton: 2 individual blister packs, each containing two 10 mg nasal spray devices

UTILIZATION CRITERIA

The member has a diagnosis of intermittent, stereotypic episodes of frequent seizure activity.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

6 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a neurologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

Five years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL AND OTHER INFORMATION

Approve by HICL.

VASCEPA® (ICOSAPENT ETHYL)

Updated: October 30, 2023

Length of Authorization:	5 years
Initiative:	PAR: Vascepa (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.
- As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

FDA-RECOMMENDED DOSE

4 grams per day, taken as either four 0.5-gram capsules twice daily or two 1 gram capsules twice daily.

HOW SUPPLIED

0.5 gram capsules in 240-count bottles and 1 gram capsules in 120-count bottles.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS (PRIMARY ASCVD PREVENTION)

- The member has TG levels ≥ 500 mg/dL **or** has type-2 diabetes with TG levels ≥ 150 mg/dL; **AND**
- The member is currently on statin or PCSK9 therapy, unless otherwise contraindicated; **AND**
- The member has tried and failed a generic fibric acid derivative (fenofibrate, fenofibric acid, or gemfibrozil), unless otherwise contraindicated.

FOR INITIAL COVERAGE REQUESTS (SECONDARY ASCVD PREVENTION)

- The member has established cardiovascular disease; **AND**
- The member has elevated triglycerides ≥ 150 mg/dL; **AND**
- The member is currently on a statin or PCSK9 therapy, unless otherwise contraindicated.

FOR CONTINUATION COVERAGE REQUESTS

The member must have documentation of clinical benefit as attested to by the member's prescribing provider.

REQUIRED MEDICAL INFORMATION

Chart notes or medical records documenting current TG levels

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a cardiologist, lipid specialist, or endocrinologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

N/A

VEOZAH® (FEZOLINETANT)

Updated: April 23, 2024

Length of Authorization:	12 months
Initiative:	PAR: Veozah (2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of moderate to severe vasomotor symptoms (VMS) due to menopause.

FDA-RECOMMENDED DOSAGE

45 mg orally once daily.

HOW SUPPLIED

45 mg tablets in 30- or 90-count bottle.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of moderate to severe VMS due to menopause, AND
- The member has tried and failed three (3), unless contraindicated to all, agents for VMS due to menopause in the following classes:
  - Hormone therapy
  - SSRI/SNRI
  - Gabapentinoid
  - Oxybutynin

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A.

AGE RESTRICTIONS

N/A.

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

VENCLEXTA® (VENETOCLAX)

Updated: March 24, 2023

Length of Authorization:	5 years
Initiative:	PAR: Venclexta (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
- In combination with acytidine, or decitabine, or low-dose cytarabine for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults who are aged 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

FDA-RECOMMENDED DOSE

See package insert for ramp-up and maintenance dosing schedules.

HOW SUPPLIED

10 mg, 50 mg, and 100 mg tablets in various blister packs, wallets, and bottle sizes.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **For CLL/SLL:**
  - The member has a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
- **For Newly Diagnosed AML:**
  - The member has newly diagnosed acute myeloid leukemia (AML) OR the member has residual disease after 1 cycle of induction therapy; **AND**
  - The member will be using venetoclax with azacytidine, decitabine, or low-dose cytarabine; **AND**
  - The member meets one of the following:
    - The member is at least 60 years of age; **OR**
    - The member is unable to receive intensive induction therapy due to comorbidities (e.g., ECOG > 2, moderate hepatic impairment, severe cardiac or pulmonary disease, Creatinine clearance < 45 mL/min, serum albumin < 3.2 g/dL).
- **For Relapsed/Refractory AML:**
  - The member has a diagnosis of relapsed or refractory AML.
- **For Mantle Cell Lymphoma (MCL):**
  - The member has a diagnosis of mantle cell lymphoma (MCL); **AND**
  - The member has received induction therapy for their MCL.
- **For Multiple Myeloma (MM):**
  - The member has relapse or progression of previously treated multiple myeloma; **AND**
  - The member has t(11;14) cytogenetics; **AND**
  - The member will be using venetoclax with dexamethasone.

- **For Systemic Light Chain Amyloidosis (relapsed or refractory):**
  - The member has a diagnosis of relapsed or refractory systemic light chain amyloidosis; **AND**
  - The member has t(11;14) cytogenetics.
- **For Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma:**
  - The member has a diagnosis of Waldenström macroglobulinemia/lymphoplasmacytic lymphoma (WM/LPL), **AND**
  - The member's disease has been previously treated.

For Continuation Coverage Requests:

- Member has had a positive clinical response to therapy, as documented by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

For Initial Coverage Requests:

- **For Newly Diagnosed AML:**
  - Documentation of comorbidities precluding intensive induction therapy.
- **For Systemic Light Chain Amyloidosis and MM diagnosis**:
  - Documentation of t(11;14) cytogenetics.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or a hematologist

REVIEWER REQUIREMENTS

Must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

18 years

QUANTITY RESTRICTIONS

Refer to formulary quantity limits.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

VERQUVO® (VERCIGUAT)

Updated: November 3, 2023

Length of Authorization:	24 months
Initiative:	PAR: Verquvo (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

To reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction (EF) less than 45%.

FDA-RECOMMENDED DOSE

- 2.5 mg by mouth once daily with food.
- Double the dose approximately every 2 weeks to reach the target maintenance dose of 10 mg once daily, as tolerated.

HOW SUPPLIED

- 2.5 mg and 5 mg tablets in 14-count bottle, 30-count bottle, and 100-count carton of 10 blister cards.
- 10 mg tablets in 30-count bottle, 90-count bottle, and 100-count carton of 10 blister cards

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member's baseline NT-proBNP levels are less than 5,300 (i.e., Q4); **AND**
- The member has an Implantable Cardioverter Defibrillator (ICD), or biventricular pacemaker implemented prior to treatment; **AND**
- The member has a diagnosis of chronic heart failure (i.e., NYHA Class II, III, or IV) with reduced ejection fraction (i.e., < 45%) and worsening heart failure, defined as
  - a decompensation event of hospitalization for heart failure within the last 6 months of the time of initial review; **OR**
  - outpatient IV diuretic therapy for heart failure within the last 3 months of the time of initial review; **AND**
- The member is actively adherent to maximally tolerated ACC/AHA guideline-directed medical therapy (GDMT) for heart failure, as attested to by the physician, for at least 3 months prior to decompensation event, unless otherwise contraindicated or not tolerated, including:
  - One of the following: ACE inhibitor or ARB or angiotensin II–neprilysin inhibitor (ARNI);
  - An evidence-based beta-blocker (i.e., carvedilol, metoprolol, or bisoprolol);
  - A mineralocorticoid receptor antagonist (i.e., spironolactone or eplerenone);
  - An SGLT2 inhibitor (i.e., dapagliflozin or empagliflozin);
  - Ivabradine, for patients with NYHA Class II or III, a resting heart rate of ≥ 70 bpm, and on a maximally tolerated beta-blocker in sinus rhythm;
  - Hydralazine/isosorbide dinitrate, for patients with NYHA Class III or IV **or** for patients who do not tolerate an ACE inhibitor, ARB, or ARNI.

For Renewal Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

- Chart notes or medical records documenting:
  - Diagnosis; **AND**
  - Baseline NT-proBNP levels; **AND**
  - Implant status; **AND**
  - Current therapeutic regimen.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a cardiologist.

COVERAGE DURATION

24 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by HICL.

VERZENIO® (ABEMACICLIB)

Updated: May 1, 2023

Length of Authorization:	12 months Maximum of 2 years of treatment for early breast cancer indication.
Initiative:	PAR: Verzenio (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- In combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence:
  - In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.
  - In combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy
  - As monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting

FDA-RECOMMENDED INITIAL DOSE

- 150 mg orally twice daily with fulvestrant, tamoxifen, or an aromatase inhibitor.
- 200 mg orally twice daily as monotherapy.

HOW SUPPLIED

50, 100, 150, and 200 mg tablets in 14-count (7-day) blister packs.

UTILIZATION CRITERIA

For Initial coverage requests:

- **Advanced or metastatic breast cancer:**
  - The member must have documentation of HR-positive, HER2-negative metastatic breast cancer; **AND**
  - The member must be a postmenopausal women OR premenopausal women treated with ovarian ablation or suppression **or** a man, **AND**
  - The member will use abemaciclib:
    - With an aromatase inhibitor as initial endocrine therapy; **OR**
    - With fulvestrant with disease progression following endocrine therapy; **OR**
    - As monotherapy following prior chemotherapy and endocrine therapy; **OR**
    - As second-line therapy or beyond in combination with fulvestrant if a CDK4/6 inhibitor has not previously been used.
- **Early breast cancer:**
  - The member must have documentation of HR-positive, HER2-negative; **AND**
  - The member is high risk of recurrence.

For Continuation Coverage Requests:

- The member must have confirmed response to treatment, as attested to by the member's treating oncologist.

REQUIRED MEDICAL INFORMATION

Tumor status (HR/HER2)

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

- 12 months
- Maximum of 2 years of treatment for early breast cancer indication.

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by HICL.

VIBERZI® (ELUXADOLINE)

Updated: July 26, 2023

Length of Authorization:	12 months
Initiative:	PAR: Viberzi (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of irritable bowel syndrome with diarrhea (IBS-D).

FDA-RECOMMENDED DOSE

100 mg orally twice daily

HOW SUPPLIED

75 mg and 100 mg tablets

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D) with uncontrolled symptoms; **AND**
- The member has had other GI conditions ruled out that could explain these symptoms (abdominal pain, diarrhea, constipation, bloating, urgency, incomplete evacuation, mucus, sense of incomplete evacuation, or gas); **AND**
- The member has tried and failed, or is contraindicated to, at least one OTC antidiarrheal agent such as loperamide, **AND**
- The member has tried and failed, or is contraindicated to, rifaximin (Xifaxan), **AND**
- The member does not have any of the following contraindications:
  - Biliary duct obstruction
  - Consume more than 3 alcoholic beverages per day
  - History of pancreatitis (including known or suspected pancreatic duct obstruction)
  - Severe hepatic impairment (Child-Pugh Class C)
  - History of chronic or severe constipation

FOR CONTINUATION COVERAGE REQUESTS

Member has had a positive clinical response to therapy, as documented by the member's gastroenterology provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a gastroenterologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by HSN.

VITRAKVI® (LAROTRECTINIB)

Updated: April 25, 2023

Length of Authorization:	5 years
Initiative:	PAR: Vitrakvi (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity and have no satisfactory alternative treatments or that have progressed following treatment.

FDA-RECOMMENDED DOSAGE

100 mg orally twice daily

HOW SUPPLIED

- 25 mg and 100 mg capsules in 60-count bottles
- 20 mg/mL oral solution in 100 mL bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a neurotrophic tyrosine kinase (NTRK) fusion positive solid tumor cancer**.**

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by an oncologist.

REQUIRED MEDICAL INFORMATION

Documentation of NTRK gene fusion

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

18 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approval by HICL.

VIZIMPRO® (DACOMITINIB)

Updated: April 28, 2023

Length of Authorization:	5 years
Initiative:	PAR: Vizimpro (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test

FDA-RECOMMENDED STARTING DOSE

45 mg once daily

HOW SUPPLIED

15 mg, 30 mg, and 45 mg tablets in 30-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of NSCLC; **AND**
- The member's tumor expresses one of the following:
  - EGFR S768I mutation
  - EGFR L861Q mutation
  - EGFR G719X mutation
  - EGFR exon 19 deletion
  - Exon 21 L858R mutation

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's oncologist

REQUIRED MEDICAL INFORMATION

Lab results confirming applicable tumor mutation/deletions.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL INSTRUCTIONS/ADDITIONAL INFORMATION

Approve by HICL.

VONJO® (PACRITINIB)

Updated: October 26, 2023

Length of Authorization:	5 years
Initiative:	PAR: Vonjo (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) with a platelet count below 50 × 109/L.

FDA-RECOMMENDED DOSE

200 mg orally twice daily.

HOW SUPPLIED

100 mg capsules in 120-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of myelofibrosis (MF); **AND**
- The member meets one of the following clinical scenarios:
  - The member has prognostic scoring indicative of intermediate or high-risk primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis (PPV MF), or post-essential thrombocythemia myelofibrosis (PET MF); **AND**
    - The member is not a transplant candidate; **AND**
      - The member has a platelet count below 50 × 109/L; **OR**
  - The member has prognostic scoring indicative of low-risk PMF, PPV MF, or PET MF; **AND**
    - The member's condition is symptomatic; **AND**
    - The member has a platelet count below 50 × 109/L; **AND**
    - The member has tried and failed therapy with ruxolitinib, peginterferon alfa-2a, or hydroxyurea.

For Continuation Coverage Requests:

- The member must have a documented 35% reduction in spleen volume as measured by CT or MRI (or 50% reduction in palpable spleen length); **OR**
- The member must have a documented decrease in symptoms vs baseline.

REQUIRED MEDICAL INFORMATION

Any specific medical information required for confirming diagnosis or dosage.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by a hematologist or oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

VOSEVI® (SOFOSBUVIR, VELPATASVIR, AND VOXILAPREVIR)

Updated: October 26, 2023

Length of Authorization:	12 weeks
Initiative:	PAR: Vosevi (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with chronic hepatitis C (HCV) without cirrhosis or with compensated cirrhosis (Child-Pugh A), and:

FDA-RECOMMENDED DOSE

One tablet daily for 12 weeks.

HOW SUPPLIED

Sofosbuvir 400 mg/velpatasvir 100 mg/voxilaprevir 100 mg tablet in a 28-count bottle.

UTILIZATION CRITERIA

FOR ALL COVERAGE REQUESTS

- The member has a diagnosis of HCV; **AND**
- The member has had an HCV RNA drawn and measured within the previous 6 months; **AND**
- The member meets one of the following prior therapy scenarios:
  - For HCV genotypes 1-6, the member has previously received treatment with one of the following NS5A agents: daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir; **OR**
  - For HCV genotypes 1a and 3, the member has previously received treatment with a sofosbuvir-containing regimen without an NS5A inhibiting component; **AND**
- The member has been evaluated to be absent of current alcohol or other substance abuse issues and has been advised/cautioned on such activities.

REQUIRED MEDICAL INFORMATION

- HCV RNA viral load with date, HCV genotype.
- Previous treatment history.

AGE RESTRICTIONS

18 years of age or older.

PRESCRIBER RESTRICTIONS

Must be prescribed by a gastroenterologist, hepatologist, or infectious disease specialist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 weeks

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

VOTRIENT® (PAZOPANIB)

Updated February 1, 2024

Length of Authorization:	5 years
Initiative:	PAR: Votrient (IE 2462/NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of adults with advanced renal cell carcinoma (RCC).
- For the treatment of adults with advanced soft tissue sarcoma (STS) who have received prior chemotherapy.

FDA-RECOMMENDED DOSE

800 mg (four 200 mg tablets) orally once daily

HOW SUPPLIED

200 mg tablets in 120-count bottles.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of one of the following:
  - Metastatic Chondrosarcoma; **OR**
  - Gastrointestinal Stromal Tumors (GIST); **OR**
  - Advanced/Metastatic Non-adipocytic Sarcoma; **OR**
  - Desmoid Tumors (Aggressive Fibromatosis); **OR**
  - Advanced/Metastatic Pleomorphic Rhabdomyosarcoma; **OR**
  - Alveolar Soft Part Sarcoma (ASPS); **OR**
  - Angiosarcoma; **OR**
  - Dermatofibrosarcoma Protuberans (DFSP) with Fibrosarcomatous Transformation; **OR**
  - Dedifferentiated Chordoma; **OR**
  - Solitary Fibrous Tumor; **OR**
  - von Hippel-Lindau (VHL)-associated Renal Cell Carcinoma; **OR**
  - Relapsed or Stage IV Renal Cell Carcinoma; **OR**
  - Follicular Thyroid Carcinoma; **OR**
  - Hürthle Cell Thyroid Carcinoma (aka Oncocytic Carcinoma); **OR**
  - Papillary Thyroid Carcinoma; **OR**
  - Medullary Thyroid Carcinoma; **OR**
  - Recurrent uterine neoplasm

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies as applicable to place in therapy.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

18 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by GSN

VOXZOGO® (VOSORITIDE)

Updated: October 23, 2023

Length of Authorization:	12 months
Initiative:	PAR: Voxzogo (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

To increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses. This indication is approved under accelerated approval based on an improvement in annualized growth velocity.

FDA-RECOMMENDED DOSE

Dose is based on the patient's actual body weight and is administered subcutaneously once daily.

Actual Body Weight	Vial Strength for Reconstitution*	Dose	Injection Volume
10–11 kg	0.4 mg	0.24 mg	0.3 mL
12–16 kg	0.56 mg	0.28 mg	0.35 mL
17–21 kg	0.56 mg	0.32 mg	0.4 mL
22–32 kg	0.56 mg	0.4 mg	0.5 mL
33–43 kg	1.2 mg	0.5 mg	0.25 mL
44–59 kg	1.2 mg	0.6 mg	0.3 mL
60–89 kg	1.2 mg	0.7 mg	0.35 mL
≥ 90 kg	1.2 mg	0.8 mg	0.4 mL

* The concentration of vosoritide in reconstituted 0.4 mg vial and 0.56 mg vial is 0.8 mg/mL. The concentration of vosoritide in reconstituted 1.2 mg vial is 2 mg/mL.

HOW SUPPLIED

Single-dose 2 mL vials containing 1.2 mg, 0.56 mg, or 0.4 mg of vosoritide in packs of 10 vials.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has a diagnosis of achondroplasia with genetic testing confirming fibroblast growth factor receptor 3 (FGFR3) mutation; **AND**
- The member must have open epiphyses at the time of the request, as attested to by the member's prescriber; **AND**
- The member will not be receiving any concurrent human growth hormone treatments (e.g., Genotropin, Humatrope, etc.); **AND**
- The member does not have planned limb lengthening surgery during therapy with vosoritide

FOR CONTINUATION COVERAGE REQUESTS

- The member must have experienced an increase in annualized growth velocity compared to their baseline annualized growth velocity value, as substantiated by chart note documentation; **AND**
- The member must have open epiphyses at the time of the request, as attested to by the member's prescriber.

REQUIRED MEDICAL INFORMATION

- Current weight for all requests.
- Documentation of FGFR3 mutation for initial requests.
- Documented baseline and current annualized growth rates for continuation requests.

AGE RESTRICTIONS

Member must be 5–18 years of age.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an endocrinologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

- Approve for a maximum quantity per 30 days commensurate with appropriate FDA dose for the member's submitted weight.
  - When calculating restriction, add 10 kg to the member's current weight to allow for growth during their approval cycle.

OPERATION NOTES AND OTHER INFORMATION

Approve by HICL.

VYLEESI® (BREMELANOTIDE)

Updated: November 15, 2023

Length of Authorization:	12 months
Initiative:	PAR: Vyleesi (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to a co-existing medical or psychiatric condition, problems with the relationship, or the effects of a medication or drug substance.

FDA-RECOMMENDED DOSE

1.75 mg subcutaneously as needed, 45 minutes before anticipated sexual activity.

HOW SUPPLIED

1.75 mg/0.3 mL single-dose, disposable prefilled autoinjector in 4-count cartons.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member is a premenopausal woman; **AND**
- The member has a diagnosis of HSDD; **AND**
- The member's symptoms of HSDD have been present for at least 6 months, **AND**
- The member has tried and failed counseling, such as couples therapy and/or sex therapy; **AND**
- The member does not have HSDD attributable to a co-existing medical or psychiatric condition, problems with the relationship, or the effects of a medication or drug substance.

For Continuation Coverage Requests:

- The member has had a positive response to therapy, as documented by the member's specialty provider; **AND**
- The member is a premenopausal woman.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a psychiatrist or women's health specialist.

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 8 weeks
- Continuation: 12 months

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL INSTRUCTIONS AND ADDITIONAL INFORMATION

Approve by GSN.

VYNDAQEL®/VYNDAMAX® (TAFAMIDIS)

Updated: October 31, 2023

Length of Authorization:	Two years
Initiative:	PAR: Tafamidis (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.

FDA-RECOMMENDED DOSE

- Vyndaqel®: 80 mg once daily
- Vyndamax®: 61 mg once daily

HOW SUPPLIED

- Vyndaqel®: 20 mg capsules in 120-count blister pack cartons
- Vyndamax®: 61 mg capsules in 30-count blister pack cartons

UTILIZATION CRITERIA

FOR INITIAL COVERAGE (ALL MUST BE MET)

- The member has a confirmed diagnosis of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM); **AND**
- The member has New York Heart Association (NYHA) Class I-III symptoms.

FOR CONTINUATION OF COVERAGE

The member has had a positive response to therapy, as documented by the member's specialty provider.

REQUIRED MEDICAL INFORMATION

Initial requests: Chart notes or medical records confirming diagnosis.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a cardiologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

Two years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND ADDITIONAL INFORMATION

Approve by GSN

WAKIX® (PITOLISANT)

Updated: June 29, 2023

Length of Authorization:	• Initial: 3 months (see operational notes) • Continuation: 12 months
Initiative:	PAR: Wakix (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy.

FDA-RECOMMENDED DOSE

17.8 mg to 35.6 mg orally once daily upon wakening.

HOW SUPPLIED

4.45 mg and 17.8 mg tablets in 30-count bottles.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS (EDS):

- The member has a diagnosis of EDS; **AND**
- The member has a diagnosis of narcolepsy and meets one of the following:
  - The member has both a polysomnography and a multiple sleep latency test (MSLT) confirming diagnosis; **OR**
  - The member has documentation of one or more confounding factors impacting MSLT accuracy and the member has documented history of narcolepsy diagnosis throughout chart notes; **AND**
- The member is neither currently using nor plans to use pitolisant concurrently with a sodium oxybate product; **AND**
- The member has tried and failed therapeutic trials of each of the following, unless otherwise contraindicated:
  - Modafinil/Armodafinil
  - Methylphenidate/Dexmethylphenidate
  - Amphetamine/Dextroamphetamine
  - Solriamfetol.

FOR INITIAL COVERAGE REQUESTS (CATAPLEXY)

- The member has a diagnosis of cataplexy; **AND**
- The member has a diagnosis of narcolepsy and meets one of the following:
  - The member has both a polysomnography and a multiple sleep latency test (MSLT) confirming diagnosis; **OR**
  - The member has documentation of one or more confounding factors impacting MSLT accuracy and the member has documented history of narcolepsy diagnosis throughout chart notes; **AND**
- The member is neither currently using nor plans to use pitolisant concurrently with a sodium oxybate product; **AND**
- The member has tried and failed therapeutic trials of each of the following:
  - Dextroamphetamine/Amphetamine
  - Venlafaxine
  - Fluoxetine

FOR INITIAL COVERAGE REQUESTS (IDIOPATHIC HYPERSOMNIA)

- The member has a diagnosis of IH; **AND**
- The member must not have untreated or inadequately-treated sleep-disordered breathing; **AND**
- The member is neither currently using nor plans to use pitolisant concurrently with a sodium oxybate product; **AND**
- The member has tried and failed therapeutic trials of each of the following, unless otherwise contraindicated:
  - Modafinil/Armodafinil
  - Methylphenidate/Dexmethylphenidate

FOR ALL CONTINUATION COVERAGE REQUESTS:

- The member has had a positive response to therapy, as documented by the member's specialty provider; **AND**
- The member is neither currently using nor plans to use pitolisant concurrently with a sodium oxybate product.

REQUIRED MEDICAL INFORMATION

Documentation of polysomnography and sleep latency test.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist or sleep specialist.

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 3 months (see operational notes)
- Continuation: 12 months

QUANTITY RESTRICTIONS

Coverage for the first three months of therapy is limited to maximum dose of 17.8 mg per day. Continuation requests can be approved for 35.6 mg (two 17.8 mg tablets) per day, if requested.

OPERATIONAL NOTES AND OTHER INFORMATION

- For initial approvals, enter the following for loading dose:
  - Authorization 1 (one-month duration): Allow one fill for a quantity of 14 of the 4.45 mg tablets for a seven day supply (MDD 2). Enter metric quantity and days' supply of #14/7 DS.
  - Authorization 2 (three-month duration): Allow MDD 1 for the 17.8 mg tablets
- For continuation requests, allow up to an MDD 2 for the 17.8 mg tablets.
- Approve by GSN

WEIGHT LOSS GLP-1S: LIRAGLUTIDE (SAXENDA®), SEMAGLUTIDE (WEGOVY®), TIRZEPATIDE (ZEPBOUND®)

Updated: April 23, 2024

Length of Authorization:	Varies, see below
Initiative:	PAR: Weight Loss Agents: HICL (IE 2462 / NCPDP 75 – HICL) PAR: Wegovy (IE 2462/NCPDP 75) (List ID = UOMWLGLP1DL) PAR: Saxenda/Zepbound (IE 2462/NCPDP 75) (List ID = UOMWLGLP1L2)

FDA-APPROVED INDICATION(S)

- Liraglutide (Saxenda®) and semaglutide (Wegovy®) and tirzepatide (Zepbound):
  - As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial BMI ≥ 27 kg/m^2 with additional weight-related risk factor (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) or BMI ≥ 30 kg/m^2.
  - Saxenda only: Pediatric patients 12 years of age and older with body weight above 60 kg and an initial BMI corresponding to 30 kg/m^2 for adults (obese) by international cut-offs (Cole Criteria).
  - Wegovy only, in combination with a reduced calorie diet and increased physical activity:
    - Pediatric patients 12 years of age and older with an initial BMI in the 95th percentile or greater standardized for age and sex.
    - To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight.

FDA-RECOMMENDED DOSE

- Liraglutide (Saxenda®): 3 mg subcutaneously daily. Initiate at 0.6 mg daily for one week, increasing weekly as tolerated until a dose of 3 mg is reached.
- Semaglutide (Wegovy®): 0.25 mg per week for the first four weeks, 0.5 mg per week for weeks 5 through 8, 1 mg per week for weeks 9 through 12, 1.7 mg per week for weeks 13 through 16, and 2.4 mg per week thereafter.
- Tirzepatide (Zepbound): Subcutaneously once weekly. The recommended starting dose is 2.5 mg weekly. The dosage may be increased in 2.5 mg increments after at least 4 weeks on the current dose. The recommended maintenance dosages are 5, 10, or 15 mg weekly. The maximum dose is 15 mg weekly.

HOW SUPPLIED

Various, refer to package inserts.

UTILIZATION CRITERIA

WEIGHT MANAGEMENT: FOR INITIAL COVERAGE REQUESTS (ADULT MEMBERS AGED 18 YEARS AND OLDER)

- Initial BMI ≥ 27 with additional weight-related risk factor (e.g., hypertension, hyperlipidemia, or type 2 diabetes mellitus) **or** initial BMI ≥ 30 in the absence of other weight-related risk factors; **AND**
- Other organic/medical cause of obesity (e.g., hypothyroidism, Cushing's syndrome, Bardet-Biedl syndrome have been ruled out); **AND**
- The member agrees to continue a restricted calorie diet, physical activity, and behavioral support; **AND**
- The requested medication will not be used concurrently with other prescription agents for weight loss; **AND**
- The member has tried and failed 12-week treatments of both products below, unless otherwise contraindicated or clinically inappropriate: **(rationale required)**

  - Contrave
  - Qsymia; **AND**
- If the provider is not a weight-loss specialist* or endocrinologist, the member has been unable to lose weight under Omada or a comprehensive weight management program including calorie restriction, physical exercise, and behavioral support for at least 6 months; **AND**
  - The program is supervised by a healthcare provider; **AND**
  - The program includes regular monitoring of weight (at baseline and throughout the program); **AND**
- If the requested product is Wegovy, the member has tried and failed 12 weeks of Zepbound.

FOR INITIAL COVERAGE REQUESTS (PEDIATRIC MEMBERS AGED 12 TO 17 YEARS, WEIGHT LOSS)

- The member's BMI is at or above the 95th percentile for children and teens of the same age and sex; **AND**
- Other organic/medical cause of obesity (e.g., hypothyroidism, Cushing's syndrome, Bardet-Biedl syndrome have been ruled out; **AND**
- The member agrees to continue a restricted calorie diet, physical activity, and behavioral support; **AND**
- The requested medication will not be used concurrently with other prescription agents for weight loss; **AND**
- The member has tried and failed at least a 12-week treatment of Qsymia unless otherwise contraindicated or clinically inappropriate (rationale required); **AND**
- If the provider is not a weight-loss specialist* or endocrinologist, the member has been unable to lose weight under Omada or a comprehensive weight management program including calorie restriction, physical exercise, and behavioral support for at least 6 months; **AND**
  - The program is supervised by a healthcare provider; **AND**
  - The program includes regular monitoring of weight (at baseline and throughout the program).

*Weight-loss specialists are providers who are board certified in obesity medicine or ABOM certified or who participate as a provider in a structured weight-loss clinical program (i.e., Michigan Medicine's Weight Navigation Program, Weight Management and Obesity Program).

FOR CONTINUATION REQUESTS AFTER THE FIRST 12 WEEKS OF TREATMENT (WEIGHT LOSS)

- The member has lost at least 5% of their initial body weight; **AND**
- The member has not experienced any adverse effects from the medication; **AND**
- The member agrees to continue a restricted calorie diet, physical activity, and behavioral support.

FOR CONTINUATION REQUESTS AFTER 12 MONTHS OF TREATMENT (WEIGHT LOSS)

- The member is maintaining weight loss or continuing to lose weight; **AND**
- The member has not experienced any adverse effects from the medication; **AND**
- The member continues restricted calorie diet, physical activity, and behavioral support.

CARDIOVASCULAR RISK REDUCTION: FOR INITIAL COVERAGE REQUESTS

- The requested medication is Wegovy; **AND**
- The member has an initial BMI ≥ 27; **AND**
- The member has documented prior myocardial infarction, prior stroke, or peripheral arterial disease.

CARDIOVASCULAR RISK REDUCTION: FOR CONTINUATION REQUESTS

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Weight Management:

- Initial requests:
  - Medical records/chart notes supporting regular weight monitoring during comprehensive weight management program (obesity specialists and endocrinologists exempt from this documentation requirement).
  - Medical records/chart notes documenting baseline weight (i.e., pre-weight loss agent weight).
  - Claims or medical records demonstrating use of previous weight-loss therapies or clinical rationale to avoid use.
- Continuation requests:
  - Medical records/chart notes documenting baseline (i.e., pre-weight loss agent) and current weight.

CV Risk Reduction:

- Initial requests:
  - Medical records/chart notes documenting baseline weight (i.e., pre-weight loss agent weight).
  - Medical records/chart notes supporting diagnosis of prior myocardial infarction, prior stroke, or peripheral arterial disease

AGE RESTRICTIONS

- Weight management: 12 years of age and older
- CV risk reduction: 45 years of age and older.

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

Weight management:

- Initial coverage: 12 weeks
- Continuation of coverage: 12 months

CV risk reduction:

- 12 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES/OTHER INFORMATION

- Approve by HSN
- Pediatric BMI coverage requirements are intentionally aligned
- If the member's dose necessitates greater than a 34 DS, due to package size limitations, an authorization may be entered to permit up to a 38 DS with a duration matching the clinical PA
- Members using Wegovy for CV risk reduction who meet all criteria above are not subject to weight loss GLP-1 lifetime max.

WELIREG™ (BELZUTIFAN)

Updated: February 13, 2024

Length of Authorization:	24 months
Initiative:	Par: Welireg (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery.
- For the treatment of adult patients with advanced RCC following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI).

FDA-RECOMMENDED DOSE

120 mg administered orally once daily.

HOW SUPPLIED

40 mg tablets in 90-count bottles

UTILIZATION CRITERIA

For Initial Coverage Requests:

- For VHL disease:
  - The member has a diagnosis of VHL, AND
  - The member has a diagnosis of renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET).
- For Advanced RCC:
  - The member has a diagnosis of advanced RCC, AND
  - The member has trialed a PD-1 inhibitor, PD-L1 inhibitor and VEGF-TKI.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Initial Review: documentation of confirmatory diagnosis of VHL.

AGE RESTRICTIONS

18 years of age or older

PRESCRIBER RESTRICTIONS

Must be prescribed by a hematologist or oncologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

24 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

WINLEVI® (CLASCOTERONE 1% CREAM)

Updated: August 2, 2023

Length of Authorization: 12 weeks (initial); 12 months (continuation)
Initiative: PAR: Winlevi (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the topical treatment of acne vulgaris in patients 12 years of age and older

FDA-RECOMMENDED DOSE

A thin layer applied to affected areas of face twice daily

HOW SUPPLIED

1% cream in a 60-gram tube

UTILIZATION CRITERIA

For Initial Coverage Requests

- The member is diagnosed with acne vulgaris; **AND**
- The member has had an adequate trial and failure of each of the following topical products, as monotherapy or in combination, unless otherwise contraindicated:
  - Adapalene
  - Dapsone
  - Clindamycin or erythromycin
  - Tretinoin

For Renewal Coverage Requests

- The member continues to have a beneficial response to therapy, as assessed by the member's provider; **AND**
- The member has not experienced any adverse effects from the medication.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies

AGE RESTRICTIONS

12 years of age and older.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

PRESCRIBER RESTRICTIONS

N/A

COVERAGE DURATION

- Initial: 12 weeks
- Continuation: 12 months

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

XALKORI® (CRIZOTINIB)

Updated: February 1, 2024

Length of Authorization:	5 years
Initiative:	PAR: Xalkori (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test.
- For the treatment of pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK
- For the treatment of pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblast tumor (IMT) that is ALK-positive.

FDA-RECOMMENDED DOSE

250 mg orally twice daily

HOW SUPPLIED

- 250 mg and 200 mg tablets in 60-count bottles.
- 20mg, 50mg, and 150mg pellets in 60-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **NSCLC Requests:**
  - The member has a diagnosis of NSCLC; **AND**
  - The member has one of the following as evidenced by testing results:
    - ALK rearrangement-positive disease
    - ROS1 rearrangement-positive disease
    - MET exon 14 skipping mutation.
- **Histiocytic Neoplasm Requests:**
  - The member has a diagnosis of one of the following:
    - Langerhans Cell Histiocytosis
    - Rosai-Dorfman Disease
    - Erdheim-Chester Disease; **AND**
  - The member has ALK rearrangement-positive disease as evidenced by testing results.
- **Soft Tissue Sarcoma/Uterine Sarcoma Requests:**
  - The member has a diagnosis of an inflammatory myofibroblastic tumor (IMT); **AND**
  - The member has ALK rearrangement-positive disease as evidenced by testing results.
- **Melanoma** Requests:
  - The member has a diagnosis of metastatic or unresectable cutaneous melanoma; **AND**
  - The member has ROS1 gene fusion positive disease; **AND**
  - The member is using Crizotinib as subsequent therapy for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy.
- **T-Cell Lymphoma Requests:**
  - The member has relapsed or refractory anaplastic large cell lymphoma; **AND**
  - The member has ALK rearrangement-positive disease as evidenced by testing results.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Testing confirming applicable rearrangement or mutation status.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by an Oncologist or hematologist.

REVIEWER REQUIREMENTS

Must be reviewed by a pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HSN

XDEMVY™ (LOTILANER)

Updated September 28, 2023

Length of Authorization:	2 months
Initiative:	PAR: Xdemvy (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adults with a confirmed diagnosis of Demodex blepharitis.

FDA-RECOMMENDED DOSE

One drop in each eye twice daily (approximately 12 hours apart) for 6 weeks.

HOW SUPPLIED

0.25% ophthalmic solution in multidose 10 mL bottle.

UTILIZATION CRITERIA

For initial coverage requests:

- The member has a diagnosis of Demodex blepharitis, as evidenced by:
  - The presence of at least mild erythema of the upper eyelid margin; **AND**
  - The presence of mites upon examination of eyelashes by light microscopy or presence of collarettes on slit lamp examination.

For continuation coverage requests:

- The member has had a positive clinical response to therapy, as attested to by the member's optometrist or ophthalmologist.

REQUIRED MEDICAL INFORMATION

Chart notes or medical records demonstrating diagnosis of Demodex blepharitis.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an optometrist or ophthalmologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

2 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

XELJANZ®, XELJANZ XR, XELJANZ ORAL SOLUTION (TOFACITINIB CITRATE)

Updated: December 18, 2023

Length of Authorization:	6 months (initial), 12 months (continuation).
Initiative:	PAR: Xeljanz: Other (IE 2462 / NCPDP 75 – GSN) PAR: Xeljanz: UC (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

Xeljanz/Xeljanz XR oral tablets:

- For the treatment of adults with moderately to severe rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more TNF blockers.
- For the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to one or more TNF blockers.
- For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have an inadequate response or who are intolerant to one or more TNF blockers.
- For the treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers.

Xeljanz IR tablets/Xeljanz oral solution:

- For the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers.

FDA-RECOMMENDED DOSE

- RA, PsA: 5 mg twice daily or 11 mg extended-release once daily.
- UC: 10 mg twice daily for at least 8 weeks, then 5 mg or 10 mg twice daily; 22 mg extended-release once daily for at least 8 weeks, then 11 mg once daily.
- pcJIA:
  - 10 kg–20 kg: 3.2 mg (3.2 mL oral solution) twice daily
  - 20 kg–40 kg: 4 mg (4 mL oral solution) twice daily
  - ≥ 40 kg: 5 mg (one 5 mg tablet or 5 mL oral solution) twice daily

HOW SUPPLIED

- 5 mg tablets in 28 and 60-count bottles
- 10 mg tablets in 28, 60, and 180-count bottles
- 11 mg extended-release tablets in 14 and 30-count bottles
- 22 mg extended-release tablets in 30-count bottles
- 1 mg/mL oral solution supplied in 240 mL bottles

UTILIZATION CRITERIA

FOR INITIAL REVIEW

For All Indications:

- The member has tried and failed, or has contraindications to, a TNF-inhibitor; **AND**
- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib).

For the treatment of RA (IR/XR tablets only):

- The member has a diagnosis of moderately to severely active rheumatoid arthritis; **AND**
- The member has had a previous trial of or contraindication to at least one of the following:
  - Methotrexate
  - Leflunomide
  - Hydroxychloroquine
  - Sulfasalazine

For the treatment of PsA (IR/XR tablets only):

- The member has a diagnosis of active psoriatic arthritis; **AND**
- The member has had a previous trial of, or contraindication to, at least one of the following:
  - Methotrexate
  - Sulfasalazine
  - Cyclosporine
  - Leflunomide

For the Treatment of UC (IR/XR tablets only):

- The member has a diagnosis of moderate to severely active Ulcerative Colitis; **AND**
- The member has had a previous trial of or contraindication to at least one of the following:
  - Thiopurines (i.e., 6-mercaptopurine or azathioprine)
  - Corticosteroids; **OR**
  - **The member has tried and failed one or more previous biologic therapies (e.g.** infliximab, certolizumab, vedolizumab, golimumab, ustekinumab, or natalizumab).

For the Treatment of pcJIA (IR/Oral Solution only):

- The member has a diagnosis of polyarticular course juvenile idiopathic arthritis; **AND**
- The member has had a previous trial of or contraindication to at least one of the following:
  - Methotrexate
  - Leflunomide
  - Hydroxychloroquine
  - Sulfasalazine

For the Treatment of AS (IR/XR tablets only):

- The member has a diagnosis of AS; **AND**
- The member has had a previous trial of at least **one**, or contraindication to **all**, of the following:
  - Nonsteroidal anti-inflammatory drugs (NSAIDs)
  - Methotrexate
  - Sulfasalazine

FOR CONTINUATION REQUESTS

- The member has had a positive clinical response to therapy, as documented by the member's specialist provider; **AND**
- The member's liver enzymes are below three times the upper limit of normal (per lab specified range); **AND**
- The member's lymphocyte count is greater than 500 cells/mm^3; **AND**
- The member's absolute neutrophil count (ANC) is greater than 500 cells/mm^3; **AND**
- The member's hemoglobin level is greater than 8 g/dL; **AND**
- The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib).

REQUIRED MEDICAL INFORMATION

- For continuation: Lymphocyte counts, liver enzymes (AST, ALT), neutrophil counts (ANC), and hemoglobin levels, documented within the six months preceding the coverage request.
- Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

- 18 years of age and older for RA, PsA, AS, and UC
- 2 years of age and older for pcJIA

PRESCRIBER RESTRICTIONS

- RA, AS, and pcJIA: must be prescribed by or in consultation with a rheumatologist.
- PsA: must be prescribed by or in consultation with a rheumatologist or dermatologist.
- UC: must be prescribed by or in consultation with a gastroenterologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

6 months (initial), 12 months (continuation)

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

- RA/PsA/AS authorizations are only approvable for the 5 mg IR and 11 mg XR strengths and should be entered at the GSN level.
- UC authorizations should be entered at the HSN level.
- pcJIA authorizations are only approvable for the 5 mg IR and oral solution formulations and should be entered at the GSN level.
- Internal note: The following website may be useful to convert lab values to the required units: https://unitslab.com/node/8

XENAZINE® (TETRABENAZINE)

Updated: August 16, 2023

Length of Authorization:	5 years
Initiative:	PAR: Xenazine (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of chorea associated with Huntington's disease.

FDA-RECOMMENDED DOSE

The dose of tetrabenazine should be individualized (see package insert for details).

HOW SUPPLIED

12.5 and 25 mg tablets in 112-count bottles.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member must have a diagnosis of chorea associated with Huntington's disease or Tardive Dyskinesia (TD); **AND**
- The member must not be taking a concurrent VMAT2 inhibitor.

FOR CONTINUATION COVERAGE REQUESTS

- The member continues to have a beneficial response to therapy as assessed and documented by the member's specialist provider; **AND**
- If the member requires a dose above the formulary quantity limit, they must have confirmation via genotyping that they are a CYP2D6 extensive metabolizer; **AND**
- The member must not be taking concurrent VMAT2 inhibitor.

REQUIRED MEDICAL INFORMATION

- Genotyping results if requesting dose above formulary quantity limits.
- Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist, movement disorder specialist, or psychiatrist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

- For standard dose approvals: Refer to formulary.
- For CYP2D6 dose approvals: Enter a quantity exception to override the formulary quantity limit to permit the requested dose.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HSN.

XENLETA® (LEFAMULIN)

Updated: May 18, 2023

Length of Authorization:	2 months
Initiative:	PAR: Xenleta (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adults with community acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae, and Chlamydophila pneumoniae.

FDA-RECOMMENDED DOSE

600 mg orally every 12 hours for 5 days.

HOW SUPPLIED

600 mg tablet in 10- and 30-count bottle.

UTILIZATION CRITERIA

For All Coverage Requests:

- The member must have diagnosis of CABP caused by a susceptible microorganism; **AND**
- One of the following
  - The member must have a contraindication or intolerance to two or more formulary antibiotics of different classes used for CABP; **OR**
  - The member has initiated a course of lefamulin in an inpatient setting.

REQUIRED MEDICAL INFORMATION

- Susceptibility results.
- Medical records or chart notes demonstrating contraindication or intolerance to formulary antibiotics of different classes used for CABP, as applicable.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an infectious disease specialist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

2 months

QUANTITY RESTRICTIONS

Max 10 tablets allowed per approval.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

XERMELO® (TELOTRISTAT)

Updated: March 23, 2023

Length of Authorization:	5 years
Initiative:	PAR: Xermelo (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.

FDA-RECOMMENDED DOSE

250 mg three times daily

HOW SUPPLIED

- 250 mg tablets in 84-count case.
- Xermelo® is dispensed in a monthly case for a total of 28 days of therapy. Each monthly case contains four weekly boxes. Each weekly box contains seven daily dose packs (day pack).

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member has a confirmed diagnosis of carcinoid syndrome; **AND**
- The member will be using Xermelo® in combination with a somatostatin analog (e.g., octreotide); **AND**
- The member has been inadequately controlled by monotherapy with a somatostatin analog.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an oncologist or endocrinologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary quantity limits.

OPERATIONAL INSTRUCTIONS ANDADDITIONAL INFORMATION

Approve by GSN.

XIFAXAN® (RIFAXIMIN)

Updated: April 21, 2023

Length of Authorization:	Varies, see below
Initiative:	PAR: Xifaxan (IE 2462 / NCPDP 75 – GSN), (IE 15110 / NCPDP 76 – GSN)

POLICY AND PRODUCT INFORMATION

- 200 mg tablets are covered with a quantity limit of 9 tablets per fill (3 times daily for 3 days) for members without prior authorization (traveler's diarrhea recommended dosing).
- 550 mg tablets require prior authorization

FDA-APPROVED INDICATION(S)

- 200 mg tablet: for the treatment of travelers' diarrhea (TD) caused by noninvasive strains of Escherichia coli in adults and pediatric patients 12 years of age and older.
- 550 mg tablet: for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults and for reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults.

FDA-RECOMMENDED DOSE

- IBS-D: the recommended dose is one 550 mg tablet taken orally three times a day for 14 days. Patients who experience a recurrence of symptoms can be retreated up to two times with the same dosage regimen.
- HE: one 550 mg tablet taken orally two times a day.

HOW SUPPLIED

As 200 mg in 30-count bottles and 550 mg tablets in 60-count bottles, 60-count cartons, and 42-count cartons.

COVERAGE CRITERIA

Initial Requests:

- **IBS-D:**
  - The member has a confirmed diagnosis of IBS-D; **AND**
  - The member has tried and failed at least one other therapy for this condition.
- **HE:**
  - The member has a confirmed diagnosis of HE; **AND**
  - The member has tried and failed lactulose.
- **SIBO:**
  - The member has a confirmed diagnosis of SIBO; **AND**
  - The member has tried and failed at least one generic antibiotic.

Continuation Requests:

- **IBS-D:**
  - The member has recurrent symptoms after the completion of the prior course of treatment (maximum of 2 renewals will be provided in accordance with FDA label).
- **HE:**
  - The member continues to have a beneficial response to therapy, as assessed by the member's provider.
- **SIBO:**
  - The member has recurrent symptoms after the completion of the prior course of treatment.

REQUIRED MEDICAL INFORMATION

- Chart notes or medical records supporting diagnosis.
- Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a gastroenterologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or a physician.

COVERAGE DURATION

- SIBO and IBS-D: 1 month
- HE: 12 months

QUANTITY/PARTIAL-FILL RESTRICTIONS

- SIBO and IBS-D: enter a quantity limit override for three 550 mg tablets per day, max of 42 tablets (14 DS).
- HE: refer to formulary.

OPERATIONAL NOTES

Approve by GSN.

XOLAIR® (OMALIZUMAB)

Updated: April 23, 2024

Length of Authorization: 12 months
Initiative: PAR: Xolair (IE 2462 / NCPDP 75 – GSN; IE 7001 / NCPDP 76 – GSN)

FDA-APPROVED INDICATIONS

- For adults and pediatric patients 6 years of age and older with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.
- For add-on maintenance treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.
- For the treatment of adults and adolescents 12 years of age and older with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment.
- For the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy.

FDA-RECOMMENDED STARTING DOSE

- Asthma: 75 mg to 375 mg by subcutaneous injection every 2 or 4 weeks based on serum total IgE level (IU/mL)
- Nasal polyps: 75 mg to 600 mg by subcutaneous injection every 2 or 4 weeks based on serum total IgE level (IU/mL)
- CIU: 150 mg or 300 mg by subcutaneous injection every 4 weeks

HOW SUPPLIED

150 mg injectable solution (single-dose vial), 75 or 150 mg prefilled syringe

COVERAGE CRITERIA

FOR INITIAL COVERAGE REQUESTS:

For all indications:

- The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib).

Allergenic Asthma:

- The member has a positive skin test or in-vitro reactivity to a perennial aeroallergen; **AND**
- The member has tried and failed, or is otherwise intolerant to, chronic administration of a systemic corticosteroid or high-dose inhaled corticosteroids in combination with long-acting inhaled beta-agonists or leukotriene modifier; **AND**
- For members 6 to 11 years of age, the baseline IgE level is between 30 – 1300 IU/mL; **OR**
- For members 12 years of age and older, the baseline IgE level is between 30 – 700 IU/mL

Chronic Idiopathic Urticaria:

- The member has a diagnosis of CIU; **AND**
- The member has chronic hives for at least six weeks; **AND**
- The member has tried and failed at least one other treatment for the management of CIU.

Nasal Polyps:

- The member has a diagnosis of nasal polyps; **AND**
- The member will use omalizumab in combination with intranasal corticosteroids unless unable to tolerate or contraindicated; **AND**
- The member has tried and failed **one** of the following:
  - Intranasal corticosteroids; **OR**
  - Surgical intervention

IgE-Mediated Food Allergy:

- The member has chart note documentation of an IgE mediated food allergy to peanut **AND** at least two of the following:
  - Cashew
  - Milk
  - Egg
  - Wheat
  - Hazelnut
  - Walnut ; **AND**
- The member has documentation of the following for all three foods indicated:
  - Positive food specific IgE (≥6 kUA/L); **AND**
  - Positive skin prick test (SPT) to food

FOR CONTINUATION COVERAGE REQUESTS:

- **For all indications:**
  - The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib).
- **Allergenic Asthma:**
  - The member has experienced a decrease in the frequency of exacerbations and improvement in symptoms, as attested to by the member's specialist provider.
- **Chronic Idiopathic Urticaria, IgE-mediated Food Allergy, and Nasal Polyps:**
  - The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

- For initial Allergenic Asthma requests: Documentation of pre-treatment IgE levels
- For initial IgE-Mediated Food Allergy requests: Documentation of allergy in chart notes, documentation of food specific IgE and SPT tests.

AGE RESTRICTIONS

- Asthma: 6 years of age and older
- Nasal polyps: 18 years of age and older
- CIU: 12 years of age and older
- IgE Food Allergy: 1 year – 17 years of age

PRESCRIBER RESTRICTIONS

Must be prescribed by a dermatologist, allergist, immunologist, pulmonologist, or an Ear, Nose and Throat (ENT) specialist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

- All approvals should be limited to the quantity recommended within the package insert for the indication, according to the member's current age, weight, and pre-treatment IgE levels, as applicable.

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve by GSN.
- **Internal note:** If two strengths are required, place PAs for each strength if multiple formulations are needed to achieve a desired dose.
  - For example, 225 mg every 4 weeks (75 mg/0.5 mL and 150 mg/1 mL prefilled syringes) would be entered as 2 PAs, one for 75 mg 0.5mL and the other for 150mg 1mL

XOSPATA® (GILTERITINIB)

Updated: May 3, 2023

Length of Authorization:	5 years
Initiative:	PAR: Xospata (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with an FMS-like tyrosine kinase 3 (FLT3) mutation, as detected by an FDA-approved test.

FDA-RECOMMENDED STARTING DOSE

120 mg orally once daily

HOW SUPPLIED

40 mg tablets in 90-count bottles

UTLIZATION CRITERIA

For Initial Coverage Requests:

- **For AML:**
  - The member has a diagnosis of AML; **AND**
  - The member has relapsed or refractory disease; **AND**
  - The member has documentation of an FLT3 mutation (ITD or TKD).
- **For myeloid and lymphoid neoplasms:**
  - The member has a diagnosis of a myeloid or lymphoid neoplasm with eosinophilia; **AND**
  - The member has documentation of an FLT3 rearrangement.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Documentation of an FLT3 mutation or rearrangement

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by GSN.

XPHOZAH® (TENAPANOR)

Updated: March 2024

Length of Authorization:	12 weeks
Initiative:	PAR: Xphozah (IE 2462 / NCPDP 75 – HSN)

FDA-APPROVED INDICATION(S)

To reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

FDA-RECOMMENDED DOSE

30 mg orally twice daily. May decrease dose if needed based on serum phosphate concentration and GI tolerability.

HOW SUPPLIED

20 mg and 30 mg tablets in 60-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member is currently on dialysis for CKD; **AND**
- The member has persistently elevated serum phosphate despite use of phosphate binders and dietary restrictions; **AND**
- The member has tried and failed at least two generic phosphate binders.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- Chart notes or medical records demonstrating serum phosphate levels.
- Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

N/A

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

12 weeks

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approve by HSN.

XPOVIO® (SELINEXOR)

Updated: May 1, 2023

Length of Authorization:	5 years
Initiative:	PAR: Xpovio (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For use in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma (MM) who have received at least one prior therapy.
- For use in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.
- For the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy.

FDA-RECOMMENDED DOSE

- **MM, in combination with bortezomib and dexamethasone:**
  - 100 mg taken orally once weekly on day 1 of each week.
- **RRMM, in combination with dexamethasone:**
  - 80 mg (four 20 mg tablets) taken orally on days 1 and 3 of each week.
- **DLBCL:**
  - 60 mg taken orally on days 1 and 3 of each week.

HOW SUPPLIED

- 20 mg, 40mg, 50mg, and 60mg tablets in weekly blister packs.
- Cartons of 4,8, 12, 16, 20, 24, and 32 tablets supplied for a 28-day supply.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **For Multiple Myeloma:**
  - The member must have a diagnosis of MM; **AND**
  - The member must meet one of the following clinical scenarios:
    - The member has received one prior therapy and selinexor will be used in combination with one of the following:
      - Bortezomib and dexamethasone; **OR**
      - Daratumumab and dexamethasone; **OR**
      - Carfilzomib and dexamethasone; **OR**
      - Pomalidomide and dexamethasone; **OR**
  - The member is refractory to each of the following:
    - Two proteasome inhibitors (e.g., bortezomib, carfilzomib, and ixazomib)
    - Two immunomodulatory agents (e.g., lenalidomide, pomalidomide, thalidomide)
    - An anti-CD38 monoclonal antibody (e.g., daratumumab).
- **For B-Cell Lymphoma:**
  - The member has a diagnosis of relapsed or refractory DLBCL; **AND**
  - The member has received at least two prior lines of systemic therapy for the indication.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approve by HICL.

XTANDI® (ENZALUTAMIDE)

Updated February 1, 2024

Length of Authorization:	5 years
Initiative:	PAR: Xtandi (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

For the treatment of castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer and non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis.

FDA-RECOMMENDED DOSE

160 mg (four 40 mg capsules) administered orally once daily.

HOW SUPPLIED

- 40 mg capsule in 120-count bottles
- 40 mg, 80 mg tablets in 120-count and 60-count bottles

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS

- The member has one of the following diagnoses:
  - Castration-resistant prostate cancer,
  - Metastatic castration-sensitive prostate cancer,
  - Non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis; **AND**
- The member meets one of the following clinical scenarios:
  - The member is also receiving a gonadotropin-releasing hormone (GnRH) analog concurrently; **OR**
  - The member has had bilateral orchiectomy

FOR CONTINUATION COVERAGE REQUESTS

The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

- Claims or medical records demonstrating concurrent use of hormone suppression therapy, as applicable
- Medical records documenting orchiectomy, as applicable

AGE RESTRICTIONS

None

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with an oncologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by HSN

XURIDEN® (URIDINE TRIACETATE)

Updated: May 19, 2023

Length of Authorization:	12 months
Initiative:	PAR: Xuriden (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

Indicated in adult and pediatric patients for the treatment of hereditary orotic aciduria.

FDA-RECOMMENDED DOSE

- The recommended starting dosage oral is 60 mg/kg once daily. Increase the dosage to 120 mg/kg (not to exceed 8 grams) once daily for insufficient efficacy, such as occurrence of one of the following:
  - Levels of orotic acid in urine remain above normal or increase above the usual or expected range for the patient; **OR**
  - Laboratory values (e.g., red blood cell or white blood cell indices) affected by hereditary orotic aciduria show evidence of worsening; **OR**
  - Worsening of other signs or symptoms of the disease

HOW SUPPLIED

2 grams of uridine triacetate per packet in a 30-packet carton.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a confirmed diagnosis of hereditary orotic aciduria with documentation of mutation in the uridine monophosphate synthase (UMPS) gene; **AND**
- The member has elevated urinary orotic acid levels according to an age-specific reference range.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

- Member current weight (kg)
- Genetic test confirming diagnosis.
- Urinary orotic acid levels.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by, or in consultation with a specialist in inherited metabolic disease.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to package insert for weight-specific daily dosing. Approved quantities must be limited per current weight (kg), not to exceed 8 grams per day. When calculating restriction, add 10 kg to the member's current weight to allow for growth during their approval cycle.

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by HICL.

XYREM®, XYWAV®, LUMRYZ (SODIUM OXYBATE)

Updated: June 29, 2023

Length of Authorization:	3 months (initial), 12 months (continuation).
Initiative:	PAR: Xyrem (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- Xyrem, Xywav: For the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.
- Xywav: For the treatment of idiopathic hypersomnia (IH) in adults.
- Lumryz: For the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy.

FDA-RECOMMENDED DOSE

- Adults: An initial dose of 4.5 grams per night divided into two doses (single dose for Lumryz), titrated upwards at weekly intervals to an effective dose of no more than 9 grams per night in two divided doses (single dose for Lumryz). For IH, may also dose 3 grams per night, titrated upwards at weekly intervals to no more than 6 grams per single dose.
- Pediatrics: An initial dose of 2 to 4.5 grams per night (per patient weight), titrated upwards at weekly intervals to an effective dose of no more than 6 to 9 grams per night.

HOW SUPPLIED

- Xyrem, Xyway: 0.5 g per mL in 180 mL bottles.
- Lumryz: 4.5, 6, 7.5, and 9 g packets in 7- or 30-count cartons.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS (ALL INDICATIONS)

- The member is not currently using sedative hypnotics, other CNS depressants, or alcohol; **AND**
- The member does not have a succinic semialdehyde dehydrogenase deficiency; **AND**
- The member does not have a history of drug abuse; **AND**
- The member is currently enrolled in the Xyrem®, Xywav®, or Lumryz REMS program; **AND**
- If requesting Xywav, the member must have documented reason for requiring low-sodium diet (e.g., hypertension, renal impairment, heart failure).

FOR INITIAL COVERAGE REQUESTS (IDIOPATHIC HYPERSOMNIA; XYREM/XYWAY ONLY)

- The member has a diagnosis of IH; **AND**
- The member must not have untreated or inadequately treated sleep-disordered breathing; **AND**
- The member has tried and failed therapeutic trials of each of the following, unless otherwise contraindicated:
  - Modafinil/Armodafinil
  - Methylphenidate/Dexmethylphenidate

FOR INITIAL COVERAGE REQUESTS (CATAPLEXY; ANY PRODUCT)

- The member has a diagnosis of cataplexy; **AND**
- The member has a diagnosis of narcolepsy and meets one of the following:
  - The member has both a polysomnography and a multiple sleep latency test (MSLT) confirming diagnosis; **OR**
  - The member has documentation of one or more confounding factors impacting MSLT accuracy and the member has documented history of narcolepsy diagnosis throughout chart notes; **AND**
- The member has tried and failed a therapeutic trial of each of the following serotonin or norepinephrine reuptake inhibitors:
  - Dextroamphetamine/Amphetamine
  - Venlafaxine
  - Fluoxetine

FOR INITIAL COVERAGE REQUESTS (EXCESSIVE DAYTIME SLEEPINESS; ANY PRODUCT)

- The member has a diagnosis EDS; **AND**
- The member has a diagnosis of narcolepsy and meets one of the following:
  - The member has both a polysomnography and a multiple sleep latency test (MSLT) confirming diagnosis; **OR**
  - The member has documentation of one or more confounding factors impacting MSLT accuracy and the member has documented history of narcolepsy diagnosis throughout chart notes; **AND**
- The member has tried and failed therapeutic trials of each of the following, unless otherwise contraindicated:
  - Modafinil/Armodafinil
  - Methylphenidate/Dexmethylphenidate
  - Amphetamine/Dextroamphetamine
  - Solriamfetol
  - Pitolisant

FOR CONTINUATION COVERAGE REQUESTS

- The member has had a positive response to therapy, as documented by the member's specialty provider; **AND**
- The member is not currently using sedative hypnotics, other CNS depressants, or alcohol.

REQUIRED MEDICAL INFORMATION

- Weight (for members 7 to 18 years of age)
- Documentation of polysomnography and sleep latency test or chart noes as applicable per criteria above.

AGE RESTRICTIONS

- Xyrem/Xyway (Cataplexy or EDS): 7 years of age and older.
- Xyrem/Xywav (Idiopathic Hypersomnia): 18 years of age and older.
- Lumryz: 18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a neurologist or sleep specialist.

REVIEWER REQUIREMENTS

All requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 3 months
- Continuation: 12 months

QUANTITY RESTRICTIONS

Refer to formulary

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by GSN.

YUPELRI® (REVEFENACIN)

Updated: November 15, 2022

Length of Authorization:	Initial: 3 months Continuation: 12 months
Initiative:	PAR: Yupelri (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)

FDA-RECOMMENDED DOSE

One 175 mcg vial (3 mL) once daily via nebulized inhalation

HOW SUPPLIED

Unit-dose vials of 175 mcg revefenacin in 3 mL aqueous solution

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of COPD; **AND**
- The member must meet one of the following:
  - The member has tried and failed or has contraindication or intolerance to ALL available handheld long-acting muscarinic antagonist (LAMA) inhalers, including:
    - Tiotropium bromide (Spiriva)
    - Umeclidinium (Incruse)
    - Aclidinium (Tudorza)
    - Glycopyrrolate (Seebri); **OR**
  - The member has inability to use a handheld inhaler device, per provider attestation.

For Continuation Coverage Requests:

- Member continues to tolerate and have a beneficial response to treatment, as attested to by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

All handheld LAMAs tried and failed with dates of each trial, if applicable

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a pulmonologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

- Initial: 3 months
- Continuation: 12 months

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

ZAVESCA® (MIGLUSTAT)

Updated: May 8, 2023

Length of Authorization:	12 months
Initiative:	PAR: Miglustat (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g., due to allergy, hypersensitivity, or poor venous access).

FDA-RECOMMENDED STARTING DOSE

100 mg orally three times daily

HOW SUPPLIED

100 mg capsules in six 15-count blister-packs per carton (#90 capsules per carton)

COVERAGE CRITERIA

For Initial Coverage Requests:

- The member has a confirmed diagnosis of type 1 Gaucher disease; **AND**
- The member is not a candidate for enzyme replacement therapy; **AND**
- The member has symptomatic manifestations of the disease, such as anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly; **AND**
- The member is NOT receiving concurrent enzyme replacement therapy.

For Continuation Coverage Requests:

- The member has had a beneficial response to treatment, as attested to by the member's specialist provider; **AND**
- The member is NOT receiving concurrent enzyme replacement therapy.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by an endocrinologist, geneticist, or other provider who specializes in Gaucher disease

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

12 months

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS AND OTHER INFORMATION

Approve by GSN.

ZEJULA® (NIRAPARIB)

Updated: December 22, 2023

Length of Authorization:	5 years
Initiative:	PAR: Zejula (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.
- For the maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy

FDA-RECOMMENDED DOSE

- For first-line maintenance treatment of advanced ovarian cancer:
  - For patients weighing < 77 kg (< 170 lbs.) **or** with a platelet count < 150,000/microliter: 200 mg taken orally once daily.
  - For patients weighing ≥77 kg (≥ 170 lbs.) **and** a platelet count ≥ 150,000/microliter: 300 mg taken orally once daily.
- For other indications: 300 mg taken orally once daily.

HOW SUPPLIED

100 mg, 200 mg, and 300 mg tablets in 30-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **For Ovarian, Fallopian Tube, or Primary Peritoneal Cancer:**
  - The member has a diagnosis of recurrent ovarian cancer, fallopian tube cancer, or primary peritoneal cancer; **AND**
  - The member's cancer, as confirmed with the FDA approved companion diagnostic test, is associated with a homologous recombination deficiency positive status defined as either of the following:
    - Deleterious or suspected deleterious BRCAm
    - Genomic instability (loss of heterozygosity, telomeric allelic imbalance and large-scale state transitions), in a member that has progressed more than six months after response to their last platinum-based chemotherapy; **AND**
  - The member is in complete or partial response to their primary therapy; **OR**
  - The member has been treated with at least three prior chemotherapy regimens
- **For Uterine Neoplasms:**
  - The member must have a diagnosis of a BRCA altered uterine leiomyosarcoma (uLMS); **AND**
  - The member will be using niraparib after trial and failure of at least one other therapy for uLMS

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Mutation results as applicable per criteria above.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist

REVIEWER REQUIREMENTS

Must be reviewed by a pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

- Refer to formulary.
- Formulary quantity limits are intentionally designed to optimize use lowest cost dosage forms for equivalent doses; these limits are not overridable without plan review.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

ZELBORAF® (VEMURAFENIB)

Updated: May 4, 2023

Length of Authorization:	5 years.
Initiative:	PAR: Zelboraf (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

- For the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.
- For the treatment of patients with Erdheim-Chester Disease (ECD) with BRAF V600 mutation.

FDA-RECOMMENDED DOSE

960 mg (four 240 mg tablets) orally every 12 hours.

HOW SUPPLIED

240 mg film-coated tablets in 112-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- **For the treatment of Melanoma:**
  - The member has documentation of unresectable or metastatic melanoma; **AND**
  - The member has a BRAF V600E mutation as detected by an FDA-approved test
- **For the treatment of Central Nervous System Cancers:**
  - The member has a documented diagnosis of circumscribed glioma, glioblastoma, pilocytic astrocytoma, pleomorphic xanthoastrocytoma (PXA), or ganglioglioma; **AND**
  - The member has a BRAF V600E mutation as detected by an FDA-approved test
- **For the treatment of Histiocytic Neoplasms:**
  - The member has documented diagnosis of ECD or Langerhans Cell Histiocytosis (LCH); **AND**
  - The member has a BRAF V600E mutation as detected by an FDA-approved test
- **For the treatment of Hairy Cell Leukemia (HCL), Non-Small Cell Lung Cancer (NSCLC), or Thyroid Carcinoma:**
  - The member has a diagnosis of recurrent, advanced, or metastatic HCL, NSCLC, or Thyroid Carcinoma; **AND**
  - The member has a BRAF V600E mutation as detected by an FDA-approved test.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's specialist provider.

REQUIRED MEDICAL INFORMATION

- BRAF mutation test results
- Chart notes or medical records supporting diagnosis.

AGE RESTRICTIONS

N/A

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

ZEPATIER® (ELBASVIR AND GRAZOPREVIR)

Updated: October 26, 2023

Length of Authorization:	Varies, see below
Initiative:	PAR: Zepatier (ID 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of chronic hepatitis C virus (HCV) genotype 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kg, with ribavirin in certain populations.

FDA-RECOMMENDED DOSAGE

- One tablet by mouth daily.
- 16-week treatment duration populations:
  - Genotype 1a and treatment-naïve or peginterferon alfa (PegIFN)/ribavirin (RBV) experienced without baseline NS5A polymorphisms.
  - Genotype 4 and PegIFN/RBV experienced.
- 12-week treatment duration populations:
  - All other eligible patients.

HOW SUPPLIED

Elbasvir 50 mg/grazoprevir 100 mg tablet in a 28-count carton.

UTILIZATION CRITERIA

For All Coverage Requests:

- The member has a diagnosis of HCV genotype 1 or 4 with HCV RNA drawn and measured within the previous 6 months; **AND**
- The member has been tested for NS5A resistant polymorphisms if HCV genotype 1a; **AND**
- The member has been evaluated to be absent of current alcohol or other substance abuse issues, and has been advised/cautioned on such activities; **AND**
- The member does not have documentation of moderate or severe liver disease (Child-Pugh B, C).

REQUIRED MEDICAL INFORMATION

HCV RNA viral load with date, HCV Genotype, NS5A polymorphism test results, previous treatment history, Child-Pugh Score.

AGE RESTRICTIONS

12 years of age and older

PRESCRIBER RESTRICTIONS

Must be prescribed by a gastroenterologist, hepatologist, or infectious disease specialist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- 16 weeks:
  - Genotype 1a and treatment-naïve or peginterferon alfa (PegIFN)/ribavirin (RBV) experienced without baseline NS5A polymorphisms.
  - Genotype 4 and PegIFN/RBV experienced.
- 12 weeks: All other eligible patient populations

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL INSTRUCTIONS/OTHER INFORMATION

Approve by GSN.

ZEPOSIA® (OZANIMOD)

Updated: December 18, 2023

Length of Authorization:	For members with Ulcerative Colitis • 3 months (initial) • 12 months (continuation). For members with MS • 12 months (initial and continuation).
Initiative:	PAR: Zeposia (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

- For the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS), and active secondary progressive disease (SPMS) in adults.
- For the treatment of moderately to severely active ulcerative colitis (UC) in adults.

FDA-RECOMMENDED DOSE

0.23 mg once daily on days 1–3, 0.46 mg once daily on days 5–7, and 0.92 mg once daily thereafter.

HOW SUPPLIED

0.23, 0.46, and 0.92 mg capsules in 30-count bottles and 7-day 28-day and 37-day starter kit blister packs.

COVERAGE CRITERIA

For Initial Coverage Requests:

- For the treatment of MS:
  - The member has a diagnosis of relapsing-remitting disease (RRMS) or active secondary progressive disease (SPMS); **AND**
  - Member has not had a cardiac event (e.g., myocardial infarction, unstable angina, TIA, decompensated heart failure requiring hospitalization, class III or IV heart failure) within the previous six months of the initial coverage request; **AND**
  - Member must have tried and failed one of the following or have a contraindication to the following products if requested for a shared indication: Avonex®, Betaseron®, fingolimod, Gilenya®, glatiramer acetate, Glatopa®, Kesimpta®, Mayzent®, Plegridy®, or dimethyl fumarate.
- For the treatment of UC:
  - The member has a diagnosis of moderate to severely active UC; **AND**
  - The member has had a previous trial of, or contraindication to, at least one of the following:
    - Thiopurines (i.e. 6-mercaptopurine or azathioprine)
    - Corticosteroid; **OR**
    - The member has tried and failed one or more previous biologic therapies (e.g., infliximab, certolizumab, vedolizumab, golimumab, ustekinumab, or natalizumab); **AND**
  - The member has had a previous trial of or contraindication to at least **two** of the following preferred agents:
    - Adalimumab
    - Stelara®
    - Xeljanz®; **AND**
  - The member will not be receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib)

For Continuation Coverage Requests:

- The member continues to have a beneficial response to treatment, as attested to by the member's specialist provider; **AND**
- The member has not had a cardiac event (e.g., myocardial infarction, unstable angina, TIA, decompensated heart failure requiring hospitalization, class III or IV heart failure) since initiating treatment; **AND**
- **For Ulcerative Colitis:**
  - The member is not receiving concurrent treatment with another monoclonal antibody biologic, tumor necrosis factor (TNF) inhibitor, biologic response modifier, or potent non-biologic agent (e.g., abrocitinib, apremilast, tofacitinib, baricitinib, upadacitinib); **AND**
  - The member must have achieved either clinical response or clinical remission by week 8 of therapy.[1]

[1] Clinical response or remission for UC must be substantiated by endoscopic improvement **or** clinically important differences in baseline and reassessment scores on a validated disease assessment instrument.

REQUIRED MEDICAL INFORMATION

- For UC first continuation: documentation of clinical response or remission as described above.
- For UC: Claims or medical records demonstrating use of previous therapies.

AGE RESTRICTIONS

18 years of age or older

PRESCRIBER RESTRICTIONS

- UC: must be prescribed by or in consultation with a gastroenterologist.
- MS indications: must be prescribed by or in consultation with a neurologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician

COVERAGE DURATION

- For members with Ulcerative Colitis
  - 3 months (initial)
  - 12 months (continuation).
- For members with MS
  - 12 months (initial and continuation).

QUANTITY/PARTIAL-FILL RESTRICTIONS

Refer to formulary.

ZILUCOPLAN (ZILBRYSQ)

Updated: February 26, 2024

Length of Authorization:	Initial: 3 months Continuation: 12 months
Initiative:	PAR: Zilbrysq (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

FDA-RECOMMENDED DOSE

- < 56 kg: 16.6 mg subcutaneously once daily.
- 56 kg – < 77 kg: 23 mg subcutaneously once daily.
- > 77 kg: 32.4 mg subcutaneously once daily.

HOW SUPPLIED

- 16.6 mg/0.416 mL, 23 mg/0.574 mL, or 32.4 mg/0.81 mL in 28 single-dose prefilled syringes (4 cartons each containing 7 syringes for a total of 28 syringes).

UTILIZATION CRITERIA

For initial coverage requests:

- The member has a diagnosis of gMG with positive serological test for anti-AChR antibodies; **AND**
- The member has an MGFA clinical classification of Class II to IV disease; **AND**
- The member has an MG-ADL total score ≥ 6; **AND**
- The member's condition has progressed on one of the following: cholinesterase inhibitors, steroids, or non-steroidal immunosuppressive therapies (NSISTs); **AND**
- The member's condition has progressed on Soliris or Ultomiris

For continuation coverage requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

- Initial requests:
  - Chart notes or medical records demonstrating:
    - Positive serological test for anti-AChR antibodies.
    - MGFA clinical classification of Class II to IV disease.
    - MG-ADL total score ≥ 6.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by, or in consultation with, a neurologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

COVERAGE DURATION

- Initial: 3 months.
- Continuation: 12 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

ZOKINVY® (LONAFARNIB)

Updated: May 30, 2023

Length of Authorization:	Initial: 4 months Continuation:6 months
Initiative:	PAR: Zokinvy (IE 2462 / NCPDP 75, IE 2641 / NCPDP 76, IE 15110 / NCPDP 76 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of patients 12 months of age and older with a body surface area of 0.39 m^2 and above:

- To reduce risk of mortality in Hutchinson-Gilford Progeria Syndrome (HGPS),
- For treatment of processing deficient Progeroid Laminopathies (PL) with either
  - Heterozygous LMNA mutation with progerin-like protein accumulation
  - Homozygous or compound heterozygous ZMPSTE24 mutations.

FDA-RECOMMENDED DOSE

115 mg/m^2 twice daily for four months, then increased to 150 mg/m^2 twice daily.

HOW SUPPLIED

50 mg and 75 mg capsules in 30-count bottles.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member is diagnosed with Hutchinson-Gilford Progeria Syndrome (HGPS); **OR**
- The member is diagnosed with processing deficient Progeroid Laminopathies (PL) with
  - Heterozygous LMNA mutation with progerin-like protein accumulation; **OR**
  - Homozygous or compound heterozygous ZMPSTE24 mutations.

For Renewal Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

- Chart notes or medical records supporting diagnosis with genetic tests, as applicable.
- Body service area (BSA).

AGE RESTRICTIONS

12 months of age and older.

PRESCRIBER RESTRICTIONS

N/A

COVERAGE DURATION

- Initial: 4 months
- Continuation: 6 months

QUANTITY RESTRICTIONS

For each authorization, current body surface area (BSA) must be collected. The approvable dose is limited to the maximum recommended dose as described in tables 1 and 2 of the package insert.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

ZTALMY® (GANAXOLONE)

Updated: June 29, 2023

Length of Authorization:	• Initial: 4 months. • Continuation: 1 year.
Initiative:	PAR: Ztalmy (IE 2462 / NCPDP 75 – GSN)

FDA-APPROVED INDICATION(S)

For the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older.

FDA-RECOMMENDED DOSE

- Patients weighing ≤ 28 kg:
  - Starting dose: 6 mg/kg three times daily (18 mg/kg/day).
  - Max dose: 21 mg/kg three times daily (63 mg/kg/day).
- Patients weighing > 28 kg:
  - Starting dose: 150 mg three times daily (450 mg/day).
  - Max dose: 600 mg three times daily (1800 mg/day).

HOW SUPPLIED

Ganaxolone 50 mg/mL suspension in a 135 mL bottle in 1-count or 5-count cartons.

UTILIZATION CRITERIA

FOR INITIAL COVERAGE REQUESTS:

- The member has a diagnosis of seizures associated with CDD; **AND**
  - The member has at least 16 major motor seizures (defined as bilateral tonic, generalized tonic-clonic, bilateral clonic, atonic, or focal to bilateral tonic-clonic) per month on current treatment; **AND**
  - The member has inadequate seizure control after trial of at least 2 antiseizure medications (e.g., levetiracetam, valproate, topiramate, clobazam, vigabatrin); **AND**
  - The member does not have a current diagnosis of West Syndrome with hypsarrhythmia pattern on EEG or seizures primarily of infantile spasm etiology.

FOR CONTINUATION COVERAGE REQUESTS:

The member continues to maintain a clinically meaningful decrease in the frequency or severity of seizures, as assessed by the member's treating provider.

REQUIRED MEDICAL INFORMATION

Genetic testing to confirm CDKL5 mutation and patient weight (kg).

AGE RESTRICTIONS

2 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by or in consultation with a neurologist or provider specializing in CDD.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

- Initial: 4 months.
- Continuation: 1 year.

QUANTITY RESTRICTIONS

- Quantity should be restricted to a maximum of 63 mg/kg/day for members weighing ≤ 28 kg.
- For members weighing > 28 kg the maximum quantity is 1800 mg per day.

OPERATION NOTES AND OTHER INFORMATION

Approve by GSN.

ZURZUVAE (ZURANOLONE)

Updated: January 29, 2024

Length of Authorization:	2 months
Initiative:	PAR: Zurzuvae (IE 2462 / NCPDP 75 - GSN)

FDA-APPROVED INDICATION(S)

For the treatment of postpartum depression (PPD) in adults.

FDA-RECOMMENDED DOSE

- 50 mg orally once daily in the evening for 14 days. Can be used alone or as an adjunct to oral antidepressant therapy.
  - If patients experience CNS depressant effects within the 14-day period, consider reducing the dosage to 40 mg once daily in the evening within the 14-day period.
  - When used concomitantly with a strong CYP3A4 inhibitor, reduce the dosage to 30 mg orally once daily in the evening for 14 days.

HOW SUPPLIED

20 and 30 mg capsules in 14-count bottles. 25 mg also available in 28-count blister pack.

UTILIZATION CRITERIA

For Initial Coverage Requests:

- The member has a diagnosis of moderate to severe PPD; **AND**
- The member is ≤ 12 months post-partum; **AND**
- The member will cease breastfeeding from just prior to receiving drug until 7 days after the last dose.

For Continuation Coverage Requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

Medical records/chart notes documenting moderate to severe PPD and member is ≤ 12 months post-partum.

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by, or in consultation with, a psychiatrist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

2 months.

QUANTITY RESTRICTIONS

Refer to formulary.

OPERATIONAL NOTES AND OTHER INFORMATION

- Approve requested GSN only
- The plan will allow an updated approval for an alternate GSN if a dose decrease is needed. It may be requested by pharmacy, patient, or provider.
  - **Note**: the new approval should **only** allow a quantity sufficient for the remainder of a total 14-day course of therapy.

ZYDELIG® (IDELALISIB)

Updated: February 1, 2024

Length of Authorization:	5 years
Initiative:	PAR: Zydelig (IE 2462 / NCPDP 75 – HICL)

FDA-APPROVED INDICATION(S)

In combination with rituximab, for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL) for whom rituximab alone would be considered appropriate therapy due to other co-morbidities.

FDA-RECOMMENDED DOSE

150 mg administered orally twice daily.

HOW SUPPLIED

100 and 150 mg tablets in 60-count bottles

UTILIZATION CRITERIA

For initial coverage requests:

- For CLL or SLL requests:
  - The member has a diagnosis of CLL or SLL; **AND**
  - The member has tried and failed at least one prior therapy for their indication.

For continuation coverage requests:

- The member continues to have a beneficial response to therapy, as assessed by the member's provider.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTIONS

18 years of age and older.

PRESCRIBER RESTRICTIONS

Must be prescribed by an oncologist or hematologist.

REVIEWER REQUIREMENTS

All coverage requests must be reviewed by a licensed pharmacist or physician.

COVERAGE DURATION

5 years

QUANTITY RESTRICTIONS

Refer to formulary quantity limits.

OPERATIONAL NOTES AND OTHER INFORMATION

Approve by HICL.

REVISION HISTORY

Date	Issues/Updates
06/01/2024	Updated: Cost Exceeds Maximum Policy, Veozah, Non-Formulary Policy, Compound Policy, Weight Loss GLP Policy, Xolair Added: Rivfloza
05/01/2024	Updated: Empaveli, Xolair Added: Xphozah, Fabhalta, Truqap, Eohilia
04/12/2024	Updated: Bosulif, Cosentyx, Erleada, Imbruvica, Inlyta, Jaypirca, Krazati, Mektovi, Nexavar, Orserdu, Prevymis, Sprycel, Votrient, Weight Loss, Welireg, Xtandi, Zydelig, Cibinqo, Rinvoq, Nucala, Xolair, Dupixent, Growth Hormone, Compound Policy Added: Bimzelx, Omvoh, Velsipity, Zilbrysq, Zykadia Deleted: Elidel, Protopic
03/28/2024	Updated: Bosulif, Cosentyx, Erleada, Imbruvica, Inlyta, Jaypirca, Krazati, Mektovi, Nexavar, Orserdu, Prevymis, Sprycel, Votrient, Weight Loss, Welireg, Xtandi, Zydelig Added: Bimzelx, Omvoh, Velsipity, Zilbrysq, Zykadia
03/01/2024	Updated: Xalkori, Zoryve, Rozlytrek, Humira Biosimilars, Inhaled Corticosteroids Added: Augtyro, Zurzuvae. Fruzaqla, Ogsiveo
01/17/2024	Updated: CGRP inhibitors, GLP-1 Agonists, Reyvow, Orencia, Humira Biosimilars, Kineret, Otezla, Olumiant, Siliq, Cimzia, Zejula, Pancreatic Enzymes, PCSK9 Inhibitors, Tremfya, Taltz, Zeposia, Skyrizi, Kevzara, Sotyktu, Enbrel, Simponi. Cosentyx, Actemra, Xeljanz IR/XR/Solution, Rinvoq, Stelara, Stimulants Added: Akeega, Jesduvroq Deleted: Daliresp
12/14/2023	Updated: Vyleesi, Nuedexta, Orilissa, Spravato, Infertility Drugs, Spritam, Korlym, Ofev, Isturisa, Signifor, Nuplazid, Esbriet, Pulmonary Hypertension agents, Yupelri, Testosterone products, Palovarotene, Natpara Hormone Injection, Trulance, Motegrity, Myfembree, Tenapanor, Oriahnn, Promacta, Linzess, Amitiza, Fluoxetine Tablets, SGLT Inhibitors,
11/27/2023	Updated: Adbry, Auvi-Q, Bempedoic (Nexletol, Nexlizet), Bronchitol, Camzyos, Cayston, Cibinqo, Corlanor, Cresemba, Dibenzyline, Dupixent, Elidel, Epclusa, Growth Hormone, Harvoni, Increlex, Juxtapid, Kalydeco, Mavyret, Multaq, Myalept, Mycapssa, Non-Formulary Policy, Odactra, Orkambi, Palforzia, PDE5 Inhibitors, Pollen Immunotherapy, Protopic, Rinvoq, Somavert, Sovaldi, Symdeko, Tafamidis (Vyndaqel, Vyndamax), Trikafta, Vascepa, Verquvo, Vonjo, Vosevi, Voxzogo, Zepatier Added: Sohonos, Vanflyta, Ojjaara
10/31/2023	Updated: Austedo, CGRP Inhibitors, Evrysdi, Firdapse, GLP-1 agonists, Growth Hormone, Hyftor, Ingrezza, Lenvima, Medial Necessity for Brand, Noxafil, Opzelura, Palynziq, Rubraca, Stimulants, Takhyzro, Talzenna, Winlevi, Xenazine, Zoryve, Aczone, Ampyra, Aubagio, Envarsus XR, DEFERASIROX (JADENU, EXJADE), Fintepla, Galafold, Ocaliva, Ponvory, Radicava, Rebif, Tecfidera, Uceris, Vivjoa, Vtama Added Litfulo and Xdemvy
08/25/2023	Updated: Reaffirmed: Actemra, Adbry, Afrezza, Alternative Dosage Form, Arcalyst, Austedo, Azelex, Benlysta, Bylvay, Cambia, CGRP, Chantix, Cholbam, Cibinqo, Cimzia, Cordran Tape, Cosentyx, Dupixent, Elmiron, Enbrel, Ergot Derivatives, Fasenra, Humira Biosimilars, Imcivree, Inbrija, Keveyis, Kevzara, Kineret, Linzess, Lokelma, Lotronex, Lucemyra, Lupkynis, Non-Formulary, Nourianz, Nucala, Olumiant, Omnipod, Orencia, Otezla, Oxervate, Oxybryta, Pancreatic Enzymes, Proton Pump Inhibitors, Qbrexa, Rhopressa and

Date	Issues/Updates
	Rocklatan, Rinvoq, Siliq, Simponi, Skyrizi, Sotyktu, Stelara, Sucraid, Taltz, Tezspire, Thiola, Tremfya, Viberzi, Xeljanz, Xolair, Zejula, Zeposia Added: Indocin, Miebo, Vowst Deleted: Alprostadil, Relistor, Fentanyl
07/26/2023	Updated: CGRP initiatives, Cimzia, Clinical Criteria: required medical information, Corlanor, Dupixent, Emsam, GLP-1 agonists, Growth Hormone, Kalydeco, Mekinist, , Rinvoq, Sunosi, Tafinlar, Testosterone, Trikafta, Wakix, Weight Loss, Xyrem/Xywav/Lumryz, Ztalmy Added: Veozah
06/23/2023	Updated: Firazyr, Toujeo, Cresemba, Prevymis, Mulpleta, Emverm, Nayzilam, Zavesca, Pyrukynd, Lampit, Nityr/Orfadin, Bylvay, Empaveli, Dibenzyline, Symlin, Daraprim, Banzel, Enspryng, Sovaldi, Jynarque/Samsca, Xuriden, Oxbryta, Off-label Use, Nuzyra, Trulance, Motegrity, Koselugo, Step therapy policy, Diacomit, Tapentadol (Nucynta, Nucynta ER), Sivextro, Ibsrela, Teriparatide, Egaten, Arikayce, Kynmobi, Strensiq, Doptelet, Orladeyo, Haegarda, Ruconest, Cablivi, Contraceptive Tier Policy, H.P Acthar, Symtuza, Cibinqo, Regranex, Benznidazole, Epidiolex, Eucrisa, Zepatier, Descovy, Kerendia, GLP-1, Reyvow, Xenleta, Linzess, Zokinvy, Amitiza, Livmarli, Impavido, Mupirocin, Diazepam Nasal Spray, Juluca, Cerdelga, Promacta, Hemlibra, Accrufer, Dificid, Tavalisse, Rukobia, Copaxone, Hematopoietic Agents, DAW Policy Deleted: Farydak, Truseltiq, Zelnorm
05/30/2023	Updated: CGRP, Non-Formulary Policy, Xifaxan, Rezurock, Onureg, Retevmo, Odomzo, Tazverik, Xermelo, Tepmetko. Fotivda, Mekinist, Bosulif, Lonsurf, Tukysa, Zelboraf, Venclexta, Brukinsa, Alecensa,Piqray, Scemblix, Ayvakit, Mektovi, Bosulif, Alunbrig, Cabometyx, Cometriq, Cotellic, Xalkori, Tafinlar, Vizimpro, Nubeqa, Inqovi, Copiktra, Idhifa, Braftovi, Rozlytrek, Inrebic, Xospata, Zydelig, Tibsovo, Ninlaro, Vitrakvi, Revlimid, Lorbrena, Rydapt, Exkivity, Tasigna, Zejula, Lynparza, Tagrisso, Pemazyre, Pomalyst, Stivarga, Besremi, Verzenio, Calquence, Gilotrif, Welireg, Tabrecta, Balversa, Afinitor Disperz, Iressa. Daurismo, Lenvima, Nerlynx, Ibrance, Iclusig, Gavreto, Orgovyx, Kisqali, Qinlock, Rubraca, Jakafi, Xpovio, Talzenna, Thalomid Deleted: Differin, Tazorac, Added: Joenja, Rezlidhia, Skyclarys, Filspari, Daybue, Topical Retinoids
04/25/2023	Updated: Turalio, Lumakras, Erleada, Takhzyro, Nucala, Zeposia, Skyrizi, Cosentyx, Tezspire, Actemra, Xeljanz, Rinvoq, Stelara, Xolair, Orencia, Humira and Biosimilars, Adbry, Kineret, Olumiant, Siliq, Cimzia, Cibinqo, Sotyktu, Dupixent, Enbrel, Fasenra, Simponi, Tremfya, Taltz, Otezla, Kevzara, GLP-1 Agonists Added: Demser
03/28/2023	Updated: CGRP Policy, Humira and Biosimilars Added: Orserdu, Inhaled Corticosteroids, Jaypirca, Tezspire
03/01/2023	Updated: Brexafemme, Skyrizi, Rebif, Tecfidera, Copaxone, Ponvory, Proton Pump Inhibitors, Aubagio, Zeposia Added: Sirturo, Krazati Deleted: Nuvigil/Provigil, Kapvay ER
02/06/2023	Annual Review and Updates: Nuvigil/Provigil, Cayston, Nexletol/Nexlizet, Vyleesi, Cabometyx, Kapvay, Nuedexta, Multaq, Dupixent, Oriahnn, Orilissa, Trikafta, AuviQ, Spravato, Fluoxetine, Growth Hormone, Odactra, Vaspeca, Infertility, Corlanor, Kalydeco, Spritam, Juxtapid, Orkambi, Bronchitol, Camzyos, Increlex, Myalept, Korlym, Ofev, Mycapssa, Isturisa, Natpara, Signifor, PCSK9 Inhibitors, Palforzia, Somavert, Dibenzyline, Nuplazid, Esbriet, Wakix, Pollen Immunotherapy, Pulmonary Hypertension Agents, Myfembree, Yupelri, Daliresp, Sodium Oxybate, Sunosi, Vyndamax/Vyndaqel, Testosterone, Symdeko, Verquvo, Voxzogo, Weight Loss Products Removed: Ukoniq

Date	Issues/Updates
01/17/2023	Updated: Stimulants Added: Inlyta, Sprycel, Xtandi, Furoscix, Lytgobi, Imbruvica, Tykerb, Ibrance, Votrient, Kuvan, Nexavar, Erivedge
12/30/2022	Updated: Dupixent, Abdry, Nucala, Rinvoq, Orencia, Olumiant, Siliq, Cimzia, Enbrel, Tremfya, Taltz, Zeposia, Skyrizi, Kevzara, Cosentyx, Actemra, Xeljanz, Stelara, Humira, Kineret, Takhzyro, Weight loss Products Added: Cibinqo, Sotyktu
11/17/2022	Updated: Dupixent, Protopic, PDE5 Inhibitors, Orkambi Added: Radicava
10/24/2022	Annual review and Updates: Lokelma, Chantix, Ingrezza, Tiopronin, Xenazine, Aubagio, Xermelo, Tafamidis, Tacrolimus ointment, Envarsus XR, Stimulants, Step Therapy Exception Policy, , Sodium Oxybate, SGLT2 Policy, Sucraid, Opzelura, Proton Pump Inhibitor Policy,Ponvory, Pollen Immunotherapy, Wakix, Elidel, Elmiron, Palynziq, Palforzia, PCSK9 Inhibitors, Signifor, Omnipod, Xolair, Ocaliva, Netarsudil, Netarsudil and Lananoprost, Galafold, Korlym, Relistor, Nucala, Medical Necessity for Brand policy, Mannitol, Lucemyra, Inbrija, Somatuline Depot, Nourianz, Afrezza, Infertility Policy, Vascepa, Odactra, Qbrexza, GLP-1 Policy, Mavyret, Cordran Tape, Fentanyl Quantity Limit PA Policy, Ergot Derivatives, AuviQ, Viberzi, Dupixent, Tecfidera, Cambia, Keveyis, Nuedexta, Austedo, Deferasirox, Aczone, Ampyra, Eucrisa, Cholbam, Oxervate, Fasenra, Azelex, Firdapse, Alternative Dosage Forms Policy, Lotronex, Adapalene, Myfembree, Cosentyx, CGRP Policy Added: Ibsrela, Hyftor, Zoryve, Vivjoa, Uceris
09/29/2022	Updated: Rebif, Pimecrolimus, Pulmonary Hypertension Agents, Imcivree, Tacrolimus, Winlevi, Noxafil, Pollen Immunotherapy, SGLT2, Lupkynis, Evrysdi, Fintepla Added: Tapinarof Removed: Synera
09/02/2022	Updated: Growth Hormone, Ledipasvir and sofosbuvir, Ocaliva, Vosevi, Tacrolimus, Epclusa, Eucrisa, Tyrvaya Added: Adbry Removed: Cesamet, Evzio
08/08/2022	Updated: Bempedoic Acid, Tremfya, Corlanor, Lynparza, Arcalyst, Rubraca, Jakafi, Cosentyx, Venclexta, Orencia, Adapalene, Benlysta
07/26/2022	Updated “Approved Using Off-Label Criteria” email template link
07/15/2022	Minor update to Humira, annual review pancreatic enzymes, updated Emgality strengths per diagnosis, updated duration for alprostadil, updated duration and quantity limits for PDE5 Inhibitors.
07/08/2022	Updated: Otezla formatting, weight loss products reviewer requirement and required medical information, Tazorac updated age, Ofev required medical information.
06/10/2022	Updated: Testosterone, Eucrisa, Rinvoq, Cimzia, Simponi, Cosentyx, Taltz, Zeposia, Sildenafil, Revatio, Ajovy Added: Ztalmy, Juxtapid, Camzyos
05/31/2022	Updated: Evolocumab, Alirocumab
05/27/2022	Updated: Pimecrolimus and Tacrolimus, Weight loss drugs
05/16/2022	Added pediatric HIV treatment indication and formulation for Descovy. Added UC and AS indications for Rinvoq. New policies for Pyrukynd and Vonjo.

Date	Issues/Updates
05/09/2022	Updated medication trials and authorization duration for Actemra, Cimzia, Cosentyx, Enbrel, Humira, Kevzara, Kineret, Olumiant, Orencia, Otezla, Rinvoq, Siliq, Simponi, Skyrizi, Stelara, Taltz, Tremfya and Xeljanz. Removed criteria for Caplyta. Added renewal criteria for off-label use policy.
04/26/2022	Removed criteria for Gilenya and Mayzent.
04/25/2022	Added initiative information to SGLT2 class.
04/22/2022	Added drugs without criteria procedure. Prescriber attestations of attacks added to Ruconest. Added age restriction to Kapvay and policy for SGLT2 class. Added 160 mg dose as an NCCN 2A indication for progressive CNS disease or leptomeningeal disease for Tagrisso. New combined policy for pulmonary hypertension agents: Letairis, Tracleer, Ventavis, Tyvaso, Opsumit, Uptravi, Orenitram, Adempas. Added utilization criteria for Imcivree. Added required medical information for EDS for Sunosi. Added Bonsity to teriparatide policy. Updated utilization criteria for Verquvo. Updated required medical information for Lupkynis. Minor updates and annual reviews: Nuvigil/Provigil, Nexletol and Nexlizet, Orladeyo, Vyleesi, Haegarda, Winlevi, H.P. Acthar, Multaq, Spravato, Dificid, fluoxetine tablets, Copaxone, Firazyr, Rebif, Corlanor, Takhzyro, Linzess, Zokinvy, Amitiza, Nuplazid, Trulance, Motegrity, Emsam, testosterone products.
04/01/2022	Updated requirements for CRSwNP indication for Dupixent, Nucala and Xolair.
03/14/2022	Annual review and minor updates: alprostadil, Banzel, Benlysta, benznidazole, Cablivi, Diacomit, Doptelet, Enspryng, Evrysdi, hematopoietic agents, Hemlibra, Increlex, Inqovi, Kerendia, Lampit, Mulpleta, Nayzilam, Nerlynx, Ninlaro, Nubeqa, Odomzo, Onureg, Orilissa, PDE5 inhibitors, Pemazyre, Piqray, Promacta, Revlimid, Rydapt, Somavert, Spritam, Stivarga, Strensiq, Talzenna, Tavalisse, Tazverik, Tibsovo, Tukysa, Valtoco, Vitrakvi, Xospata, Xpovio, Xuriden, Yupelri, Zavesca, Zydelig, Verzenio added indication for early breast cancer. Kineret, added prescriber type for CAPS and DIRA and removed infection monitoring requirements. Lowered minimum age for Epidiolex and added 60ml bottle. Added NCCN indications for Histiocytic Neoplasms and exon14 skipping in NSCLC and increased duration to 5 years for Xalkori. Added NCCN indication for EGFR S768I, L861Q, and/or G719X mutations, increased duration to 5 years for Vizimpro. Removed additional allergen statement for pollen immunotherapy. Removed requirement for NTRK positive tumors progression on prior therapy for Rozlytrek based on NCCN guidelines and updated duration. Added NCCN indication of uLMS to Zejula. Updated Lynparza to match NCCN guidelines. Added qualifying mutations for Tagrisso. Added indication of histiocytic neoplasm to Turalio. Added indications of primary CNS lymphoma and systemic light chain amyloidosis to Pomalyst. Added indication of thyroid carcinoma to Gavreto. Added indications of uLMS to Rubraca. Added indication of idiopathic hypersomnia to Xywav. Added indication of LCH for Zelboraf. Added indication of systemic light chain amyloidosis and WM/LPL to Venclexta. Updated coverage duration for Noxafil. Added contraceptive agents to non-formulary policy. Added lonapegsomatropin to growth hormone policy and added SHOX deficiency as accepted diagnosis for pediatric patients. Added state regarding contraceptive agents to Medical Necessity of brand name policy. New policies: Besremi, Voxzogo, Contraceptive Tier Exception
02/22/2022	Added step through addition of teriparatide 620 mcg/2.48 mL pens requirement for brand name Forteo.
02/15/2022	Added the initiatives to the new policies: Tavneos, Livtencity, and Lybalvi
02/08/2022	New policies for Lybalvi, Livtencity, and Tavneos. Updated age limit and dosage form for Oxbryta.
01/25/2022	Added Omnipod policy. Added internal note for Stelara approvals
01/12/2022	Cotellic corrected V600 requirement to align with NCCN for Cotellic and Mekinist. Mavyret required information updated.

Date	Issues/Updates
01/05/2022	Added indication to Nuvigil and Provigil. Updated Dupixent new pediatric asthma indication (6-11 years of age) with new 100 mg formulation. New policy for Scemblix, Welireg, Livmarli, Tasigna, Bylvay, Tyrvaya.
11/17/2021	Annual review and updates for the following clinical policies: Gilotrif, Alecensa, Erleada, Cayston, Benznidazole, Tabrecta, Copiktra, Oriahnn, Idhifa, Fintepla, Xenleta, Prevymis, Nuzyra, Isturisa, Farydak, Daraprim, Xifaxan, Arcalyst, Qinlock, Koselugo, Vosevi, Sivextro, Thalomid, Egaten Calquence added diagnoses of Splenic and Nodal MZL and MALT lymphoma. Updated age limit for Arikayce. Kynmobi titration kit added and annual review. Ayvakit annual review and AdvSM indication added. Bosulif annual review and added NCCN indications (ALL and MLNw/E) and mutation restrictions. Alunbrig annual review and added NCCN indication (IMT) Cabometyx annual review, add FDA indication (DTC), added NCCN indications (endometrial cancers, GIST, bone cancers). Dificid annual review, updated reviewer requirements and quantity limit. Cometriq annual review, updated utilization criteria. Cotellic annual review, updated approvable conditions per NCCN guidelines. Tafinlar annual review, updated approvable conditions per NCCN guidelines. Symtuza annual review, added reviewer and prescriber requirements, age restriction, weight requirement, modified coverage criteria and approval duration. Juluca annual review, added continuation coverage and reviewer requirements. Cerdelga annual review, prescriber restrictions added. Braftovi Separate policy. Balversa annual review and updated initial approval duration. Afinitor Disperz annual review, updated FDA dose, required medical information, reviewer requirements and quantity restrictions. Inrebic added NCCN indications and annual review. Rukobia annual review and required medical information added. Iressa annual review, removed side effect counseling requirement. Daurismo annual review, retreatment indication added per NCCN. Mavyret annual review, age restriction updated, reviewer requirements added. Cresemba annual review, updated age restriction. Harvoni annual review, age restriction updated, and operation notes added. Lenvima annual review and added indication for thymic carcinoma and DTC radioactive iodine requirement. Lorbrena annual review, ST for ALK+ disease removed. Emverm annual review, added age restriction. Impavido annual review add CDC indication amebic meningoencephalitis. Nityr annual review, added Orfadin to policy. Natpara annual review, added required medical information and age restriction. New policy for Dibenzyline. Iclusig annual review and updated indications. Noxafil annual review, updated dosing, and indication. Kisqali removed tamoxifen requirement. Retevmo added indications. Sovaldi annual review, updated indications, and duration. Mekinist annual review and updated indications. Lonsurf annual review and updated indications. Epclusa annual review, added decompensated cirrhosis 24-week pathway and updated age restrictions. Brukinsa annual review, added indications and updated duration. Added Atogepant to CGRP policy. Taltz clarified PsA/PsO quantity limit. Added policies for Exkivity and Opzelura. Updated medication trials for Humira, Kevzara, Kineret, Olumiant, Orencia, Otezla, Xeljanz, Added policies for Lupkynis and Verquvo
10/19/2021	Updated Stelara trials for Crohn's and PsA to just 1 conventional product Removed Vumerity from step through process for Tecfidera and Aubagio
09/30/2021	Added RA ST with Actemra and Orencia to Cimzia, Kevzara, Simponi. Formatting updated. Update of prophylaxis continuation for Cresemba. Formatting updated. Removed policy for expedited fax/call escalations. Added new indication of recurrent pericarditis to Arcalyst.
09/20/2021	Added new clinical policies for Rezurock, Idhifa, Kerendia, Brexafemme, Truseltiq, Empaveli, Myfembree Updated Jakafi and Oriahnn policies
09/01/2021	Made minor updates to Non-Formulary, Off Label Use, and Tapentadol policies. Clarified criteria for Samsca in the Tolvaptan policy.
08/09/2021	Updated the triptan step therapy for abortive agents to include an allowance for triptan contraindications.

Orange Text = Emphasis Blue Text = Links Red Text = New Info Green Text = Auto PA

Date	Issues/Updates
	Updated PsO criteria for Enbrel, Skyrizi, Stelara, Tremfya, Cimzia, Cosentyx, Otezla, Siliq, and Taltz. Updated EGPA criteria for Nucala. Updated Descovy operational notes to instruct to set cost share to $0 if approved for PrEP, removed aged restrictions, and removed prescriber restrictions.
07/28/2021	Updated Orencia, Aubagio, Ponvory, Rebif, Zeposia, Tecfidera, and Copaxone for rebates compliance. Removed Plegridy criteria since PA removed. Added new policies of Accrufer, Mannitol, and Lumakras. Removed cataplexy as an exclusion for coverage for members with narcolepsy in Stimulants and Nuvigil and Provigil clinical policy. Annual review and updates for the following clinical policies: Off-Label Use Policy, CGRP Inhibitors, Nurtec ODT, Ubrelvy, Esbriet, Ergotamine Derivatives, Differin, Alternative Dosage Forms, Azelex, Regranex, Siliq, Fasenra, Eucrisa, Aczone, Cambia, Dupixent, Trikafta, Nucala, Weight Loss, Auvi-Q, Fentanyl, Cordran Tape, GLP-1 Agonists, Qbrexza, Vascepa, Toujeo, Afrezza, Kalydeco, Taltz, Reyvow, Synera, Lucemyra, Orkambi, Medical Necessity for Brand, Korlym, Galafold, Mupirocin Cream, Ofev, Non-Formulary Policy, Xolair, Palynziq, Elidel, Symlin, Orgovyx, Skyrizi, Daliresp, Cosentyx, Step Therapy Exception Policy, Stimulants, Protopic, Tazorac, Symdeko, Actemra, Jynarque, Chantix, and Lokelma.
07/07/2021	Added new clinical policy of Ponvory.
06/09/2021	Updated the stimulants policy to remove cataplexy as an exclusion for coverage in narcolepsy. Added new policies for Xolair and Ponvory. Updated the Step Therapy policy to include the indication must be supported by the requested product's FDA-approved label or meets the plan's off-label use policy. Updated prescriber restrictions on Orgovyx.
05/10/2021	Updated the prescriber requirements for Actemra. Updated reconsiderations timeframe to 90 days from initial denial.
04/29/2021	Annual review and updates for the following clinical policies: Lotronex, Letairis, Firdapse and Ruzurgi, Nuvigil and Provigil, Nexletol and Nexlizet, Tracleer, Vyleesi, Oxervate, Cholbam, Kapvay, Ampyra, Jadenu, Austedo, Nuedexta, Keveyis, Tecfidera, Multaq, Viberzi, Spravato, Fintepla, Tremfya, Odactra, Ventavis, Nourianz, Corlanor, Inbrija, Linzess, Amitiza, Caplyta, Opsumit, Relistor, Cesamet, Evzio, Rhopressa and Rocklatan, Ocaliva, Pancreatic Enzymes, Palforzia, Elmiron, Nuplazid, Wakix, Trulance, Pollen Immunotherapy, Proton Pump Inhibitors, Motegrity, Adempas, Sucraid, Emsam, Uptravi, Xyrem and Xywav, Sunosi, Stimulants, Envarsus XR, Vyndaqel and Vyndamax, Zelnorm, Xermelo, Aubagio, Xenazine, Thiola, Tyvaso and Orenitram ER, and Ingrezza. Updated policies for PCSK9 Inhibitors, Taltz, Infertility Drugs, Actemra, CGRP Inhibitors, and GLP-1 Agonists.
04/19/2021	New policies added for Tepmetko, Fotivda, and Ukoniq.
02/23/2021	New policies added for Zokinvy, Orgovyx, Imcivree, Winlevi, and Orladeyo. Updated Haegarda, Ruconest, Firazyr, and Takhzyro. Updated the timeframes to request appeal for clarification.
02/01/2021	Added internal note for Rozerem stating it is excluded below age 65. Removed reference to BRCA+ for maintenance therapy of Lynparza. Updated Forteo/Tymlos per guideline updates. Updated Descovy to clarify intent of labs. Updated/Added policies for Growth Hormone, Hematopoietic Agents, Aubagio, Copaxone, Rebif, Tecfidera, and Zeposia to align with new MS, GH and ESA strategies. Updated Xyrem policy to include Xywav.

Date	Issues/Updates
	Added rheumatologist to uveitis diagnosis for Humira provider restriction. Clarified backdating procedure and clarified samples procedure for medications received through patient assistance programs. Made minor updates to the following for annual review: Actemra, Acthar, Alprostadil, Alprostadil, Arcalyst, Banzel, Benlysta, Cablivi, Cimzia, Diacomit, Doptelet, Enbrel, Epidiolex, Fluoxetine, GLP1 Agonists, Hematopoietic Agents, Hemlibra, Humira, Kevzara, Kineret, Mulpleta, Nayzilam, Nerlynx, Ninlaro, Nubeqa, Odomzo, Olumiant, Orencia, Otezla, Oxbryta, PDE5 Inhibitors, Pemazyre, Piqray, Pomalyst, Promacta, Revlimid, Rinvoq, Rozlytrek, Rubraca, Rydapt, Simponi, Spravato, Spritam, Stelara, Stivarga, Tagrisso, Talzenna, Tavalisse, Tazverik, Testosterone, Tibsovo, Tukysa, Turalio, Valtoco, Venclexta, Verzenio, Vitrakvi, Vizimpro, Xalkori, Xeljanz, Xospata, Xpovio, Xuriden, Zejula, Zelboraf, and Zydelig.
11/12/2020	Added new clinical policies for Lampit, Gavreto, and Enspryng. Made minor updates to Humira. Updated Vascepa to include criteria for primary and secondary ASCVD prevention. Updated Multaq to clarify criteria surrounding history of heart failure. Updated Yupelri to include inability to use a handheld inhaler device per provider attestation. Updated testosterone age restrictions. Updated alternative dosage forms clinical policy to include reference to doses unobtainable with the conventional dosage form and renewal criteria.
10/27/2020	Updated Cosentyx Quantity/Partial-Fill Restrictions
10/22/2020	Added new clinical policies for Onureg, Inqovi, and Evrysdi. Updated off-label use policy to include use of well-designed clinical trials. Updated Step Therapy policy to include trial and failure of all required step drugs. Updated infertility section to includes list of medications included in the max 5 fills policy, point of sale rejection, supplemental language, and INF indicator on the drug look up tool. Made minor updates to the following for annual review: Acthar, Afinitor Disperz, Alecensa, Alunbrig, Arikayce, Ayvakit, Balversa, Benznidazole, Bosulif, Braftovi Mektovi, Brukinsa, Cabometyx, Calquence, Cayston, Cerdelga, Cometriq, Copiktra, Cotellic, Cresemba, Daraprim, Daurismo, Descovy, Dificid, Egaten, Emverm, Epclusa, Erleada, Farydak, Forteo, Tymlos, Gilotrif, Harvoni, Iclusig, Idhifa, Impavido, Increlex, Infertility, Inrebic, Iressa, Isturisa, JAKAFI, Juluca, Kisqali, Lenvima, Lonsurf, Lorbrena, Lynparza, Mavyret, Mekinist, Miglustat, Natpara, Nityr, Noxafil, Nuzyra, Orilissa, Prevymis, Signifor, Sivextro, Somatuline Depot, Somavert, Strensiq, Symtuza, Tafinlar, Thalomid, Vosevi, Xenleta, and Xifaxan.
10/01/2020	Removed Rapaflo/silodosin. Updated Nurtec ODT prescriber restrictions. Updated Dupixent prescriber restrictions and added "moderate-to-severe" to asthma sections. Clarified technician process for External Third Level Appeal Requests. Updated compound criteria to clarify coverage of two covered ingredients. Updated Actemra, Cimzia, Cosentyx, Kevzara, Kineret, Olumiant, Orencia, Otezla, Siliq, Simponi, Taltz, and Xeljanz to align with new autoimmune strategy.
09/18/2020	Updated Harvoni criteria to include criteria for pellet packs. Updated Nexletol criteria to include Nexlizet. Updated Aczone criteria to extend coverage duration for renewal requests. Updated Stimulants policy initiative to approve at HICL. Updated fluoxetine criteria to remove provider requirement and extend approval duration. Updated Step Therapy criteria to remove 180-day look back for manual reviews. Clarified quantity limits criteria for requests above the formulary limit. Added new policies for Fintepla, Kynmobi, Oriahnn, Rukobia, and Sovaldi Pellets.
08/31/2020	Added clarification to Ubrelvy and Nurtec ODT criteria for acceptable trials and clarified renewal criteria for Ubrelvy. Updated verbiage for NF cost exceeds requests to match rest of document.
08/07/2020	Updated Dupixent criteria to evaluate for FDA approved dosing for atopic dermatitis. Clarified technician process for Cost Exceeds Max requests. Added internal note for 1 ingredient compounds for peds patients.
07/22/2020	Updated Jynarque criteria to include Samsca. Updated Cosentyx and Taltz to included indication of nr-axSpA. Updated Dupixent to change age edit for atopic dermatitis. Updated Lynparza to add new indication. Added new policies for Koselugo, Qinlock, Retevmo, Tabrecta, and Zeposia.

Date	Issues/Updates
06/26/2020	Initial creation