Pharmacy Coverage Policy Manual

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Preferred Drug List (PDL)
This contains coverage rules for medications including prior authorization criteria for medications billed by pharmacy point of sale systems and for HCPCS codes billed by a physician/clinic through an 837P transactions.

Preferred Diabetes Supply List (PDSL)
This is a list of diabetes supplies billed by pharmacy point of sale systems.

Prior Authorization Review Dates
Please see our DUR Board Vendor Website

Rules

1. Requests for non-preferred brand name agents with a generic formulation available must meet the Dispense as Written (DAW1) criteria for approval in addition to as any other applicable coverage criteria/rule (unless otherwise noted).
2. Non-solid dosage preparations must meet Non-Solid Dosage Preparations prior authorization criteria even if they are preferred in the clinical category.
3. Renewal Request Criteria must be met for all renewal requests.
4. The use of all preferred and non-preferred agents must meet recommendations found in the FDA label or compendia (e.g., diagnosis, age, dosage, frequency, route). Compendia supported use is defined as at least of level of IIa efficacy rating and IIb recommendation. ND Medicaid uses DrugDex ® compendia. Requests outside of FDA approved or compendia supported use are not reviewable by prior authorization and the request will be dismissed on PA review. Sec. 1927. [42 U.S.C. 1396r-8] (d).
5. Clinical justification must be provided explaining how the requested drug is expected to benefit or has benefited the member's condition based on available evidence and outcomes of the drug (subject to clinical review).
6. Clinical justification may be provided when criteria does not encompass a standard of care or guideline supported therapy or a member's unique scenario, by faxing supporting chart notes and evidence using the General Prior Authorization Form.
7. Grandfathering may be allowed in cases where the clinical condition has been verified by a specialist, member is currently receiving FDA or compendia approved medication, and there is clinical evidence for decompensation of member's condition if agent is switched (subject to clinical review).
8. A trial will be considered a failure if a product was not effective at the maximum therapeutic dose with good compliance (defined as the condition is continuously being treated) with most recent trial within the past 3 months, as evidenced by paid claims or pharmacy print outs. If unable to titrate dose to maximum therapeutic dose due to contraindication, intolerance, or lack of effect; trial requirements must be met with alternative preferred product(s) when applicable. Mitigation efforts must be provided, as applicable, with a request to bypass a trial for a preferred product(s) due to intolerance (subject to clinical review). A preferred product must be trialed prior to a non-preferred product approval.
9. The use of pharmaceutical samples or direct to consumer sales will not be considered when evaluating the member's medical condition or prior prescription history for drugs that require prior authorization.
10. Unless otherwise specified, the listing of a brand or generic name includes all legend formulations of that drug. OTC drugs are not covered unless specified. All drugs are pharmacy billed medications unless otherwise specified.
11. Please use the following forms unless otherwise indicated:
    - Pharmacy Point of Sale: General Prior Authorization Form
    - Medical Office Billing: Provider Administered Drug (Medical Billing) PA Form
    - Requested product is same active ingredient as preferred product: MedWatch Form
12. For pharmacy billed medication: please use the prior authorization website to access PA forms, NDC Drug Lookup, quantity limits, and prior authorization information for all medications.

13. For medical billed medications: Please use the Procedure Code Look-up Tool to search for the HCPCS codes that require prior authorization.
14. All requirements outlined in the Pharmacy Provider Manual and any other federal or ND Medicaid manuals, policies, or guidance still apply. For example, when the PDL says a drug is covered without prior authorization, that does not imply that ND Medicaid will pay for that drug if someone has Medicare coverage.
15. If member is 65 years or older, on chronic renal dialysis or has had a kidney transplant within the past 3 years, Medicare eligibility must be ruled out (6-month approval may be allowed to determine eligibility)

Prior Authorization Updates

Drug name	PA Status	Class
methylphenidate patch	PA	ADHD Stimulants
Awiqli	PA	Insulin

Version Changes

Category	Change
ADHD non-stimulants	Preferred Products and Criteria Updated - Onyda XR
ADHD stimulants	Criteria Updated - Cotempla XR ODT
Allergic Fungal Rhinosinusitis	Criteria Updated - Dupixent
Alzheimer's Disease	Criteria Updated - Leqembi Iqlik
Biosimilars	Preferred Products Updated - Pegfilgrastim
Biosimilars	Preferred Products Updated - Ranibizumab
Bowel Prep Agents	Preferred Products Updated - generic Suprep
DPP-4 Inhibitors / SGLT2 Inhibitors Combination	Preferred Products Updated - Glyxambi
Hematopoietic, Erythropoiesis Stimulating Agents	Preferred Products Updated - Mircera
Insulins	Criteria Updated - Awiqli new to market
Mucooplysaccharidosis II - Hunter Syndrome	Criteria Updated
Non-Cystic Fibrosis Bronchiectasis	Criteria Updated - Brinsupri
Opioid Reversal Medications	Preferred Products Updated - Rextovy
SGLT2 Inhibitors	Preferred Products Updated - Synjardy XR
Thyroid Eye Disease	Preferred Products and Criteria Updated - Lumvoa new to market
Vaginal Anti-infectives	Preferred Products Updated

General Policies

Biosimilar Agents:

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a 90-day trial of each preferred medication, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).
- A MedWatch form for each trial of each NDC from the available manufacturer(s) is filled out and attached to request.

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-fkjp	adalimumab-aacf
HADLIMA (adalimumab-bwwd)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm
SIMLANDI (adalimumab-ryvk)	adalimumab-ryvk
this space intentionally left blank	AMJEVITA (adalimumab-atto)
this space intentionally left blank	CYLTEZO (adalimumab-abdm)
this space intentionally left blank	HULIO (adalimumab-fkjp)
this space intentionally left blank	HYRIMOZ (adalimumab-adaz)
this space intentionally left blank	YUFLYMA (adalimumab-aaty)
this space intentionally left blank	YUSIMRY (adalimumab-aqvh)

Aflibercept

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PAVBLU (aflibercept-ayyh) – Medical Billing	EYLEA (aflibercept) – Medical Billing

Bevacizumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALYMSYS (bevacizumab-maly) – Medical Billing	AVASTIN (bevacizumab) – Medical Billing *C9257 for ophthalmology injections does not require PA.
MVASI (bevacizumab-awwb) – Medical Billing	JOBEVNE (bevacizumab-nwgd) – Medical Billing
ZIRABEV (bevacizumab-bvzr) – Medical Billing	VEGZELMA (bevacizumab-acdc) – Medical Billing

Denosumab

Subcutaneous

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BILDYOS (denosumab-nxxp) – Medical Billing	BOSAYA (denosumab-kyqq) – Medical Billing

ENOBY (denosumab-qbde) – Medical Billing	CONEXXENCE (denosumab-bnht) – Medical Billing
JUBBONTI (denosumab-bbdz) – Medical Billing	OSPOMYV (denosumab-dssb) – Medical Billing
this space intentionally left blank	OSVYRTI (denosumab-desu) – Medical Billing
this space intentionally left blank	PROLIA (denosumab) – Medical Billing
this space intentionally left blank	STOBOCLO (denosumab-bmwo) – Medical Billing

Intraveneous

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BILPREVDA (denosumab-nxxp) – Medical Billing	AUKELSO (denosumab-kyqq) – Medical Billing
WYOST (denosumab-bbdz) – Medical Billing	BOMYNTRA (denosumab-bnht) – Medical Billing
XTRENBO (denosumab-qbde) – Medical Billing	JUBEREQ (denosumab-desu) – Medical Billing
this space intentionally left blank	OSENVELT (denosumab-bmwo) – Medical Billing
this space intentionally left blank	XGEVA (denosumab) – Medical Billing

Eculizumab

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EPYSQLI (eculizumab-aagh) – Medical Billing	BKEMV (eculizumab-aeeb) – Medical Billing
this space intentionally left blank	SOLIRIS (eculizumab) – Medical Billing

Filgrastim

Medical Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GRANIX (TBO-filgrastim) – Medical Billing	NEUPOGEN (filgrastim) – Medical Billing
NIVESTYM (filgrastim-aafi) – Medical Billing	RELEUKO (filgrastim-ayow) – Medical Billing
ZARXIO (filgrastim-sndz) – Medical Billing	this space intentionally left blank

Pharmacy Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEUPOGEN (filgrastim)	FILKRI (filgrastim-laha)
this space intentionally left blank	GRANIX (TBO-filgrastim)
this space intentionally left blank	NIVESTYM (filgrastim-aafi)
this space intentionally left blank	NYPOZI (filgrastim-txid)
this space intentionally left blank	RELEUKO (filgrastim-ayow)
this space intentionally left blank	ZARXIO (filgrastim-sndz)

Pegfilgrastim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FULPHILA (pegfilgrastrim-jmdb)	NEULASTA (pegfilgrastim)
FULPHILA (pegfilgrastrim-jmdb) – Medical Billing	NEULASTA (pegfilgrastim) – Medical Billing

FYLNETRA (pegfilgrastim -pbbk)	NEULASTA ONPRO (pegfilgrastim) – Medical Billing
FYLNETRA (pegfilgrastim -pbbk) – Medical Billing	NYVEPRIA (pegfilgrastim–apgf)
this space intentionally left blank	NYVEPRIA (pegfilgrastrim–apgf) – Medical Billing
this space intentionally left blank	STIMUFEND (pegfilgrastim-fpgk)
this space intentionally left blank	STIMUFEND (pegfilgrastim-fpgk) – Medical Billing
this space intentionally left blank	UDENYCA (pegfligrastim-cbqv)
this space intentionally left blank	UDENYCA (pegfligrastim-cbqv) – Medical Billing
this space intentionally left blank	UDENYCA ONBODY (pegfligrastim-cbqv) – Medical Billing
this space intentionally left blank	ZIEXTENZO (pegfilgrastim-bmez)
this space intentionally left blank	ZIEXTENZO (pegfilgrastim-bmez) – Medical Billing

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – Medical Billing	RENFLEXIS (infliximab-abda) – Medical Billing
INFLECTRA (infliximab-dyyb) – Medical Billing	REMICADE (infliximab) – Medical Billing
infliximab – Medical Billing	ZYMFENTRA (infliximab-dyyb)

Insulin Aspart – Novolog/Fiasp

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FIASP (insulin aspart)	KIRSTY (insulin aspart-xjhz)
this space intentionally left blank	MERILOG (insulin aspart-szjj)
this space intentionally left blank	NOVOLOG (insulin aspart)
this space intentionally left blank	RELION NOVOLOG (insulin aspart)

Insulin Glargine - Lantus

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LANTUS U-100 (insulin glargine) – Brand Required	BASAGLAR (insulin glargine)
this space intentionally left blank	insulin glargine-yfgn U-100 (generic Semglee)
this space intentionally left blank	REZVOGLAR U-100 (insulin glargine-aglr)

Natalizumab

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

TYSABRI (natlizumab) – Medical Billing	TYRUKO (natlizumab-sztn) – Medical Billing

Ranibizumab

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CIMERLI (ranibizumab-eqrn) – Medical Billing	BYOOVIZ (ranibizumab-nuna) – Medical Billing
LUCENTIS (ranibizumab) – Medical Billing	this space intentionally left blank

Rituximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – Medical Billing	RITUXAN (rituximab) – Medical Billing
RUXIENCE (rituximab-pvvr) – Medical Billing	this space intentionally left blank
TRUXIMA (rituximab-abbs) – Medical Billing	this space intentionally left blank

Tocilizumab

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
TYENNE (tocilizumab-aazg) VIAL – Medical Billing	ACTEMRA (tocilizumab) VIAL – Medical Billing
this space intentionally left blank	AVTOZMA (tocilizumab-anoh) AUTOINJECTOR, SYRINGE
this space intentionally left blank	AVTOZMA (tocilizumab-anoh) VIAL – Medical Billing
this space intentionally left blank	TOFIDENCE (tocilizumab-aazg) VIAL – Medical Billing

Trastuzumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRAZIMERA (trastuzumab-qyyp) – Medical Billing	HERCEPTIN (trastuzumab) – Medical Billing
this space intentionally left blank	HERCESSI (trastuzumab-strf) – Medical Billing
this space intentionally left blank	HERZUMA (trastuzumab-pkrb) – Medical Billing
this space intentionally left blank	KANJINTI (trastuzumab-anns) – Medical Billing
this space intentionally left blank	OGIVRI (trastuzumab-dkst) – Medical Billing
this space intentionally left blank	ONTRUZANT (trastuzumab-dttb) – Medical Billing

Ustekinumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

PYZCHIVA (ustekinumab-ttwe)	IMULDOSA (ustekinumab-srlf)
SELARSDI (ustekinumab-aekn)	IMULDOSA (ustekinumab-srlf) – Medical Billing
STARJEMZA (ustekinumab-hmny)	OTULFI (ustekinumab-aauz)
STEQEYMA (ustekinumab-stba) -- Medical Billing	OTULFI (ustekinumab-aauz) – Medical Billing
this space intentionally left blank	PYZCHIVA (ustekinumab-ttwe) – Medical Billing
this space intentionally left blank	SELARSDI (ustekinumab-aekn) – Medical Billing
this space intentionally left blank	STARJEMZA (ustekinumab-hmny) – Medical Billing
this space intentionally left blank	STELARA (ustekinumab)
this space intentionally left blank	STELARA (ustekinumab) – Medical Billing
this space intentionally left blank	STEQEYMA (ustekinumab-stba)
this space intentionally left blank	ustekinumab
this space intentionally left blank	ustekinumab – Medical Billing
this space intentionally left blank	ustekinumab-aauz
this space intentionally left blank	ustekinumab-aekn – Medical Billing
this space intentionally left blank	ustekinumab-aekn
this space intentionally left blank	ustekinumab-ttwe
this space intentionally left blank	ustekinumab-ttwe – Medical Billing
this space intentionally left blank	YESINTEK (ustekinumab-kfce)
this space intentionally left blank	YESINTEK (ustekinumab-kfce) - Medical Billing
this space intentionally left blank	WEZLANA (ustekinumab-auub)
this space intentionally left blank	WEZLANA (ustekinumab-auub) – Medical Billing

Dispense as Written (DAW1)

Member or prescriber preference is NOT criteria considered for approval.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Request must meet one of the following (A or B):
  A. Primary insurance requires a ND Medicaid non-preferred branded product.
  B. All the following are met (1-4):
     1. The requested brand-name product must not have an authorized generic available.
     2. The member must have failed a 30-day trial of each pharmaceutically equivalent generic product at maximum tolerated dose from each available manufacturer, as evidenced by paid claims or pharmacy print outs.
     3. Clinical justification is provided for the different clinical outcome expected for the requested brand and other alternatives (e.g., medications in same class) are not an option for the member (subject to clinical review)

4. A MedWatch form for each trial of each NDC from the available manufacturer(s) is filled out and attached to request.

Generic Non-Preferred Requests

Member or prescriber preference is NOT criteria considered for approval.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months (1 month for short-term request)

- Request must meet one of the following (A, B, or C):
  - A. Primary insurance requires a ND Medicaid non-preferred generic product.
  - B. Pharmacy requests a short-term approval due to dose titration, supply issue, or to fulfill a first fill requirement prior to using ND Medicaid brand required medication.
  - C. All the following are met (1-3):
    1. The member must have failed a 30-day trial of preferred brand product, as evidenced by paid claims or pharmacy print outs.
    2. Clinical justification has been provided for the different clinical outcome expected for the requested generic and other alternatives (e.g., medications in same class) are not an option for the member (subject to clinical review)
    3. A MedWatch form for each trial of each product from the available manufacturer(s) is filled out and attached to request.

Medications that cost over $3000/month

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

A. Both of the following must be met:
   1. The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
   2. The medication must be used as recommended in available guidelines or expert consensus statements, including medication trials that are recommended prior to use of requested medication.

B. The requested medication must be prescribed by, or in consult with, a specialist in the member's treated diagnosis.

C. As applicable, confirmation of diagnosis must be provided as evidenced by serum markers or pathogenic gene variants amenable to treatment.

D. Baseline labs, signs or symptoms that can be utilized for comparison to show member has experienced clinical benefit upon renewal have been submitted with request.

PA REQUIRED
ABECMA (idecabtagene vicleucel) – Medical Billing
ACTHAR (corticotropin) SELF-INJECTOR

ADSTILADRIN (nadofaragene firadenovec-vncg) – Medical Billing
AUCATZYL (obecabtagene autoleucel) – Medical Billing
AVMAPKI/FAKZYNJA (avutometinib/defacitinib)
BIZENGRI (zenocutuzumab-zbco) – Medical Billing
BLINCYTO (blinatumomab) – Medical Billing
BREYANZI (lisocabtagene maraleucel) – Medical Billing
CABLIVI (caplacizumab-yhdp)
CARVYKTI (ciltacabtagene autoleucel) – Medical Billing
CHOLBAM (cholic acid)
CORTROPHIN (corticotropin) GEL SYRINGE
CRENESSITY (crinecerfont)
CTEXLI (chenodiol)
CYSTADROPS (cysteamine)
CYSTARAN (cysteamine)
DANYELZA (naxitamab-gqgk) – Medical Billing
DAYBUE (trofinetide)
DAYBUE STIX (trofinetide) PACKET
DATROWAY (datopotamab deruxtecan-dlnk) – Medical Billing
DECNUPAZ (pivekimab sunirine-pvzy) – Medical Billing
DOJOLVI (triheptanoin)
EMRELIS (telisotuzumab vedotin-tllv) – Medical Billing
ENCELTO (revakinagene taroretcel-lwey) – Medical Billing
EPIOXA (riboflavin 5-phosphate) – Medical Billing
EPKINLY (epcoritamab-bysp) – Medical Billing
FIRDAPSE (amifampridine)
FOLOTYN (pralatrexate) – Medical Billing
FORZINITY (elamipretide)
FUROSCIX (furosemide)
FUROSCIX (furosemide) – Medical Billing
FYARRO (sirolimus protein-bound particles) – Medical Billing
GATTEX (teduglutide)
HEPCLUDEX (bulevirtide-gmod)
INCRELEX (mecasermin)
JOENJA (leniolisib)
KIMMTRAK (tebentafusp-tebn) – Medical Billing
KYGEVVI (doxecitine/doxribtimine)
KYMRIAH (tisagenlecleucel) – Medical Billing
LASIX ONYU (furosemide)
MODEYSO (dordaviprone)
NULIBRY (fosdenopterin)
OXERVATE (cenegermin-bkbj)
OTARMENI (lunsotogene parvec-cwha) – Medical Billing
PAPZIMEOS (zopapogene imadenovec-drba) – Medical Billing
phenoxybenzamine
PYRUKYND (mitapivat)
REDEMPLO (plozasiran)
REVCOVI (elapedademase-lvir)

RYONCIL (remestemcel-l-rknd) – Medical Billing
SKYCLARYS (omaveloxolone)
SPEVIGO (spesolimab-sbzo)
SOHONOS (palovarotene)
STRENSIQ (asfotase alfa)
TECARTUS (brexucabtagene autoleucel) – Medical Billing
TECELRA (afamitresgene autoleucel) – Medical Billing
TECVAYLI (Inj teclistamab cqyv 0.5 mg) – Medical Billing
TIVDAK (tisotumab vedotin-tftv) – Medical Billing
TRYNGOLZA (olezarsen)
VEOPOZ (pozelimab) – Medical Billing
VIJOICE (alpelisib)
VYKAT XR (diazoxide)
WELIREG (belzutifan)
XENPOZYME (olipudase alfa) – Medical Billing
XOLREMDI (mavorixafor)
YARTEMLEA (narsoplimab-wuug) – Medical Billing
YESCARTA (axicabtagene ciloleucel) – Medical Billing
ZIIHERA (zanidatamab-hrii) – Medical Billing
ZOKINVY (lonafamib)
ZYCUBO (copper histidinate)
ZYNLONTA (loncastuximab tesirine-lpyl) – Medical Billing

Non-Solid Dosage Forms

Electronic Age Verification

- Non-Solid Dosage Forms that do not require prior authorization for clinical criteria will reject at the point of sale for members 10 years and older to verify they meet Non-Solid Dosage Form prior authorization criteria.
- The member must not be on other solid dosage forms (this may reject for Therapeutic Duplication)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 years (1 month for short-term restriction)

- One of the following criteria is met:
  1. The member has a feeding tube placed and the medication is not available in a dosage form that can be crushed or poured into the tube
  2. The member does not have a feeding tube placement but one of the following apply:
     - Swallow study documentation has been submitted showing inability to swallow
     - Permanent disability of swallowing solid dosage forms
     - Short-term restriction (e.g., mouth surgery)

Renewal Requests

Prior Authorization Criteria

Renewal Criteria

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication (subject to clinical review).
- The member must continue to meet applicable initial criteria. Additional renewal criteria may apply as indicated under specific category.
- One of the following must be met (1 or 2):
  1. *Approval Duration: regular renewal approval duration or 1 year*
     1. The member was at least 80% adherent to medication, excluding any claim gaps due to hospitalization or eligibility.
  2. *Approval Duration: 3 months*
     2. All the following must be met -
        - Clinical justification must be provided for the non-adherence.
        - A method to improve adherence must be provided such as addressing adherence barriers, implementing a treatment plan, medication therapy management (MTM), etc.
        - Clinical justification must be provided to continue treatment and how efficacy is assessed despite non-adherence.

Allergy/Immunology

Therapeutic Duplication

- One strength of one medication is allowed at a time.

Allergic Fungal Rhinosinusitis (AFRS)

Steroids – Nasal Spray

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
See Steroid – Nasal Spray	XHANCE (fluticasone)

Initial Criteria - Approval Duration: 12 months

- Xhance (fluticasone) Only: The member has failed two 30-day trials of steroid nasal sprays of different active ingredients, one must be fluticasone.

Biologics

Anti-IL-4/13 biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

DUPIXENT (dupilumab)	this space intentionally left blank

Prior Authorization Criteria

Prior Authorization Form - Nasal Polyps

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an ear/nose/throat specialist or allergist/immunologist.
- The member must have a history of sino-nasal surgery.
- The member must meet one of the following:
  - The member must have failed a 12-week trial of intranasal corticosteroids, as evidenced by paid claims or pharmacy printouts.
  - The member must have trialed at least two courses of a 10-day trial of oral glucocorticoids in the past year, as evidenced by paid claims or pharmacy printouts.
- The member must have polyps (unilateral or bilateral) confirmed by sinus CT, anterior rhinoscopy, or nasal endoscopy.

Renewal Criteria - Approval Duration: 12 months

- The member must have received a therapeutic response as evidenced by a significant reduction in nasal polyp size and symptoms since treatment initiation.
- The member must be receiving intranasal steroids.

Chronic Spontaneous Urticaria (Chronic Idiopathic Urticaria)

Biologic Agents

PA REQUIRED
DUPIXENT (dupilumab)
RHAPSIDO (remibrutinib)
XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR
XOLAIR (omalizumab) VIALS – *Medical Billing*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 3 months

- The member must have failed a 60-day trial of a dose of fourfold normal dosing of second-generation H_1 antihistamine (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine) as evidenced by paid claims or pharmacy printouts

References

1. Khan DA. Chronic spontaneous urticaria: Treatment of refractory symptoms. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2025
2. Schaefer P. Acute and Chronic Urticaria: Evaluation and Treatment. Am Fam Physician. 2017 Jun 1;95(11):717-724. PMID: 28671445

3. Zuberbier, Torsten, et al. "The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria." *Allergy* 77.3 (2022): 734-766.
4. Zuberbier, T., Aberer, W., Asero, R., Bindslev-Jensen, C., Brzoza, Z., Canonica, G. W.,... & Maurer, M. (2014). The diagnosis and management of acute and chronic urticaria: 2014 update. Journal of Allergy and Clinical Immunology

Chronic Rhinosinusitis with Nasal Polyps

Steroids – Nasal Spray

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
See Steroid – Nasal Spray	XHANCE (fluticasone)

Initial Criteria - Approval Duration: 12 months

- Xhance (fluticasone) Only: The member has failed two 30-day trials of steroid nasal sprays of different active ingredients, one must be fluticasone.

Biologics

Anti-IL-4/13 biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab)	this space intentionally left blank

Anti-IL-5 biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR	this space intentionally left blank
NUCALA (mepolizumab) VIAL – *Medical Billing*	this space intentionally left blank

Eosinophil-directed biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR	this space intentionally left blank
XOLAIR (omalizumab) VIAL – *Medical Billing*	this space intentionally left blank

Thymic Stromal Lymphopoietin (TSLP) blocker

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TEZSPIRE (tezepelumab-ekko) PENS	this space intentionally left blank
TEZSPIRE (tezepelumab-ekko) VIAL and SYRINGES – *Medical Billing*	this space intentionally left blank

Prior Authorization Criteria

Prior Authorization Form - Nasal Polyps

Initial Criteria - Approval Duration: *3 months*

- The requested medication must be prescribed by, or in consult with, an ear/nose/throat specialist or allergist/immunologist.
- The member must have failed a 12-week trial of intranasal corticosteroids, as evidenced by paid claims or pharmacy printouts.
- The member must have trialed at least two courses of a 10-day trial of oral glucocorticoids in the past year, as evidenced by paid claims or pharmacy printouts.
- The member must have bilateral polyps confirmed by sinus CT, anterior rhinoscopy, or nasal endoscopy.

Non-Preferred Agent Criteria:

- The member must have failed a 90-day trial with each preferred agent, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria - Approval Duration: *12 months*

- The member must have received a therapeutic response as evidenced by a significant reduction in nasal polyp size and symptoms since treatment initiation.
- The member must be receiving intranasal steroids.

References:

1. Rank, Matthew A., et al. "The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis." *Journal of Allergy and Clinical Immunology* 151.2 (2023): 386-398.

Cytokine Release Syndrome

Biologic Agents

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tocilizumab – See Biosimilar Agents	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria - Approval Duration: *4 doses*

- The member must have chimeric antigen receptor (CAR) T cell-induced Cytokine Release Syndrome
- The member must have grade 3 or 4 Cytokine Release Syndrome resulting in hypotension and/or hypoxia.
- The member must be on concurrent glucocorticoids.

References

- Porter DL, Maloney DG. Cytokine Release Syndrome. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2025

Deficiency of IL-A Receptor Antagonists (DIRA)

Biologic Agents

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ARCALYST (rilonacept)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must have failed a 15-month trial of a preferred agent, as evidenced by paid claims or pharmacy printouts.

References

- Nigrovic PA. Cryopyrin-associated periodic syndromes and related disorders. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2025

ANCA-Associated Vasculitis

Eosinophilic Granulomatosis with Polyangiitis (EGPA)

Biologic Agents

Anti-B-cell Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rituximab – See Biosimilar Agents	this space intentionally left blank

Anti-IL-5 Biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FASENRA (benralizumab)	this space intentionally left blank
NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR	this space intentionally left blank
NUCALA (mepolizumab) VIAL – *Medical Billing*	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist, rheumatologist, or allergy/immunology specialist.
- The member must not have severe disease defined as vasculitis with life- or organ-threatening manifestations (e.g., active glomerulonephritis, pulmonary hemorrhage, cerebral vasculitis, progressive peripheral or cranial neuropathy, gastrointestinal bleeding due to vasculitis, cardiac

involvement (coronary vasculitis, pericarditis, or myocarditis), mesenteric ischemia, limb/digit ischemia)
- The member must have received at least 4 weeks of an oral corticosteroid dose ≥ 7.5 mg/day to control relapsing or refractory disease.
- The member must have asthmatic manifestations on a combination of high doses of inhaled glucocorticoids and long acting β2-agonist.
- The member must have blood eosinophil count of ≥ 1000 cells/mcL and/or ≥10 percent of leukocytes within the previous 6 weeks.

Renewal Criteria - Approval Duration: 12 months (one time renewal except in history of multiple relapses)
- The member must have experienced a decrease in relapses* and corticosteroid dose, and an increase of time of remission since starting treatment with the requested medication, subject to clinical review.

*Relapse is defined as active vasculitis, active asthma symptoms, active nasal or sinus disease requiring the use of glucocorticoids or immunosuppressants.

References

1. Chung SA, Langford CA, Maz M, Abril A, Gorelik M, Guyatt G, et al. 2021 American College of Rheumatology/Vasculitis Foundation guideline for the management of antineutrophil cytoplasmic antibody–associated vasculitis. *Arthritis Care Res (Hoboken)* 2021; 73: 1088– 1105.
2. Jennette, J.C., Falk, R.J., Bacon, P.A., Basu, N., Cid, M.C., Ferrario, F., Flores-Suarez, L.F., Gross, W.L., Guillevin, L., Hagen, E.C., Hoffman, G.S., Jayne, D.R., Kallenberg, C.G.M., Lamprecht, P., Langford, C.A., Luqmani, R.A., Mahr, A.D., Matteson, E.L., Merkel, P.A., Ozen, S., Pusey, C.D., Rasmussen, N., Rees, A.J., Scott, D.G.I., Specks, U., Stone, J.H., Takahashi, K. and Watts, R.A. (2013), 2012 Revised International Chapel Hill Consensus Conference Nomenclature of Vasculitides. Arthritis & Rheumatism, 65: 1-11. https://doi.org/10.1002/art.37715
3. King, Jr. TE. Eosinophilic granulomatosis with polyangiitis (Churg-Strauss): Treatment and prognosis. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023
4. Emmi, Giacomo, et al. "Evidence-Based Guideline for the diagnosis and management of eosinophilic granulomatosis with polyangiitis." *Nature reviews Rheumatology* 19.6 (2023): 378-393.

Granulomatosis with Polyangiitis (GPA)/Microscopic Polyangiitis (MPA)

Biologic Agents

Anti-B-cell Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
cyclophosphamide	this space intentionally left blank
rituximab – See Biosimilar Agents	this space intentionally left blank

Complement C5a Receptor Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	TAVNEOS+ (avacopan)

+Tavneos is under review from the FDA because new information indicates it has not been shown effective for its approved use. Further, 76 cases of drug-induced liver injury, including vanishing bile duct syndrome, have been identified with evidence suggesting a casual link to Tavneos resulting in 54 hospitalizations and 8 deaths. CDER proposes to withdraw approval of TAVNEOS | FDA

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a nephrologist, rheumatologist, pulmonologist, or other specialist.
- The member must have severe disease defined as vasculitis with life- or organ-threatening manifestations (e.g., active glomerulonephritis, pulmonary hemorrhage, progressive peripheral or cranial neuropathy, orbital pseudotumor, scleritis, gastrointestinal bleeding due to vasculitis, cardiac disease due to vasculitis such as pericarditis or myocarditis)
- The member must be receiving adjunctive standard induction therapy with rituximab or cyclophosphamide
- Clinical justification must be provided explaining why the member needs to limit use of glucocorticoids (subject to clinical review)
- Clinical justification must be provided explaining why the member would benefit from this drug despite the FDA's proposed withdraw of Tavenos because new information indicates that it has not been shown to be effective for its approved use (subject to clinical review)

Renewal Criteria - Approval Duration: 6 months (the safety and efficacy of avacopan beyond 52 weeks have not yet been addressed)

- The member must have experienced a decrease in relapses* and corticosteroid dose, and an increase of time of remission since starting treatment with the requested medication, subject to clinical review.

*Relapse is defined as active vasculitis in any organ system after remission is achieved

Food Allergy

Eosinophil-directed biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR	this space intentionally left blank
XOLAIR (omalizumab) VIAL – *Medical Billing*	this space intentionally left blank

Oral Immunotherapy

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PALFORZIA (peanut allergen powder)	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria - Approval Duration: *6 months*

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist.
- The provider must attest that the member has access to injectable epinephrine, and that the member/caregiver has been instructed and trained on its appropriate use.
- The member has one of the following (A, B, or C):
  - A. The member has a history of severe (type 1) allergic response requiring the use of epinephrine, an ER visit, or hospitalization.
  - B. Allergic reaction produced during a provider observed intake of food allergen and attestation that food allergy is likely to produce anaphylaxis as determined by allergist/immunologist.
  - C. The member has all the following:
  - o History of urticaria, angioedemia, or wheeze
  - o Skin prick wheal of at least 3 mm or positive IgE test as determined by allergist/immunologist (at least 0.35 kUA/L for Palforzia and at least 30 IU/mL for Xolair)
  - o Attestation that food allergy is likely to produce anaphylaxis as determined by allergist/immunologist.

Renewal Criteria (Palforzia Only) - Approval Duration: *6 months for continued up-titration or 12 months for maintenance of the 300 mg dose.*

- The member must have been adherent with therapy (last 6 fills must have been on time).
- One of the following must be met (A or B)
  - A. The member has been able to tolerate the maintenance dose of Palforzia (300 mg daily) OR
  - B. An up-titration plan to a final dose of 300 mg daily by week 40 and this is the first request for an up-titration renewal.

Hypereosinophilic Syndrome (HES)

Biologic Agents

PA REQUIRED
FASENRA (benralizumab)
NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR
NUCALA (mepolizumab) VIAL – *Medical Billing*

Prior Authorization Criteria

Initial Criteria - Approval Duration: *6 months*

- The requested medication must be prescribed by, or in consult with, a hematologist, or allergy/immunology specialist.
- The member must be FIP1L1-PDGFRα kinase-negative.
- The member must meet one of the following criteria:

- The member has experienced at least 2 HES flares within the past 12 months despite a 3-month trial with oral corticosteroid ≥ 7.5 mg/day, as evidenced by paid claims or pharmacy printouts.
- The member requires more than 10 mg/day of prednisone daily for control and has significant side effects from glucocorticoid therapy.

- The member must have a blood eosinophil count of 1000 cells/mcL or higher.

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit (e.g., reduction in flares, decreased blood eosinophilic count, reduction in corticosteroid dose or steroid sparing therapy) since starting treatment with the requested medication, subject to clinical review.

Gout

Flare Treatment

Oral agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
colchicine tablet	colchicine capsule
NSAIDS	GLOPERBA (colchicine) ORAL SOLUTION
Oral Corticosteroids	MITIGARE (colchicine) CAPSULE

Prior Authorization Criteria

- See applicable Preferred Dosage Form or Non-Solid Oral Dosage Form criteria.

Biologic Agents

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (PA REQUIRED)
ILARIS (canakinumab) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a rheumatologist or nephrologist.
- The member is concurrently taking a medication for prophylaxis of gout flares

- The member must have had at least three gout flares in the previous year that have been unmanaged despite at least a 7-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
    - colchicine
    - indomethacin or naproxen
    - glucocorticoids

Urate Lowering Therapy

Uricosuric Drugs

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
probenecid-colchicine tablets	this space intentionally left blank
probenecid tablets	this space intentionally left blank

Xanthine Oxidase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
allopurinol 100 mg, 300 mg	allopurinol 200 mg
azathioprine 50 mg	azathioprine 75 mg, 100 mg
febuxostat	AZASAN (azathioprine)
this space intentionally left blank	IMURAN (azathioprine)
this space intentionally left blank	ULORIC (febuxostat) TABLET

++ In clinical trials, febuxostat had a higher incidence of thromboembolic cardiovascular events and hepatic abnormalities compared to allopurinol.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- See applicable Preferred Dosage Form criteria

Uricase

PREFERRED AGENTS (PA REQUIRED)
KRYSTEXXA (pegloticase) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a rheumatologist or nephrologist.

- The member must have failed a 3-month trial of two of the following, as evidenced by paid claims or pharmacy printouts:
  - allopurinol
  - febuxostat
  - allopurinol or febuxostat in combination with probenecid
- The failure of previous trials must be documented by both of the following (A and B):
  A. A. Serum uric acid level ≥ 6 mg/dL within the past month
  B. One of the following (i, ii, or iii):
     i. At least 3 gout flares in the previous 18 months that were inadequately controlled.
     ii. At least 1 gouty tophus
     iii. Chronic gouty arthropathy/arthritis

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, subject to clinical review, including both of the following:
  - Serum uric acid level < 6 mg/dL within the past month
  - Decrease in gout flares or nonrevolving tophaceous deposits

Hereditary Angioedema (HAE)

Acute Attack

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
icatibant	BERINERT (plasma derived C1 Esterase Inhibitor)
SAJAZIR (icatibant)	BERINERT (plasma derived C1 Esterase Inhibitor)– *Medical Billing*
this space intentionally left blank	EKTERLY (sebetralstat)
this space intentionally left blank	FIRAZYR (icatibant)
this space intentionally left blank	KALBITOR (ecallantide) – *Medical Billing*
this space intentionally left blank	RUCONEST (recombinant C1 Esterase Inhibitor)
this space intentionally left blank	RUCONEST (recombinant C1 Esterase Inhibitor) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or rheumatologist.

Non-Preferred Agent Criteria:

- The member must have a contraindication to or failed a trial of all preferred agents, as evidenced by paid claims or pharmacy printouts.
  - Berinert Only: The preferred agent trial may be bypassed for members who are pregnant, breastfeeding, or under 18 years old upon request.

- Kalbitor Only: The member must have a contraindication to or failed a trial of Berinert or Ruconest, as evidenced by paid claims or pharmacy printouts.

Prophylaxis

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HAEGARDA (plasma derived C1 Esterase Inhibitor)	ANDEMBRY (garadacimab-gxii)
ORLADEYO (berotralstat)	CINRYZE (plasma derived C1 Esterase Inhibitor)
ORLADEYO (berotralstat) PELLET PACK	DAWNZERA (donidalorsen)
TAKHZYRO (lanadelumab-flyo)	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or rheumatologist.
- The member's weight and dose are provided.
- One of the following must be met (A, B, or C):
  - The member has had at least 1 moderate to severe acute attack in the past 3 months (e.g., airway swelling, facial swelling, severe abdominal pain)
  - The member is using short-term prophylaxis for one of the following:
    - a procedure related to pregnancy
    - oral cavity or invasive procedures
    - stressful life event at high risk for precipitating HAE attack (clinical justification subject to clinical review)
  - Estrogen treatment is required, and the member is at high risk for estrogen-precipitated HAE attack (clinical justification subject to clinical review)

Non-Preferred Agent Criteria:

- The member must have a contraindication to or failed a 3-month trial of all preferred agents with the same indication for use (prophylaxis or acute treatment), as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by at least a 50% reduction in the number of HAE attacks.

Quantity Override Request

- Takhyzro: The number of attacks in the last 6 months must be included if the requested dosing frequency is every 2 weeks (must be more than 0).

References

1. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol Pract. 2021;9(1):132–150. Published by Elsevier Inc. on behalf of the American Academy of Allergy, Asthma & Immunology. Available at: https://www.haea.org/assets/img/TreatmentGuidelines040321.pdf

Immune Globulins

IM

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAMASTAN (immune globul G (IgG)/glycine)	this space intentionally left blank
GAMASTAN (immune globul G (IgG)/glycine) – *Medical Billing*	this space intentionally left blank

IVIG

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BIVIGAM (human immunoglobulin G)	ALYGLO (human immunoglobulin G - stwk)
BIVIGAM (human immunoglobulin G) – *Medical Billing*	ALYGLO (human immunoglobulin G - stwk) – *Medical Billing*
GAMMAGARD S-D (human immunoglobulin G)	ASCENIV (human immune globulin G- slra)
GAMMAPLEX (human immunoglobulin G)	ASCENIV (human immune globulin G- slra) – *Medical Billing*
GAMMAPLEX (human immunoglobulin G) – *Medical Billing*	PANZYGA (human immune globulin G- ifas)
OCTAGAM (human immunoglobulin G)	PANZYGA (human immune globulin G - ifas) – *Medical Billing*
OCTAGAM (human immunoglobulin G) – *Medical Billing*	QIVIGY (human immune globulin G – kthm)
PRIVIGEN (human immunoglobulin G)	QIVIGY (human immune globulin G – kthm) – *Medical Billing*
PRIVIGEN (human immunoglobulin G) – *Medical Billing*	this space intentionally left blank

IVIG/SCIG

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAMMAGARD LIQUID (human immunoglobulin gamma)	this space intentionally left blank
GAMMAKED (human immunoglobulin gamma)	this space intentionally left blank
GAMMAKED (human immunoglobulin gamma) – *Medical Billing*	this space intentionally left blank
GAMUNEX-C (human immunoglobulin gamma)	this space intentionally left blank
GAMUNEX-C (human immunoglobulin gamma) – *Medical Billing*	this space intentionally left blank

SCIG

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CUTAQUIG (human immune globulin G - hipp)	CUVITRU (human immunoglobulin gamma)
CUTAQUIG (human immune globulin G - hipp) – *Medical Billing*	CUVITRU (human immunoglobulin gamma) – *Medical Billing*
HIZENTRA (human immunoglobulin gamma)	HYQVIA (human immune globulin G and hyaluronidase)
HIZENTRA (human immunoglobulin gamma) – *Medical Billing*	HYQVIA (human immune globulin G and hyaluronidase) – *Medical Billing*
XEMBIFY (immune globulin,gamma(IgG)klhw)	this space intentionally left blank
XEMBIFY (immune globulin,gamma(IgG)klhw) – *Medical Billing*	this space intentionally left blank

Electronic Diagnosis and Quantity Verification

- For medical billing only: the following Local Coverage Determination applies to applicable preferred and non-preferred agents: Article - Billing and Coding: Immune Globulin Intravenous (IVIg) (A57187) (cms.gov)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- If the member's BMI > 30, adjusted body weight must be provided along with the calculated dose.
- The member must meet one of the following criteria:
  - The member must have failed a trial of each of the preferred products, as evidenced by paid claims or pharmacy printouts.
  - The member is stable on current therapy (have had a paid claim for requested therapy in the past 45 days)

Steroids – Nasal Spray

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DYMISTA (azelastine-fluticasone) – *Brand Required*	azelastine-fluticasone
fluticasone	flunisolide
mometasone – labeler 60605	mometasone – labeler 65152, 59651
OMNARIS (ciclesonide)	QNASL CHILDREN (beclomethasone)
QNASL (beclomethasone)	RYALTRIS (olopatadine/mometasone)
this space intentionally left blank	XHANCE (fluticasone)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.

- Xhance (fluticasone) Only: See Preferred Dosage Form Criteria

Cardiology

Therapeutic Duplication

- One Strength of one medication is allowed at a time
  - Exceptions:
    - carvedilol IR 25 mg allowed with all other strengths
    - warfarin strengths are allowed together
    - prazosin strengths are allowed together
- Medication classes not payable together:
  - Entresto, ACE Inhibitors, ARBs, and Renin Inhibitors are not allowed with each other.
  - sildenafil, tadalafil, Adempas, nitrates are not allowed with each other.
  - carvedilol and labetalol are not allowed with other non-selective alpha blockers (Alfuzosin ER, doxazosin, prazosin, and terazosin)
    - carvedilol and labetalol are non-selective beta blockers with alpha 1 blocking activity
  - tizanidine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
    - tizanidine is also an alpha 2 agonist
  - clopidogrel is not covered with esomeprazole or omeprazole. Other PPIs such as pantoprazole are covered with clopidogrel.
    - clopidogrel is a substrate for 2C19 and esomeprazole and omeprazole are strong 2C19 inhibitors and can decrease effectiveness of clopidogrel.
  - clopidogrel, prasugrel, ticagrelor, and ticlopidine are not covered with morphine. Other opioid analgesics are covered with clopidogrel, prasugrel, ticagrelor, and ticlopidine.
    - Morphine may diminish the antiplatelet effect and serum concentrations of P2Y12 Inhibitor antiplatelet agents (clopidogrel, prasugrel, ticagrelor, and ticlopidine).

Alpha and/or Beta Blockers Therapeutic Duplication – Override Request

Overrides may be available for alpha and/or beta blockers for use within the cardiac or nephrology specialties if they have a difference in mechanism of action (e.g., non-selective or selective beta blocking activity, with or without alpha-1 blocker activity). Please request an override by calling provider relations at 1-800-755-2604.

- The prescribers of each medication must be aware of each other.
- The requested medications must be prescribed by, or in consult with, a cardiologist or nephrologist.

Anticoagulants

Anticoagulants - Direct Oral Anticoagulants (DOACs)

Solid oral dosage forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

dabigatran	PRADAXA (dabigatran)
ELIQUIS (apixaban)	SAVAYSA (edoxaban)
XARELTO (rivaroxaban)	this space intentionally left blank

Non-solid oral dosage forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELIQUIS (apixaban) SPRINKLE CAPSULE	PRADAXA (dabigatran) PELLET
ELIQUIS (apixaban) TABLET FOR SUSPENSION	rivaroxaban suspension
XARELTO (rivaroxaban) SUSPENSION – *Brand Required*	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent and warfarin, as evidenced by paid claims or pharmacy printouts.

Reduction of Risk of Major Cardiovascular Events in Chronic Coronary Artery Disease or Peripheral Artery Disease

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rivaroxaban 2.5 mg	XARELTO (rivaroxaban) 2.5 mg

Anticoagulants - Injectables

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
enoxaparin	ARIXTRA (fondaparinux)
this space intentionally left blank	fondaparinux – *No PA required for HIT diagnosis**
this space intentionally left blank	FRAGMIN (dalteparin)
this space intentionally left blank	LOVENOX (enoxaparin)

Electronic Diagnosis Verification

- Fondaparinux: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of enoxaparin, as evidenced by paid claims or pharmacy printouts.
- Fragmin only: The member must have failed a 30-day trial of fondaparinux, as evidenced by paid claims or pharmacy printouts.

Calcium Channel Blockers

Solid oral dosage forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amlodipine	diltiazem 12HR ER capsule
CARTIA XT (diltiazem) capsule	diltiazem ER(LA) tablet
diltiazem tablet	levamlodipine tablet
diltiazem ER(CD) capsule	isradipine capsule
diltiazem ER(XR) capsule	MATZIM LA (diltiazem) ER tablet
DILT-XR (diltiazem) capsule	nicardipine capsule
felodipine ER	nisoldipine ER
nifedipine	NORVASC (amlodipine)
nifedipine ER	PROCARDIA XL (nifedipine)
nimodipine capsule	SULAR ER (nisoldipine)
TIADYLT ER (diltiazem)	verapamil ER PM
verapamil tablet	this space intentionally left blank
verapamil ER/SR capsule	this space intentionally left blank
verapamil ER tablet	this space intentionally left blank

Non-solid oral dosage forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NORLIQVA (amlodipine) SOLUTION	KATERZIA (amlodipine) SUSPENSION
nimodipine solution – *PA required for non-solid dosage form*	NYMALIZE (nimodipine) SOLUTION

Prior Authorization Criteria

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a 30-day trial of each preferred medication of the same subtype (e.g., dihydropyridine, non-dihydropyridine), as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

Electronic Diagnosis Verification

- Nimodipine and Nymalize: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

Diuretics

Diuretics – Solid Dosage Forms

Diuretics - Loop

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
furosemide	ethacrynic acid
bumetanide	this space intentionally left blank
torsemide	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Ethacrynic acid: One of the following must be met:
  1. The member must have a documented sulfa allergy.
  2. The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy print outs.

Diuretics – Potassium Sparing / Sodium Channel Blocker

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amiloride	triamterene

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy print outs.

Diuretics – Potassium Sparing / Aldosterone Antagonist

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amiloride	ALDACTONE (spironolactone)
eplerenone	INSPRA (eplerenone)
spironolactone	this space intentionally left blank

Diuretics - Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
furosemide oral solution	CAROSPIR (spironolactone) SUSPENSION
spironolactone suspension	INZIRQO (hydrochlorothiazide) ORAL SUSP

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy print outs.

Heart Failure

Solid Dosage Forms

First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACE (angiotensin-converting enzyme) inhibitors – all oral agents preferred	ENTRESTO (sacubitril/valsartan)
ARBs (angiotensin receptor blockers) – all oral agents preferred	FARXIGA (dapagliflozin)
Beta blockers – all oral agents preferred	INPEFA (sotagliflozin)
dapagliflozin	SAMSCA (tolvaptan)
Diuretics	tolvaptan
JARDIANCE (empagliflozin)	this space intentionally left blank
OZEMPIC (semaglutide) INJECTION	this space intentionally left blank
sacubitril/valsartan	this space intentionally left blank

Second Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ivabradine tablet	ivabradine oral solution	CORLANOR (ivabradine)
this space intentionally left blank	KERENDIA (finerenone)	this space intentionally left blank
this space intentionally left blank	VERQUVO (vericiguat)	this space intentionally left blank

Non-Solid Dosage Forms

First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
enalapril oral solution	ENTRESTO (sacubitril/valsartan) SPRINKLE
this space intentionally left blank	EPANED (enalapril) SOLUTION

Electronic Diagnosis Verification

- Ivabradine, Entresto, and Verquvo: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Electronic Duration Verification:

- tolvaptan is payable for 30 days every year.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Ivabradine Only (oral solution only):
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member's heart rate must not be determined exclusively by a pacemaker
  - The member has a diagnosis of heart failure with left ventricular ejection fraction of ≤ 35%
  - For members 18 years or older: The member must have a resting HR ≥ 70 beats per minute despite a 30-day trial of each of the following on maximally tolerated or target beta blocker dose in sinus rhythm, as evidenced by paid claims or pharmacy printouts:
    - Metoprolol
    - Bisoprolol
    - Carvedilol
  - For members less than 18 years old: The member must have a resting HR per minute as indicated below despite a 30-day trial each of metoprolol and carvedilol at a maximally tolerated or target beta blocker dose in sinus rhythm, as evidenced by paid claims or pharmacy printouts:
    - HR ≥ 105 bpm in the age-subset 6–12 months.
    - HR ≥ 95 bpm in the age-subset 1–3 years.
    - HR ≥ 75 bpm in the age-subset 3–5 years
- Entresto Sprinkle
  - See Non-Solid Dosage Form criteria
  - The member has a diagnosis of heart failure with left ventricular ejection fraction of ≤ 45 %
  - The member has failed a 3-month trial of enalapril, as evidenced by paid claims or pharmacy printouts and a NT-proBNP that failed to decrease by 60%.
- Inpefa Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist or nephrologist.
  - The member is receiving concurrent Entresto, a beta-blocker, and a mineralocorticoid receptor antagonist as evidenced by paid claims or pharmacy printouts.
  - The member must not have diabetes type 1
  - The member has failed 30-day trials of dapagliflozin and empagliflozin (and a GLP-1 agonist if concurrent heart failure with left ventricular ejection fraction of ≥ 40% and BMI is >30 kg/m^2), as evidenced by paid claims or pharmacy printouts. Failure is defined by being admitted to the hospital, a heart failure unit, infusion center, or emergency department for worsening heart failure within the past 3 months.
- Kerendia Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member has a diagnosis of heart failure with left ventricular ejection fraction of ≥ 40%
  - The member has been admitted to the hospital, a heart failure unit, infusion center, or emergency department for worsening heart failure within the past 3 months despite 2-month trials each of spironolactone and eplerenone in combination with a SLGT-2 inhibitor (and a GLP-1 agonist if BMI is >30 kg/m^2), as evidenced by paid claims or pharmacy printouts.

- Tolvaptan Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist
  - The member is experiencing sodium levels less than 120 mEq/L despite a 30-day trial of an ACE inhibitors or ARBs in combination with a loop diuretic, as evidenced by paid claims or pharmacy printouts.
  - The member does not have liver disease.
- Verquvo Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member must have left ventricular ejection fraction (LVEF) < 45% at initiation.
  - The member must have had a hospitalization or need for IV diuretics within the past 3 months despite 2-month trial of Entresto, a beta-blocker, a SGLT-2 Inhibitor, a mineralocorticoid receptor antagonist, and vasodilator therapy (e.g., isosorbide and hydralazine or amlodipine)

Hypertrophic Cardiomyopathy

PA REQUIRED
CAMZYOS (mavacamten)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a cardiologist.
- The member must have all the following:
  - left ventricular ejection fraction (LVEF) ≥ 55%
  - NYHA class II or III
  - Resting oxygen saturation of ≥ 90%
  - Valsava left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation.
- The member must have persistent symptoms despite maximally tolerated concurrent therapy with each of the following for 90 days, as evidenced by paid claims or pharmacy printouts.
  - Non-dihydropyridine calcium channel blocker
  - beta blocker
  - disopyramide

Renewal Criteria – Approval Duration: 12 months

- The member has one of the following:
  - an improved pVO_2 by ≥ 1.5 mL/kg/min plus improvement in NYHA class by at least 1
  - an improvement of pVO_2 by ≥ 3 mL/kg/min and no worsening in NYHA class.
  - NYHA class I or II without exertion-induced syncope
  - Valsalva LVOT gradient < 50 mmHg at rest or with provocation.

References

1. Olivotto, Iacopo, et al. "Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): a randomised, double-blind, placebo-controlled, phase 3 trial." The Lancet 396.10253 (2020): 759-769.

2. Desai, Milind Y., et al. “Mavacamten in patients with hypertrophic cardiomyopathy referred for septal reduction: week 56 results from the VALOR-HCM randomized clinical trial.” JAMA cardiology 8.10 (2023): 968-977.

Lipid-Lowering Agents

ACL (ATP Citrate Lyase) Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEXLETOL (bempedioc acid)	this space intentionally left blank
NEXLIZET (bempedoic acid and ezetimibe)	this space intentionally left blank

Electronic Step Therapy Required

- Nexletol or Nexlizet:
  - PA Not Required Criteria: A total of 90-day supply of rosuvastatin or atorvastatin has been paid within 120 days prior to Nexletol or Nexlizet’s date of service.
  - PA Required Criteria: The member must have failed a 90-day trial of rosuvastatin or atorvastatin, as evidenced by paid claims or pharmacy printouts.

Cholesterol Absorption Inhibitor – 2-Azetidinone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ezetimibe	ZETIA (ezetimibe)

Eicosapentaenoic acid (ESA) Ethyl Ester

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
icosapent ethyl	this space intentionally left blank

Fenofibrate

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fenofibrate, micronized 43 mg, 67 mg, 134 mg, 200mg	fenofibrate capsules 50 mg, 150 mg
fenofibrate, nanocrystallized	fenofibrate, micronized 130 mg
fenofibrate tablets 54 mg, 160 mg	fenofibrate tablets 40 mg, 120 mg
fenofibric acid DR 45 mg, 135 mg	LIPOFEN (fenofibrate)
this space intentionally left blank	TRICOR (fenofibrate, nanocrystalized)

Prior Authorization Criteria

- See Preferred Dosage Form criteria

MTP (Microsomal Triglyceride Transfer Protein) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	JUXTAPID (lomitapide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- Clinical justification must be provided explaining why the member is unable to use all other products to lower their cholesterol (subject to clinical review)

PCSK9 (Proprotien Convertase Subtilisin/Kexin Type 9) Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
REPATHA (evolocumab)	LEROCHOL (lerodalcibep-liga)
this space intentionally left blank	PRALUENT (alirocumab)

Underutilization

- Lerochol, Praluent and Repatha must be used adherently and will reject on point of sale for late fill.

Electronic Step Therapy Required

- Repatha:
  - PA Not Required Criteria: A total of 90-day supply of rosuvastatin or atorvastatin has been paid within 120 days prior to Repatha's date of service.
  - PA Required Criteria: The member must have failed a 90-day trial of rosuvastatin or atorvastatin, as evidenced by paid claims or pharmacy printouts.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have failed a 90-day trial of the preferred PCSK9 inhibitor agent, as evidenced by paid claims or pharmacy printouts

Renewal Criteria – Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.

Statins (HMG-CoA (3-hydroxy-3-methylglutaryl-CoA Reductase Inhibitors)

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atorvastatin	amlodipine/atorvastatin
ezetimibe/simvastatin	CADUET (amlodipine/atorvastatin)
fluvastatin	CRESTOR (rosuvastatin)
lovastatin	fluvastatin ER
pravastatin	LESCOL XL (fluvastatin ER)
rosuvastatin	LIPITOR (atorvastatin)
simvastatin	LIVALO (pitavastatin)
this space intentionally left blank	pitavastatin
this space intentionally left blank	VYTORIN (ezetimibe/simvastatin)
this space intentionally left blank	ZOCOR (simvastatin)
this space intentionally left blank	ZYPITAMAG (pitavastatin)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Pitavastatin Only –
  - One of the following criteria must be met:
    - The member is receiving treatment with anti-retroviral therapy for HIV
    - The member is receiving treatment with a strong CYP3A4 inhibitor and is experiencing muscle toxicity despite 90-day trials with fluvastatin, rosuvastatin, and pravastatin, as evidenced by paid claims or pharmacy printouts.
- All other agents: See Preferred Dosage Form criteria

Non-Solid Dosage Forms

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ATORVALIQ (atorvastatin) SOLUTION	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Non-Solid Dosage Form criteria

Angiopoietin-like 3 (ANGPTL3) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	EVKEEZA (evinacumab-dgnb) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a cardiologist, endocrinologist, or lipid specialist.
- The member must have one of the following:
  - Two mutant alleles at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK9) confirmed by genetic testing
  - Untreated total cholesterol of > 325 mg/dL with one of the following:
  - tendinous xanthomata
- The member has alow-density lipoprotein cholesterol (LDL-C) level greater than 100 mg/dL after a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - PCSK9 inhibitor and ezetimibe combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg
  - Bempedoic acid and ezetimibe combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg

Renewal Criteria – Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.

siRNA (small interfering RNA) therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	LEQVIO (inclisiran) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have failed a 90-day trial of both of the following, as evidenced by paid claims or pharmacy printouts:
  - PCSK9 inhibitor combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg
  - Bempedoic acid and ezetimibe combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg

Renewal Criteria – Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.

Platelet Aggregation Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
aspirin	clopidogrel 300 mg
aspirin/dipyridamole ER	BRILINTA (ticagrelor)
clopidogrel 75 mg	EFFIENT (prasugrel)
cilostazol	PLAVIX (clopidogrel)
dipyridamole	this space intentionally left blank
prasugrel	this space intentionally left blank

ticagrelor	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed 30-day trials of at least 3 preferred platelet aggregation inhibitor agents, as evidenced by paid claims or pharmacy printouts.

Pulmonary Hypertension

Activin Signaling Inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
WINREVAIR (sotatercept-csrk)	this space intentionally left blank

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist or cardiologist.
- The member must currently be on a dual therapy combination regimen.

Renewal Criteria – Approval Duration: 12 months

- The member has received a therapeutic response as evidenced by stabilization or improvement from baseline in each of the following:
  - 6MWT (≤ 15% decline)
  - WHO functional class

Endothelin Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ambrisentan	LETAIRIS (ambrisentan)
bosentan	macitentan
bosentan tablets for suspension	OPSUMIT (macitentan)
this space intentionally left blank	OPSYNVI (macitentan/tadalafil)
this space intentionally left blank	TRACLEER (bosentan) SUSPENSION
this space intentionally left blank	TRACLEER (bosentan) TABLETS

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of ambrisentan and bosentan, as evidenced by paid claims or pharmacy printouts.

PDE-5 Inhibitors

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALYQ (tadalafil)	OPSYNVI (macitentan/tadalafil)
sildenafil tablet	REVATIO (sildenafil) TABLET
tadalafil tablet	this space intentionally left blank

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
sildenafil suspension	TADLIQ (tadalafil) SUSPENSION

Electronic Age Verification

- Sildenafil/tadalafil: Prior authorization is not required for ages less than 18 years old.
- Sildenafil suspension: Prior authorization is not required for ages less than 9 years old.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The request must include chart notes to verify diagnosis.

Non-Preferred Agents Criteria

- The member must have failed a 30-day trial of each preferred product in combination with an endothelin receptor antagonist, as evidenced by paid claims or pharmacy printouts.

Prostacyclins

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
epoprostenol	YUTREPIA (treprostinil)
FLOLAN (epoprostenol)	this space intentionally left blank
ORENITRAM ER (treprostinil) TABLET	this space intentionally left blank
REMODULIN (treprostinil) INJECTION – *Brand Co-Preferred*	this space intentionally left blank
treprostinil injection – *Generic Co-Preferred*	this space intentionally left blank
TYVASO (treprostinil) DPI	this space intentionally left blank
TYVASO (treprostinil) INHALATION	this space intentionally left blank
UPTRAVI (selexipag) TABLET	this space intentionally left blank
UPTRAVI (selexipag) VIAL	this space intentionally left blank
VELETRI (epoprostenol)	this space intentionally left blank

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist or cardiologist.
- One of the following must be met (1 or 2):
  1. The member has WHO functional class IV and is receiving dual combination therapy
  2. The member has failed a 3-month trial of combination tadalafil and ambrisentan.
     - If ambrisentan or tadalafil isn't tolerated or clinical justification has been provided why the member is not able to use ambrisentan and tadalafil (subject to clinical review), the member must have failed a 3-month trial with another dual combination therapy.

Non-Preferred Agent Criteria

- Clinical justification must be provided explaining why the member is unable to use a preferred agent (subject to clinical review).

Renewal Criteria – Approval Duration: 12 months

- The member has experienced stabilization or improvement in exercise tolerance, WHO functional class, 6-meter walking distance (< 15% decline), pulmonary artery pressure, or pulmonary vascular resistance.

Soluble Guanylate Cyclase Stimulators

PA REQUIRED
ADEMPAS (riociguat)

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet one of the following:
  - The member must have failed a 3-month trial of ambrisentan and bosentan, as evidenced by paid claims or pharmacy printouts.
    - If ambrisentan or tadalafil isn't tolerated or clinical justification has been provided why the member is not able to use ambrisentan and tadalafil (subject to clinical review), the member must have failed a 3-month trial with another dual combination therapy.
  - The member has persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) WHO group 4 that is inoperable or post-surgical treatment.

Renewal Criteria – Approval Duration: 12 months

- The member has experienced stabilization or improvement in exercise tolerance, WHO functional class, 6-meter walking distance (< 15% decline), pulmonary artery pressure, or pulmonary vascular resistance.

References:

1. Humbert, Marc, et al. "2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension: Developed by the task force for the diagnosis and treatment of pulmonary hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS). Endorsed by the International Society for Heart and Lung Transplantation (ISHLT) and the European Reference Network on rare respiratory diseases (ERN-LUNG)." *European heart journal* 43.38 (2022): 3618-3731.

Reduction of Major Adverse Cardiovascular Events (MACE)

Oral Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
See Anticoagulants	OZEMPIC (semaglutide) TABLETS
See Lipid-Lowering Agents	WEGOVY (semaglutide) TABLETS
See Platelet Aggregation Inhibitors	this space intentionally left blank
See SGLT2 Inhibitors	this space intentionally left blank
RYBELSUS (semaglutide) TABLETS	this space intentionally left blank

Injectable Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
See PCSK9 Inhibitors	WEGOVY (semaglutide) INJECTION
OZEMPIC (semaglutide) INJECTION	this space intentionally left blank

Prior Authorization Criteria

For reduction of MACE in members with diabetes, please see diabetes category for criteria on indicated agents.

Initial Criteria – Approval Duration: 12 months

- The member is between ages of ≥ 55 and < 75.
- The member does not have diabetes, as evidenced by A1c within normal range without diabetes medication.
- The member has an initial BMI of ≥ 27 kg/m^2 and < 35 kg/m^2
- The member has one of the following:
  - Prior myocardial infarction (MI)
  - Prior stroke and peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index < 0.85, peripheral arterial revascularization procure, or amputation due to atherosclerotic disease.
- The member is concurrently taking lipid-lowering and antiplatelet therapy

- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- If the member qualifies for Wegovy injection, a dose escalation to 2mg of Ozempic injection (semaglutide) must be tolerated before Wegovy will be authorized (2.4mg is the only strength indicated for reduction of MACE)
- If the member qualifies for Wegovy tablets, a dose escalation to 14mg of Rybelsus (semaglutide) must be tolerated before Wegovy will be authorized.

Non-Preferred Agent Criteria

- Wegovy tablets: The member must have failed a 12-month trial of semaglutide injection, as evidenced by paid claims or pharmacy printouts.

  *Failure is defined as one of the following:
  - The member is unable to achieve weight loss of at least 5% from baseline
  - The member is unable to achieve reduction of BMI of at least 5% from baseline
  - The member has experienced a cardiovascular event following a 5% weight loss or 5% reduction of BMI since starting medication.

Dermatology

Acne

Electronic Age Verification

- The member must be between 12 and 35 years of age for treatment of diagnosis of acne.

Adapalene

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adapalene cream	this space intentionally left blank
adapalene gel	this space intentionally left blank
adapalene gel with pump	this space intentionally left blank
adapalene/benzoyl peroxide 0.1%-2.5%	this space intentionally left blank
adapalene/benzoyl peroxide 0.3%-2.5%	this space intentionally left blank

Therapeutic Duplication

- One strength of one benzoyl peroxide containing medication is allowed at a time.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Preferred Dosage Form criteria

Androgen Receptor Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	WINLEVI (clascoterone) CREAM

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of each of the following, as evidenced by paid claims or pharmacy printouts:
    - Topical antibiotics (erythromycin, clindamycin, minocycline, or dapsone) in combination with benzoyl peroxide
    - Topical retinoids in combination with benzoyl peroxide

Clindamycin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clindamycin capsule	CLEOCIN T (clindamycin) GEL
clindamycin gel	CLEOCIN T (clindamycin) LOTION
clindamycin lotion	CLEOCIN T (clindamycin) PLEDGETS
clindamycin solution	CLINDACIN (clindamycin) FOAM
this space intentionally left blank	CLINDACIN P (clindamycin) PLEDGETS
this space intentionally left blank	CLINDACIN ETZ (clindamycin) PLEDGETS
this space intentionally left blank	clindamycin gel daily
this space intentionally left blank	clindamycin foam
this space intentionally left blank	clindamycin pledgets
this space intentionally left blank	clindamycin-tretinoin 1.2%-0.025%
this space intentionally left blank	EVOCLIN (clindamycin) FOAM

Clindamycin-Benzoyl Peroxide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clindamycin-benzoyl peroxide 1.2%-2.5%	BENZACLIN (clindamycin/benzoyl peroxide without pump) 1%-5%
clindamycin-benzoyl peroxide 1%-5% with pump	BENZACLIN (clindamycin/benzoyl peroxide with pump) 1%-5%
clindamycin-benzyl peroxide 1.2%-5%	clindamycin/benzoyl peroxide 1.2%-3.75%
clindamycin/benzoyl peroxide 1%-5% without pump	NEUAC (clindamycin/benzoyl peroxide) 1.2%-5%

Therapeutic Duplication

- One strength of one benzoyl peroxide containing medication is allowed at a time.

Retinoid

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tazarotene 0.1% cream	clindamycin-tretinoin 1.2%-0.025%
tretinoin cream	FABIOR (tazarotene) 0.1% FOAM
tretinoin gel	tazarotene 0.05% cream
this space intentionally left blank	tazarotene 0.1% foam
this space intentionally left blank	tazarotene gel
this space intentionally left blank	tretinoin microsphere gel

Therapeutic Duplication

- One strength of one retinoid medication is allowed at a time.
- One strength of one benzoyl peroxide containing medication is allowed at a time.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Preferred Dosage Form criteria

Tetracyclines

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
doxycycline hyclate capsule	demeclocycline
doxycycline hyclate tablet 20 mg, 100 mg	
doxycycline monohydrate 25 mg/5 mL suspension	DORYX MPC (doxycycline hyclate) TABLET DR
doxycycline monohydrate tablet 50 mg, 75 mg, 100 mg	doxycycline monohydrate capsule 75 mg, 150 mg
doxycycline monohydrate capsule 50 mg, 100 mg	doxycycline hyclate tablet 50 mg, 75 mg, 150 mg
minocycline capsule	doxycycline monohydrate tablet 150 mg
tetracycline capsule	doxycycline hyclate tablet DR
this space intentionally left blank	MINOCIN (minocycline) CAPSULE
this space intentionally left blank	minocycline tablet
this space intentionally left blank	minocycline tablet ER
this space intentionally left blank	MINOLIRA ER (minocycline) TABLET
this space intentionally left blank	MORGIDOX (doxycycline hyclate) CAPSULE
	tetracycline tablet

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Preferred Dosage Form criteria

Sulfonamide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BP 10-1 (sodium sulfacetamide/sulfur cleanser) 10%-1%	ACZONE (dapsone) GEL WITH PUMP 7.5%
BP CLEANSING WASH (sulfacetamide sodium/sulfur/urea) 10%-4%-10%	BP 10-1 (sulfacetamide sodium/sulfur) CLEANSER
dapsone gel pump 7.5%	SSS 10-5 (sulfacetamide) CLEANSER
dapsone gel without pump	SSS 10-5 (sulfacetamide) FOAM
sulfacetamide 10% cleansing gel	sodium sulfacetamide/sulfur pads 10%-4%
sulfacetamide 10% lotion	sodium sulfacetamide/sulfur cream 10%-2%
sulfacetamide 10% suspension	SUMADAN (sodium sulfacetamide/sulfur) WASH 9%-4.5%
sulfacetamide 10% wash	SUMAXIN (sodium sulfacetamide/sulfur) WASH 9%-4%
sodium sulfacetamide/sulfur cleanser 10%-5% (W/W)	SUMAXIN (sodium sulfacetamide/sulfur pads) PADS 10%-4%
sodium sulfacetamide/sulfur cleanser 9%-4%	SUMAXIN TS (sodium sulfacetamide/sulfur) SUSPENSION 8%-4%
sodium sulfacetamide/sulfur cleanser 9%-4.5%	ZMA CLEAR (sulfacetamide sodium/sulfur) SUSPENSION 9%-4.5%
sodium sulfacetamide/sulfur cleanser 9.8% -4.8%	this space intentionally left blank
sodium sulfacetamide/sulfur cleanser 10%-2%	this space intentionally left blank
sodium sulfacetamide/sulfur cleanser 10%-5%-10%	this space intentionally left blank
sodium sulfacetamide/sulfur cream 10%-5% (W/W)	this space intentionally left blank
sodium sulfacetamide/sulfur suspension 8%-4%	this space intentionally left blank
SUMAXIN (sodium sulfacetamide/sulfur) CLEANSER 9%-4%	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Preferred Dosage Form criteria

Actinic Keratosis

Antimicrotubular

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	KLISYRI (tirbanibulin)

Fluorouracil

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluorouracil 5% cream	fluorouracil 0.5% cream
fluorouracil 2% solution	this space intentionally left blank
fluorouracil 5% solution	this space intentionally left blank

Imiquimod

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
imiquimod 5% cream packet	imiquimod 3.75% cream packet
this space intentionally left blank	imiquimod 3.75% cream pump

Diclofenac

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diclofenac 3% sodium gel	this space intentionally left blank

Electronic Diagnosis Verification

- Diclofenac 3% sodium gel, Klisyri: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 6-month trial of each preferred agent of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- If requested product has preferred option with same active ingredient, see Preferred Dosage Form criteria

Alopecia Areata

PREFERRED AGENTS (PA REQUIRED)
LITFULO (ritlecitinib)
OLUMIANT (baricitinib)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must be less than 21 years of age.
- The member must have one of the following:
  - The member must have at least 50% scalp hair loss for more than 6 months

- The member has failed a 3-month trial of topical corticosteroids of high potency, as evidenced by paid claims or pharmacy printouts.

- Olumiant 4 mg: The member must not have had any response to 6-month trials of each Litfulo and Olumiant 2 mg, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- The member has achieved at least 80% of scalp hair coverage

Antifungals – Topical

Cream

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
butenafine cream	CICLODAN (ciclopirox) CREAM
ciclopirox cream	ERTACZO (sertraconazole) CREAM
clotrimazole cream	EXELDERM (sulconazole) CREAM
econazole cream	LOPROX (ciclopirox) CREAM
ketoconazole cream	luliconazole cream
miconazole cream	MENTAX (butenafine) CREAM
NAFTIN (naftifine) CREAM	naftifine cream
nystatin cream	oxiconazole cream
nystatin – triamcinolone cream	sulconazole cream

Foam

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ketoconazole foam	EXTINA (ketoconazole) FOAM
this space intentionally left blank	KETODAN (ketoconazole) FOAM

Gel

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ciclopirox gel	NAFTIN (naftifine) GEL

Lotion

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	OXISTAT (oxiconazole) LOTION

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALEVAZOL (clotrimazole) OINTMENT	miconazole/zinc oxide/white petrolatum ointment
nystatin ointment	this space intentionally left blank
nystatin – triamcinolone ointment	this space intentionally left blank
VUSION (miconazole/zinc/white petrolatum) OINTMENT – *Brand Required*	this space intentionally left blank

Powder

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KLAYESTA (nystatin) POWDER	this space intentionally left blank
nystatin powder	this space intentionally left blank
NYAMYC (nystatin) POWDER	this space intentionally left blank

NYSTOP (nystatin) POWDER	this space intentionally left blank

Shampoo

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ciclopirox shampoo	LOPROX (ciclopirox) SHAMPOO
ketoconazole shampoo	this space intentionally left blank

Solution

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ciclopirox solution	CICLODAN (ciclopirox) SOLUTION
clotrimazole solution	EXELDERM (sulconazole) SOLUTION
this space intentionally left blank-	tavaborole solution

Suspension

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ciclopirox suspension	LOPROX (ciclopirox) SUSPENSION

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Onychomycosis Only:
  - Diagnosis must be confirmed by potassium hydroxide (KOH) preparation.
  - The member must have had a trial of one oral agent (terbinafine, fluconazole, or itraconazole), for the length of recommended treatment time for member's particular infection, as evidenced by paid claims or pharmacy printouts.
  - Adequate time must have passed since treatment cessation to accurately assess healthy toenail outgrow (at least 6 months)
  - One of the following must be met (A or B):
    - Preferred Dosage Form Criteria
    - The active ingredient of the requested product is not available in a preferred formulation.
- Other Diagnoses:
  - The member must have failed a trial of 3 preferred agents, for the length of recommended treatment time for member's particular infection, as evidenced by paid claims or pharmacy printouts.
  - One of the following must be met (A or B):
    - Preferred Dosage Form Criteria
    - The active ingredient of the requested product is not available in a preferred formulation.

Bullous Pemphigoid

PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupliumab)

Initial Criteria - Approval Duration: 4 months

- The member has a diagnosis of bullous pemphigoid
  - Drug-induced disease must be assessed/ruled out by prescriber attestation

- The requested medication must be prescribed by, or in consult with, a dermatologist
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- Current symptoms (e.g., extent or spread of the blisters/pruritus) have been submitted
- The member has experienced new development of nontransient lesions, extension of current lesions, failure of lesion healing, or continued pruritus despite at least 3 weeks of prednisone or prednisolone at 0.75 mg/kg/day within the past 2 months

Eczema / Atopic Dermatitis

Oral

First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine 50 mg	azathioprine 75 mg
cyclosporine	azathioprine 100 mg
methotrexate	this space intentionally left blank
systemic oral corticosteroids	this space intentionally left blank

Prior Authorization Criteria

- Azathioprine: See Preferred Dosage Forms Criteria – Use enough 50 mg to make correct dosage

Topical

Aryl Hydrocarbon Receptor Agonist

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VTAMA (tapinarof) CREAM	this space intentionally left blank

Calcineurin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tacrolimus	pimecrolimus

Janus Kinase (JAK) inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OPZELURA (ruxolitinib) CREAM	ANZUPGO (delgocitinib) CREAM

Phosphodiesterase 4 (PDE-4) inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EUCRISA (crisaborole) OINTMENT	this space intentionally left blank
ZORYVE (roflumilast) CREAM	this space intentionally left blank

Topical Corticosteroids

Please see Steroids – Topical

Systemic

Interleukin (IL)-4/13 Inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab) INJECTION	this space intentionally left blank

Interleukin (IL)-13 Inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ADBRY (tralokinumab-idrm) INJECTION	this space intentionally left blank
EBGLYSS (lebrikizumab-lbkz) INJECTION	this space intentionally left blank

Interleukin (IL)-31 Inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEMLUVIO (nemolizumab) INJECTION	this space intentionally left blank

Janus Kinase (JAK) inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CIBINQO (abrocitinib) TABLET	RINVOQ ER (upadacitinib) TABLET
this space intentionally left blank	OLUMIANT (baricitinib) TABLET

Electronic Age Verification

- Tacrolimus ointment 0.1%: The member must be 16 years of age or older.
- Zoryve 0.05%: The member must be between the ages of 2 and 5 years old

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Quantity Limits

- Nemluvio: Quantity of 1 every 56 days is allowed. Override must be requested for prurigo nodularis and the initial 16 weeks of treatment for atopic dermatitis.
    - For atopic dermatitis: After the initial 16 weeks of treatment, if skin is not clear or almost clear, only one additional 16 weeks of treatment of 30mg every 4 weeks will be authorized.

Therapeutic Duplication

- Medication classes not payable together:
    - Anzupgo, Eucrisa, Opzelura, Zoryve topical treatments are not allowed concurrently with systemic agents.

Prior Authorization Criteria

Prior Authorization Form – Atopic Dermatitis

Initial Criteria – Approval Duration: 3 months (Olumiant one time approval for 16 weeks)

Systemic Agents Only

- The member must have a body surface area involvement of 10% or greater
- The member must meet both of the following in the past year:
    - The member must have failed a 6-week trial of tacrolimus or pimecrolimus, as evidenced by paid claims or pharmacy printouts:
    - One of the following must be met:
        - The member has failed a two 2-week trials of topical corticosteroids of medium or higher potency, as evidenced by paid claims or pharmacy printouts.
          OR
        - The member meets both of the following (1 AND 2):
          1. Affected area is on face, groin, axilla, or under occlusion.
          2. The member must have failed two 2-week trials of topical corticosteroids of low or higher potency, as evidenced by paid claims or pharmacy printouts.

Rinvoq ER Only

- The member must have failed a 30-day trial with Cibinqo, as evidenced by paid claims or pharmacy printouts.

Olumiant Only

- The member must meet both of the following:
    - The member must have failed a 30-day trial with Cibinqo, and Rinvoq ER, as evidenced by paid claims or pharmacy printouts.
    - The member must have failed a 90-day trial of all other preferred systemic agents.

Topical Agents Only

- The member must have failed a 6-week trial of tacrolimus or pimecrolimus, as evidenced by paid claims or pharmacy printouts
    - If the trial cannot be met due to a contraindication, one of the following must be met:
        - The member has failed a two 2-week trials of topical corticosteroids of medium or higher potency, as evidenced by paid claims or pharmacy printouts.
          OR
        - The member meets both of the following (1 AND 2):

1. Affected area is on face, groin, axilla, or under occlusion.
2. The member must have failed two 2-week trials of topical corticosteroids of low or higher potency, as evidenced by paid claims or pharmacy printouts.

Anzupgo Only

- The member must have a diagnosis of moderate to severe chronic hand eczema
- The member must have failed an 8-week trial with Opzelura, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

Systemic Agents Only:

- The member meets one of the following as attested by treating provider:
  - Reduction in disease severity (e.g., improvement in IGA score or BSA affected)
  - Improvement in symptoms and quality of life (e.g., reduced itching, inflammation)

Epidermolysis Bullosa

PREFERRED AGENTS (PA REQUIRED)
FILSUVEZ (birch triterpenes)
VYJUVEK (beremagene geperpavec-svdt)
ZEVASKYN (prademagene zamikeracel, pz-cel) – *Medical Billing*

Initial Criteria - Approval Duration: 3 months (except Zevaskyn - Authorization will be valid for 1 year for each lifetime treatment per target wound)

Zevaskyn Only:

- Genetic testing confirms pathogenic variant (e.g., COL7A1)
- Baseline symptoms (e.g., extensive skin blistering, number and size of wounds) have been submitted.
- The member has a diagnosis of Recessive Dystrophic Epidermolysis Bullosa (RDEB)
- The medication must be prescribed by a dermatologist at a Qualified Treatment Center (QTC)
- Vyjuvek or Filsuvez cannot be used on wounds treated or designated to be treated with Zevaskyn

All other products:

- The member has dystrophic epidermolysis bullosa.
- The requested medication must be prescribed by, or in consult with, a dermatologist or wound care specialist.
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- Genetic testing confirms pathogenic variant (e.g., COL7A1)
- Baseline symptoms (e.g., extensive skin blistering, number and size of wounds) have been submitted.

Renewal Criteria – Approval Duration: 3 months (Except Zevaskyn – please call if PA needs an extension)

- The member has received a therapeutic response (e.g., extensive skin blistering, number and size of wounds) from baseline.

Hidradenitis Suppurativa

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab – See Biosimilar Agents	this space intentionally left blank

Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	COSENTYX (secukinumab)
this space intentionally left blank	COSENTYX (secukinumab) – *Medical Billing*

Interleukin (IL)-17A and IL-17F inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	BIMZELX (bimekizumab-bkzx)

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Cosentyx Only: The member must have failed a 90-day trial of adalimumab, as evidenced by paid claims or pharmacy printouts.
- Bimzelx Only: The member must have failed 90-day trials of adalimumab and Cosentyx as evidenced by paid claims or pharmacy printouts.

Infantile Hemangioma

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
propranolol oral solution	HEMANGEOL (propranolol) ORAL SOLUTION
this space intentionally left blank	timolol gel forming solution (used topically)

Electronic Age Verification

- Hemangeol: The patient must be less than 1 years of age.

Electronic Diagnosis Verification

- Hemangeol: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- For timolol gel forming solution only:
  - One of the following must be met:
    - The member is being tapered off of treatment with propranolol oral solution
    - The member has a low risk and uncomplicated hemangioma (e.g., < 2 cm, not ulcerated and not located in central face, periorbital area, lips, chin, neck, oral cavity, lumbosacral, perineal, or perianal area)
- For Hemangeol only:
  - The member must have failed a 3-month trial of the propranolol oral solution, as evidenced by paid claims or pharmacy printouts.

Molluscum Contagiosum

PREFERRED AGENTS (PA REQUIRED)
ZELSUVMI (berdazimer) GEL
YCANTH (cantharidin) SOLUTION – *Medical Billing*

Initial Criteria - Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, a dermatologist or pediatrician.
- One of the following must be present (1 or 2):
  - The member is immunocompromised.
  - The member is immunocompetent but experiences severe bleeding, intense itching, recurring infection, or severe pain for greater than 6 months.

Lice / Scabies

Topical Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ivermectin lotion	CROTAN (crotamiton) LOTION
LICE KILLING SHAMPOO (piperonyl butoxide/pyrethrins)	malathion lotion
LICE TREATMENT (permethrin) 1% CRÈME RINSE LIQUID	PRURADIK (crotamiton) LOTION
NATROBA (spinosad) TOPICAL SUSPENSION – *Brand Required*	SKLICE (ivermectin) LOTION
permethrin 5% cream	spinosad topical suspension
VANALICE (piperonyl butoxide/pyrethrins) GEL	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- One of the following must be met:
  - The member must have failed a 28-day/2-application trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
  - There is a documented community breakout of a strain that is not susceptible to the preferred agents.

Plaque Psoriasis

Systemic

Biologics

Interleukin (IL)-12/IL-23p40 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ustekinumab - See Biosimilar Agents	this space intentionally left blank

Interleukin (IL)-17A Inhibitor

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)	COSENTYX (secukinumab)
this space intentionally left blank	COSENTYX (secukinumab) – *Medical Billing*

Interleukin (IL)-17A and IL-17F inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	BIMZELX (bimekizumab-bkzx)

Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TREMFYA (guselkumab)	ILUMYA (tildrakizumab-asmn) – *Medical Billing*
this space intentionally left blank	SKYRIZI (risankizumab-rzaa)

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab – See Biosimilar Agents	CIMZIA (certolizumab) SYRINGE
ENBREL (etanercept)	CIMZIA (certolizumab) VIAL – *Medical Billing*
infliximab - See Biosimilar Agents	this space intentionally left blank

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
acitretin 10 mg, 25 mg	acitretin 17.5 mg
cyclosporine	ICOTYDE (icotrokinra)
methotrexate	OTEZLA (apremilast) 20 MG
OTEZLA (apremilast) 30 MG	OTEZLA XR (apremilast)

this space intentionally left blank	SOTYKTU (deucravacitinib)

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Electronic Step Therapy Required

- Taltz:
  - PA Not Required Criteria: A total of 84-day supply of adalimumab or certolizumab pegol has been paid within 120 days prior to Taltz's date of service.
  - PA Required Criteria: The member must have failed a 3-month trial of adalimumab, certolizumab pegol, or infliximab, as evidenced by paid claims or pharmacy printouts.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of a TNF inhibitor (adalimumab, certolizumab pegol or infliximab) and Taltz, as evidenced by paid claims or pharmacy printouts.
- Acitretin 17.5 mg and Otezla XR Only: See Preferred Dosage Form criteria
- Cosentyx Only: The member must have failed a 3-month trial of a TNF inhibitor (adalimumab, certolizumab pegol or infliximab), ustekinumab and Taltz, as evidenced by paid claims or pharmacy printouts.
- Otezla 20 mg Only: The member must weigh ≥ 20 kg and < 50 kg and have failed a 3-month trial of a TNF inhibitor (adalimumab, certolizumab pegol or infliximab) and Taltz, as evidenced by paid claims or pharmacy printouts.
- Sotyktu Only: The member must have failed a 3-month trial of a TNF inhibitor (adalimumab, certolizumab pegol or infliximab) and Taltz and a 30-day trial of Otezla, as evidenced by paid claims or pharmacy printouts.
- Tremfya Only: The member must have failed a 3-month trial of an TNF inhibitor (adalimumab, certolizumab pegol or infliximab), Taltz, and Bimzelx, as evidenced by paid claims or pharmacy printouts.
- Skyrizi or Icotyde Only: The member must have failed a 3-month trial of an TNF inhibitor (adalimumab, certolizumab pegol or infliximab), Taltz, Bimzelx, and Tremfya, as evidenced by paid claims or pharmacy printouts.
- Ilumya Only: The member must have failed a 3-month trial of an TNF inhibitor (adalimumab, certolizumab pegol or infliximab), Taltz, ustekinumab, Bimzelx, and Tremfya, as evidenced by paid claims or pharmacy printouts.
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review).
- The member must have failed all preferred agents in the same class as requested product

Topical

Foams, Gel, Solution, Suspension

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene solution	calcipotriene/betamethasone suspension
calcipotriene foam	SORILUX (calcipotriene) FOAM
ENSTILAR (calcipotriene/betamethasone) FOAM	tazarotene gel
TACLONEX (calcipotriene/betamethasone) SUSPENSION – *Brand Required*	ZORYVE (roflumilast) 0.3% FOAM

Cream, Lotion

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene cream	VTAMA (tapinarof) CREAM	tazarotene cream 0.05%
tazarotene cream 0.1%	this space intentionally left blank	ZORYVE (roflumilast) CREAM

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene ointment	calcitriol ointment
calcipotriene/betamethasone ointment	this space intentionally left blank

Electronic Diagnosis Verification

- Vtama and Zoryve: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent of a unique active ingredient(s) within same route/dosage form category, as evidenced by paid claims or pharmacy printouts.
- Zoryve Cream Only:
  - The member has failed a 3 month trial of Vtama

Prurigo Nodularis

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab)	NEMLUVIO (nemolizumab-ilto)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a dermatologist.
- The member is experiencing nodular lesions that produce itch for greater than 6 weeks that has significantly diminished quality of life, including sleep disturbances.
- The member has failed a 2-week trial of a topical corticosteroid of at least high potency, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agent Criteria

- The member must have failed a 3-month trial of Dupixent, as evidenced by paid claims or pharmacy printouts.

Seborrheic Dermatitis

See Antifungals – Topical
See Steroids – Topical

Topical Phosphodiesterase-4 (PDE-4) Inhibitors

PA REQUIRED
ZORYVE (roflumilast) FOAM

Electronic Diagnosis Verification

- Zoryve: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have had a 4-week trial of concurrent use of a topical antifungal (shampoo or foam) AND a high potency topical corticosteroid (foam, spray or shampoo), as evidenced by paid claims or pharmacy printouts.

Steroids – Topical

Super-High Potency (Group 1)

Cream

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clobetasol emollient 0.05%	this space intentionally left blank
clobetasol propionate 0.05%	this space intentionally left blank
fluocinonide 0.10%	this space intentionally left blank

halobetasol propionate 0.05%	this space intentionally left blank

Lotion

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
betamethasone dipropionate, augmented 0.05%	ULTRAVATE (halobetasol) MDP0.05%
clobetasol propionate 0.05%	this space intentionally left blank

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
betamethasone dipropionate, augmented 0.05%	this space intentionally left blank
clobetasol propionate 0.05%	this space intentionally left blank
halobetasol propionate 0.05%	this space intentionally left blank

Foam, Gel, Shampoo, Solution, Spray

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clobetasol propionate foam 0.05%	betamethasone dipropionate, augmented gel 0.05%
clobetasol propionate shampoo 0.05%	clobetasol emulsion foam0.05%
clobetasol propionate solution 0.05%	Step 2: halobetasol propionate foam 0.05%
clobetasol propionate spray 0.05%	this space intentionally left blank
clobetasol propionate gel 0.05%	this space intentionally left blank

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Electronic Duration Verification

Group 1 topical steroids are covered for 30 days every 90 days. Group 1 steroids are covered with group 2 steroids to facilitate an alternating schedule.

- If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
  Approval: 1 year
  - Location of application: palms, soles, or psoriatic crusts
  - Indication: psoriasis
  - Close monitoring for side effects

Reference:

Joint AAD-NFP guidelines for management and treatment of psoriasis recommend limiting the use of Group 1 topical steroids to no more than twice daily up to 4 weeks. Transitions to lower potent agents, intermittent therapy, and combination treatment with non-steroids are recommended to minimize side effects.

High Potency (Group 2)

Cream

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
betamethasone dipropionate, augmented 0.05%	Step 2: APEXICON E (diflorasone emollient) 0.05%
desoximetasone 0.25%	halcinonide 0.10%
fluocinonide 0.05%	this space intentionally left blank

Lotion

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	BRYHALI (halobetasol) LOTION0.01%

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
betamethasone dipropionate 0.05%	diflorasone diacetate 0.05%
desoximetasone 0.25%	this space intentionally left blank
fluocinonide 0.05%	this space intentionally left blank

Gel, Solution, Spray

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
desoximetasone spray 0.25%	desoximetasone gel 0.05%
fluocinonide gel 0.05%	Step 2: halcinonide SOLUTION 0.10%
fluocinonide solution 0.05%	this space intentionally left blank

High Potency (Group 3)

Cream

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

betamethasone dipropionate 0.05%	Step 2: amcinonide 0.10%
triamcinolone acetonide 0.50%	desoximetasone 0.05%
this space intentionally left blank	Step 2: diflorasone diacetate 0.05%
this space intentionally left blank	fluocinonide-E0.05%

Cream

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
betamethasone dipropionate 0.05%	Step 2: amcinonide 0.10%
triamcinolone acetonide 0.50%	desoximetasone 0.05%
this space intentionally left blank	Step 2: diflorasone diacetate 0.05%
this space intentionally left blank	fluocinonide-E0.05%

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
betamethasone valerate 0.10%	desoximetasone 0.05%
fluticasone propionate 0.005%	this space intentionally left blank
mometasone furoate 0.10%	this space intentionally left blank
triamcinolone acetonide 0.50%	this space intentionally left blank

Foam

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
betamethasone valerate foam 0.12%	this space intentionally left blank

Medium Potency (Group 4)

Cream

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluticasone propionate 0.05%	Step 2: clocortolone pivalate 0.10%
mometasone furoate 0.10%	this space intentionally left blank
triamcinolone acetonide 0.10%	this space intentionally left blank

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluticasone acetonide 0.025%	hydrocortisone valerate 0.20%

triamcinolone acetonide 0.05%	this space intentionally left blank
triamcinolone acetonide 0.10%	this space intentionally left blank

Aerosol, Paste, Solution

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
mometasone furoate solution 0.10%	triamcinolone acetonide aerosol 0.147 MG/G
this space intentionally left blank	triamcinolone acetonide paste 0.10%

Lower-Mid Potency (Group 5)

Cream

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
betamethasone valerate 0.10%	fluocinolone acetonide 0.025%
hydrocortisone valerate 0.20%	hydrocortisone butyrate 0.10%
PANDEL (hydrocortisone probutate) 0.1%	this space intentionally left blank

Lotion

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
betamethasone dipropionate 0.05%	flurandrenolide 0.05%
triamcinolone acetonide 0.10%	fluticasone propionate 0.05%
this space intentionally left blank-	Step 2: hydrocortisone butyrate 0.10%

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
desonide 0.05%	hydrocortisone butyrate 0.10%
triamcinolone acetonide 0.025%	this space intentionally left blank

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
desonide 0.05%	hydrocortisone butyrate 0.10%
triamcinolone acetonide 0.025%	this space intentionally left blank

Gel, Solution

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydrocortisone butyrate solution 0.10%	this space intentionally left blank

Low Potency (Group 6)

Cream

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
alclometasone dipropionate 0.05%	fluocinolone acetonide 0.01%
desonide 0.05%	this space intentionally left blank
triamcinolone acetonide 0.025%	this space intentionally left blank

Lotion

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
betamethasone valerate lotion 0.10%	this space intentionally left blank
desonide lotion 0.05%	this space intentionally left blank
triamcinolone acetonide lotion 0.025%	this space intentionally left blank

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
alclometasone dipropionate 0.05%	this space intentionally left blank

Oil, Shampoo, Solution

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CAPEX (fluocinolone) SHAMPOO 0.01%	this space intentionally left blank
fluocinolone acetonide oil 0.01%	this space intentionally left blank
fluocinolone acetonide solution 0.01%	this space intentionally left blank

Least Potent (Group 7)

Cream

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydrocortisone 1.00%	this space intentionally left blank
hydrocortisone 2.50%	this space intentionally left blank

Lotion

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydrocortisone 2.50%	this space intentionally left blank

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydrocortisone 1.00%	this space intentionally left blank
hydrocortisone 2.50%	this space intentionally left blank

Solution

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	hydrocortisone 2.50%
this space intentionally left blank	HYDROXYM (hydrocortisone) GEL 2.00%
this space intentionally left blank	TEXACORT (hydrocortisone) SOLUTION 2.50%

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 2-week trial of all preferred drug entities within the same potency category and dosage form group within the last 3 months, as evidenced by paid claims or pharmacy printouts.

Agents labeled as "STEP 2"

- The member must have failed a 2-week trial of all preferred and non-preferred drug entities not labeled "STEP 2" within the same potency category and dosage form group within the last 3 months, as evidenced by paid claims or pharmacy printouts.

Vitiligo

PREFERRED AGENTS (PA REQUIRED)

OPZELURA (ruxolitinib)

Prior Authorization Criteria

Initial Criteria – Approval Duration: *6 months*

- The member must be less than 21 years of age.
- The member must have a body surface area involvement of 10% or less
- The member has vitiligo on face, neck, arms, or legs.
- The member must have failed a 6-month trial of one of the following (A or B), as evidenced by paid claims or pharmacy printouts:
  A. Tacrolimus or pimecrolimus
  B. A high potency topical steroid

Endocrinology

Acromegaly

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bromocriptine capsule	SOMAVERT (pegvisomant) INJECTION	BYNFEZIA (octreotide) PEN
lanreotide injection – *Medical Billing*	this space intentionally left blank	MYCAPSSA (octreotide) CAPSULE
octreotide injection	this space intentionally left blank	PALSONIFY (paltusotine) TABLET
octreotide depot injection – *Medical Billing*	this space intentionally left blank	SANDOSTATIN (octreotide) INJECTION
SIGNIFOR (pasireotide) INJECTION	this space intentionally left blank	SANDOSTATIN (octreotide) DEPOT – *Medical Billing*
this space intentionally left blank	this space intentionally left blank	SOMATULINE (lanreotide) DEPOT – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: *12 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, an endocrinologist and/or a neurosurgeon.
- Baseline IGF-1 and GH levels must be submitted
- The member must have had one or more of the following:
  - An inadequate response to surgery
  - An inadequate response to radiation therapy
  - Surgery or radiation therapy is not appropriate for the member, subject to clinical review

- The member must have failed a 3-month trial of octreotide or lanreotide, as evidenced by paid claims or printouts

Bynfezia and Mycapssa Only:

- The member must have failed a 3-month trial of both octreotide AND lanreotide, as evidenced by paid claims or printouts

Palsonify Only:

- The member must have failed a 3-month trial of each preferred and non-preferred agent of a unique ingredient, as evidenced by paid claims or printouts

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced one of the following:
  - Serum IGF-1 concentration ≤ 1.0 x ULN for the member's age and gender
  - Serum GH concentration ≤ 1 mcg/L

Androgens

Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
testosterone cypionate injection	AVEED (testosterone undecanoate)
testosterone enanthate injection	AVEED (testosterone undecanoate) – *Medical Billing*
this space intentionally left blank	AZMIRO (testosterone cypionate) syringe – *Medical Billing*
this space intentionally left blank	DEPO-TESTOSTERONE (testosterone cypionate)
this space intentionally left blank	XYOSTED (testosterone enanthate)

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
JATENZO (testosterone undecanoate)	methyltestosterone
TLANDO (testosterone undecanoate)	METHITEST (methyltestosterone)

Topical

Gel Packet

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
testosterone 1% (50mg/5g) gel packet	ANDROGEL (testosterone) GEL PACKET
testosterone 1% (25mg/2.5g) gel packet	testosterone 1.62% (20.25mg/1.25g) gel packet
this space intentionally left blank	testosterone 1.62% (40.5mg/2.5g) gel packet

Gel Pump

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
testosterone 2% (10mg/0.5g) gel MD PMP bottle	this space intentionally left blank
testosterone 1% (12.5mg/1.25g) gel MD PMP bottle	this space intentionally left blank
testosterone 1.62% (20.25mg/1.25g) gel MD PMP bottle	this space intentionally left blank

Gel Tube

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TESTIM (testosterone) GEL TUBE – *Brand Co-Preferred*	this space intentionally left blank
testosterone 1% (50mg/5g) gel tube	this space intentionally left blank

Nasal Gel

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	NATESTO (testosterone) GEL MD PMP

Solution MDP

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
testosterone (30mg/1.5mL)	this space intentionally left blank

Pellet

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TESTOPEL (testosterone) PELLET – *Medical Billing*	this space intentionally left blank

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent with a comparable route of administration, as evidenced by paid claims or pharmacy printouts.
- See Preferred Dosage Form Criteria

Cushing Syndrome

Adrenal Enzyme Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ketoconazole	ISTURISA (osilodrostat)
LYSODREN (mitotane)	RECORLEV (levoketoconazole)
METOPIRONE (metyrapone)	this space intentionally left blank

Electronic Diagnosis Verification

- Isturisa and Recorlev: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months
- The requested medication must be prescribed by, or in consult with, an endocrinologist or specialist in the treatment of endogenous Cushing's syndrome.
- The member must have failed a 3-month trial of combination treatment with ketoconazole tablets and metyrapone, as evidenced by paid claims or pharmacy printouts.
- The member is not a candidate for surgery or surgery has not been curative; or is waiting for surgery or effect of pituitary radiation.
- The member must have a mean (at least two measurements) 24-hour urine free cortisol (UFC) level that is 3 x above the normal range per the reporting laboratory reference range.

Renewal Criteria – Approval Duration: 12 months
- The member has normalization of 24-hour urine free cortisol (UFC) level per the reporting laboratory reference range.

Glucocorticoid Receptor Antagonist

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
mifepristone 200 mg	KORLYM (mifepristone) – *Brand Required*
this space intentionally left blank	mifepristone 300 mg

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months
- The requested medication must be prescribed by, or in consult with, an endocrinologist or specialist in the treatment of endogenous Cushing's syndrome.

- The member must have failed a 3-month trial of combination treatment with ketoconazole tablets and metyrapone, as evidenced by paid claims or pharmacy print outs.
- The member is not a candidate for surgery or surgery has not been curative; or is waiting for surgery or effect of pituitary radiation.
- The member has uncontrolled hyperglycemia (type 2 diabetes or glucose intolerance) as defined by a hemoglobin A1c > 7% or TIR < 70%, despite adherence to an anti-diabetes regimen.
- See Preferred Dosage Form Criteria

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced and maintained an improvement in cushingoid appearance, acne, hirsutism, striae, psychiatric symptoms, or excess total body weight.
- The member has improved hyperglycemia as a hemoglobin A1c decrease of 1% or greater or increase in TIR of 10% not attributed to an increase in medications, dosages, or adherence to an anti-diabetes regimen.

References:

- Fleseriu, Maria, et al. "Consensus on diagnosis and management of Cushing's disease: a guideline update." *The lancet Diabetes & endocrinology* 9.12 (2021): 847-875.

Diabetes

References:

1. American Diabetes Association Diabetes Care 2020 Jan; 43(Supplement 1): S98-S110. https://doi.org/10.2337/dc20-S009

Covered options in combination with Insulin therapy:

- GLP-1 agonists, SGLT-2 inhibitors, TZDs, and metformin
  - GLP-1 Agonist and SGLT-2 inhibitors are recommended first line treatments for every pathway indicated in the guidelines (ASCVD, HF, CKD, hypoglycemia risk, and to minimize weight gain)
  - TZDs increase insulin sensitivity and hypoglycemia risk should be monitored.
  - Metformin is recommended throughout treatment escalation.

Drug-Drug Interaction

  - Sulfonylureas and DPP-4 inhibitors are not allowed with Insulins
    - When initiating injectable therapy, sulfonylureas and DPP-4 inhibitors are typically discontinued.

Therapeutic Duplication

- One strength of one medication is allowed at a time.
- Medication classes not payable together:
  - DPP-4 Inhibitors and GLP-1 Agonists
    - GLP-1 and DPP-4 Inhibitors should not be used concurrently due to similar mechanisms of action.
  - Humulin R U-500 is not allowed with any other insulin (basal or prandial)

- Humulin R U-500 is indicated for monotherapy. It acts differently than regular insulin (U-100). It provides both basal and prandial coverage. Injections can be increased to 3 times per day for prandial coverage.

Underutilization

- Toujeo, Tresiba, and Metformin 1000 mg must be used adherently and will reject on point of sale for late fill.

Biologics

PA REQUIRED
TZIELD (teplizumab-mzwv) – *Medical Billing*

High-Cost Drug:
This 14-day treatment course costs $193,900.
- In study TN-10; 72 people were enrolled – 44 in active treatment group and 32 in placebo group. By month 36, 63.7% (28) in the active treatment group and 71.9% (23) in the placebo group had experienced Stage 3 Type 1 Diabetes onset.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- The requested medication must be prescribed by, or in consult with, an endocrinologist.
- The member has at least two of the following pancreatic islet cell autoantibodies:
  - Glutamic acid decarboxylase 65 (GAD) autoantibodies
  - Insulin autoantibody (IAA)
  - Insulinoma-associated antigen 2 autoantibody (IA-2A)
  - Zinc transporter 8 autoantibody (ZnT8A)
  - Islet cell autoantibody (ICA)
- The member has no symptoms of Type 1 Diabetes (e.g., polyuria, polydipsia, weight loss, fatigue, DKA)
- The member has abnormal blood sugar levels determined by one of the following:
  - an oral glucose tolerance test
  - Fasting glucose 100 to 125 mg/dL (5.6-6.9 mmol/L)
  - 2-hour post prandial glucose 140 to 199 mg/dL (7.8-11.0 mmol/L)
  - A1C 5.7 to 6.4%

DPP-4 Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
JENTADUETO (linagliptin/metformin)	alogliptan/pioglitazone
TRADJENTA (linagliptin)	alogliptin
this space intentionally left blank	alogliptin/metformin

this space intentionally left blank	JENTADUETO XR (linagliptin/metformin)
this space intentionally left blank	KAZANO (alogliptin/metformin)
this space intentionally left blank	NESINA (alogliptin)
this space intentionally left blank	saxagliptin
this space intentionally left blank	saxagliptin/metformin
this space intentionally left blank	sitagliptin – See Preferred Dosage Forms
this space intentionally left blank	sitagliptin/metformin – See Preferred Dosage Forms

++Clinically Non-Preferred: Alogliptin and saxagliptan have a potentially higher risk for heart failure.

Electronic Concurrent Medications Required

- A total of 28-day supply of metformin must be paid within 100 days prior to the DPP-4 Inhibitor's date of service. Members with GI intolerances to high dose IR metformin must trial at minimum a dose of 500 mg ER, as evidenced by paid claims or pharmacy printouts.
  - Metformin is recommended to be continued with therapy with DPP-4 Inhibitors**.** If metformin is not tolerated, SGLT2 inhibitor and GLP-1 Agonists are recommended as part of the glucose-lowering regimen independent of A1C or TIR and are first line alternatives.
  - Metformin is more effective than DPP-4 inhibitors and lowering A1c and weight when used as monotherapy.

* GI intolerances (typically will not be considered to bypass trial requirements):
- If on high dose IR metformin, member must trial at minimum a dose of 500 mg ER, as evidenced by paid claims or pharmacy printouts.
- The member experiencing GI side effects should be counseled: reduction in meal size, eating slower, decreased intake of greasy, high-fat or spicy food, refrain from laying down after eating.

References:

1. American Diabetes Association Diabetes Care 2020 Jan; 43(Supplement 1): S98-S110. https://doi.org/10.2337/dc20-S009

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member has been unable to achieve goal A1C (≤ 7%) or TIR (>70%) despite two 90-day trials of triple combination therapy including a preferred agent, as evidenced by paid claims or pharmacy printouts.

DPP-4 Inhibitors / SGLT2 Inhibitors Combination

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GLYXAMBI (empagliflozin/linagliptin)	STEGLUJAN (ertugliflozin/sitagliptin)
TRIJARDY XR (empagliflozin/linagliptin/metformin)	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: *12 months*

- See Preferred Dosage Form Criteria
- Clinical justification must be provided explaining why the member cannot use individual preferred products separately or preferred agent.

GLP-1 Agonists^

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OZEMPIC (semaglutide) INJECTION	exenatide
RYBELSUS (semaglutide) TABLETS	liraglutide
VICTOZA (liraglutide) - *Brand Required*	OZEMPIC (semaglutide) TABLETS
this space intentionally left blank	TRULICITY (dulaglutide)

^ See GIP/GLP-1 Agonists section for Mounjaro (tirzepatide) criteria

Clinical information: dose comparison recommendations for switching between GLP-1 agonists

- For GI side effects (start titration at lowest available dose)
- For any other reason, may consider starting at equivalent dose to minimize disruption to glycemic control
  - Victoza 1.2 mg = Trulicity 0.75 mg = Ozempic 0.25 mg Injection = Rybelsus 7 mg
  - Victoza 1.8 mg = Trulicity 1.5 mg or 3 mg = Ozempic 0.5 mg Injection = Rybelsus 14 mg = Mounjaro 2.5 mg
  - Trulicity 3 mg or 4.5 mg = Ozempic 1 mg Injection
  - Mounjaro 5 mg = Ozempic 2 mg Injection

References:

1. Almandoz JP, Lingvay I, Morales J, Campos C. Switching Between Glucagon-Like Peptide-1 Receptor Agonists: Rationale and Practical Guidance. Clin Diabetes. 2020 Oct;38(4):390-402. Doi: 10.2337/cd19-0100. PMID: 33132510; PMCID: PMC7566932.

Prior Authorization Criteria

Initial Criteria – Approval Duration: *12 months*

1. The member has been unable to achieve goal A1C (≤ 7%) or TIR (>70%) despite a 90-day trial of triple combination therapy consisting of Ozempic injection (For Trulicity, liraglutide must be trialed if semaglutide including Rybelsus is not tolerated), along with metformin, SGLT-2 inhibitor or insulin, as evidenced by paid claims or pharmacy printouts (subject to clinical review).
   - If triple therapy cannot be met with liraglutide or Ozempic injection, clinical justification must be provided (subject to clinical review*), and triple therapy must be met with SGLT-2 inhibitor + DPP4 inhibitor + metformin.
   - If triple therapy cannot be met with SGLT-2 inhibitor + DPP4 inhibitor + metformin, clinical justification must be provided (subject to clinical review*)

2. One of the following have been met (1 or 2):
   - The requested medication must be prescribed by, or in consult with, an endocrinologist or diabetes specialist.
   - The member has received diabetes education from a diabetic specialist, diabetic educator, or pharmacist (may be accomplished through the MTM program).

*GI intolerances (typically will not be considered to bypass trial requirements):

- If on high dose IR metformin, the member must trial at minimum a dose of 500 mg ER.
- If on GLP-1 agonist, the member should be evaluated on potential for GI side effects; GI effects are common across all GLP-1 agonist agents and transient in nature, typically lessening with ongoing treatment.
- If the member is experiencing GI side effects, chart documentation must be submitted that the following approaches have been trialed for at least two months:
    1. Dietary changes (e.g., eating apples, crackers, or mint- or ginger based drinks 30 minutes after administering the GLP-1 Receptor Agonist)
    2. Reduction in meal size, eating slower, decreased intake of greasy, high-fat or spicy food, refrain from laying down after eating.
    3. Prescription antiemetics
    4. Dose adjustment of GLP-1 Receptor Agonist

GIP/GLP-1 Agonists

PA REQUIRED
MOUNJARO (tirzepatide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member meets both of the following (1 and 2):
    1. The member has been unable to achieve goal, defined as meeting either A1C (≤ 7%) or TIR (>70%), despite a 90-day trial of triple combination therapy consisting of Ozempic injection (liraglutide, Rybelsus, and Trulicity must be trialed if Ozempic is not tolerated), along with metformin, SGLT-2 inhibitor or insulin, as evidenced by paid claims or pharmacy printouts (subject to clinical review).
        - If triple therapy cannot be met with liraglutide, Ozempic, Rybelsus, or Trulicity, clinical justification must be provided (subject to clinical review*), and triple therapy must be met with SGLT-2 inhibitor + DPP4 inhibitor + metformin.
        - If triple therapy cannot be met with SGLT-2 inhibitor + DPP4 inhibitor + metformin, clinical justification must be provided (subject to clinical review*)
    2. One of the following have been met (a or b):
        a. The requested medication must be prescribed by, or in consult with, an endocrinologist or diabetes specialist.
        b. The member has received diabetes education from a diabetic specialist, diabetic educator, or pharmacist (may be accomplished through the MTM program).
- The request is for Mounjaro and the member is otherwise eligible for approval for tirzepatide based on the Sleep Apnea criteria.

*GI intolerances (typically will not be considered to bypass trial requirements):

- If on high dose IR metformin, member must trial at minimum a dose of 500 mg ER.
- If on GLP-1 agonist, the member should be evaluated on potential for GI side effects, with GI effects being common across all GLP-1 agonist agents and transient in nature, typically lessoning with ongoing treatment.
- If the member is experiencing GI side effects, chart documentation must be submitted that the following approaches have been trialed for at least two months:

1. Dietary changes (e.g., eating apples, crackers, or mint- or ginger based drinks 30 minutes after administering the GLP-1 Receptor Agonist)
2. Reduction in meal size, eating slower, decreased intake of greasy, high-fat or spicy food, refrain from laying down after eating.
3. Prescription antiemetics
4. Dose adjustment of GLP-1 Receptor Agonist

Note: If the member qualifies for tirzepatide, the most cost effective tirzepatide product will be authorized.

Gastroparesis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
metoclopramide tablet	GIMOTI (metoclopramide nasal spray)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- Clinical justification must be provided explaining why the member is unable to use an oral dosage formulation (including solution formulations), subject to clinical review.

Glucose Rescue Medications

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BAQSIMI (glucagon) SPRAY	glucagon kit
GVOKE (glucagon) INJECTION	this space intentionally left blank

Electronic Duration Verification

- 4 doses are covered every 60 days without an override.

If one of the following criteria are met (A or B), please request an override by calling provider relations at 1-800-755-2604 or emailing medicaidpharmacy@nd.gov:

A. The previous dose has expired.
B. The dose was used by member for a hypoglycemic episode. (In this case, it is recommended to follow up with prescriber to discuss frequency of use and potential regimen review/adjustments)

Insulin/GLP-1 Agonist Combination

NO PA REQUIRED
SOLIQUA (insulin glargine/lixisenatide)
XULTOPHY (insulin degludec/liraglutide)

Insulin

Rapid Acting Insulin

Insulin Lispro

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMALOG U-100 (insulin lispro) CARTRIDGE	ADMELOG (insulin lispro)
HUMALOG (insulin lispro) VIAL – *Brand Required*	insulin lispro vial
HUMALOG (insulin lispro) PEN, JR PEN – *Brand Co-Preferred*	LYUMJEV U-200 (insulin lispro-aabc)
HUMALOG U-100 TEMPO PEN (insulin lispro)	
insulin lispro U-100 pen, jr pen	
LYUMJEV U-100 (insulin lispro-aabc)	
LYUMJEV U-100 TEMPO PEN (insulin lispro-aabc)	

Insulin Aspart

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FIASP (insulin aspart)	insulin aspart - See Biosimilar Agents

Insulin Glulisine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	APIDRA (insulin glulisine)

Insulin Regular, Human

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	++AFREZZA (insulin regular, human)
this space intentionally left blank	++HUMULIN R (insulin regular, human) VIAL
this space intentionally left blank	++NOVOLIN R (insulin regular, human)
this space intentionally left blank	++ RELION NOVOLIN R (insulin regular, human)

++Clinically Non-Preferred: ACOG (American College of Obstetricians and Gynecologists) guidelines prefer insulin analogues (insulin aspart and lispro) over regular insulin due to better compliance, better glycemic control, and overall fewer hypoglycemic episodes.

Electronic Step Therapy Required

- Fiasp
  - PA Not Required Criteria: A 3-month supply of insulin lispro has been paid within 180 days prior to Fiasp's date of service.
  - PA Required Criteria: The member must have failed a 3-month trial from insulin lispro, as evidenced by paid claims or pharmacy printouts.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Apidra: The member must have failed a 3-month trial of each of the following agents, as evidenced by paid claims or pharmacy printouts:
  - insulin lispro
  - Fiasp
- Humalog U-200: Request must not be for use in an insulin pump: HUMALOG® (insulin lispro) 200 Units/mL: Do Not Use in a Pump (lillymedical.com)
  - Doses ≤ 200 units/day: Clinical justification must be provided why member cannot tolerate the volume of insulin required to use Humalog U-100 or tolerate two injections per dose.
  - Doses > 200 units/day: Clinical justification must be provided why member is not a candidate for Humulin R U-500.
- Regular Insulin (Humulin R / Novolin R / Afrezza): The member must have failed a 3-month trial of each of the following agents, as evidenced by paid claims or pharmacy printouts:
  - insulin lispro
  - Fiasp
- Non-Preferred Agents: See Preferred Dosage Form Criteria

Intermediate Acting Insulin

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMULIN R U-500 (insulin regular, human)	++ HUMULIN N (insulin NPH human isophane)	++ NOVOLIN N (insulin NPH human isophane)
this space intentionally left blank	this space intentionally left blank	++ RELION NOVOLIN N (insulin NPH human isophane)

++ Clinically non-preferred: Lantus have been demonstrated to reduce the risk of symptomatic and nocturnal hypoglycemia compared with NPH insulin.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months (6 months or until due date, if known, for gestational diabetes)

- One of the following must be met:
  - The member must be pregnant or breastfeeding.
  - The member must be tube feedings.
  - The member must be post-solid organ transplant.
    - For kidney transplant – Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*
  - Clinical justification explaining why the member is unable to use Lantus (subject to clinical review)

Non-Preferred Agent Criteria

- See Preferred Dosage Form Criteria

Long-Acting Insulin

Insulin Glargine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LANTUS U-100 (insulin glargine)	insulin glargine U-300 (generic Toujeo)
TOUJEO U-300 (insulin glargine) *No PA required for doses 100 unit/day to 200 unit/day – *Brand Required*	insulin glargine (Lantus) – See Biosimilars

Insulin Degludec

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRESIBA (insulin degludec) FLEXTOUCH U-200 *No PA required for doses 100 unit/day to 200 unit/day	TRESIBA (insulin degludec) U-100

Insulin Icodec

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	AWIQLI (insulin icodec-abae)

Quantity Override Request

- Toujeo Solostar 300 unit/mL, Toujeo Max Solostar 300 unit/mL and Tresiba 200 unit/mL:
  1. Doses > 200 units/day:
     - Clinical justification must be provided explaining why the member is not a candidate for U-500R
       + Toujeo and Tresiba are not intended as replacements for U-500R insulin
  2. Doses >100 units/day to ≤ 200 units/day: No prior authorization required.
     - Please call for an override by calling provider relations at 1-800-755-2604 if the day supply is less than 30 days and dose is between 100 units/day and 200 units/day (e.g., short-cycle filling).
  3. Doses ≤ 100 units/day:
     - Must meet Prior Authorization Criteria below

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist or diabetes specialist.
- The member has had a 90-day trial of Lantus with good compliance, as evidenced by paid claims or pharmacy printouts.
- One of the following must be met, as evidenced by provided clinical notes or labs:
  - The member experiences recurrent episodes of hypoglycemia despite adjustments to current regimen (prandial insulin, interacting drugs, meal, and exercise timing).
  - The member must be experiencing inconsistent blood sugars.
- Awiqli Only: The member has had a 90-day trial each of Toujeo and Tresiba with good compliance, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced at least one of the following, as evidenced by provided clinical notes or labs:

- Reduction in frequency and/or severity of hypoglycemia
- Improved glycemic control (evidenced by A1c or TIR)

Mixed Insulin

Insulin NPL/Insulin Lispro

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	HUMALOG MIX 50/50 (insulin NPL/insulin lispro) KWIKPEN
this space intentionally left blank	HUMALOG MIX 75/25 (insulin NPL/insulin lispro)
this space intentionally left blank	insulin lispro mix 75/25 kwikpen

Insulin Aspart Protamine/Insulin Aspart

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart)
this space intentionally left blank	RELION NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart)

Insulin NPH Human/Regular Insulin Human

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMULIN MIX 70/30 (insulin NPH human/regular insulin human)	this space intentionally left blank
NOVOLIN MIX 70-30 (insulin NPH human/regular insulin human)	this space intentionally left blank
RELION NOVOLIN MIX 70-30 (insulin NPH human/regular insulin human)	this space intentionally left blank

Prior Authorization Criteria

<u>Initial Criteria – Approval Duration:</u> 12 months (6 months or until due date, if known, for gestational diabetes)

- One of the following must be met:
  - The member must be pregnant or breastfeeding.
  - The member must be on tube feedings.
  - The member must be post-solid organ transplant.
    - For kidney transplant – Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*
  - Clinical justification must be provided explaining why the member is unable to use the preferred products or a long acting plus short acting regimen (subject to clinical review).

SGLT2 Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dapagliflozin	dapagliflozin/saxagliptin
dapagliflozin/metformin ER	FARXIGA (dapagliflozin)

JARDIANCE (empagliflozin)	INVOKANA (canagliflozin)
SYNJARDY (empagliflozin/metformin)	INVOKAMET (canagliflozin/metformin)
SYNJARDY XR (empagliflozin/metformin)	INVOKAMET XR (canagliflozin/metformin)
this space intentionally left blank	STEGLATRO (ertugliflozin)
this space intentionally left blank	SEGLUROMET (ertugliflozin/metformin)
this space intentionally left blank	XIGDUO XR (dapagliflozin/metformin)

++ Canagliflozin has shown an increase in the risk of lower limb amputations and fractures in studies.
++ Dapagliflozin did not reduce atherosclerotic cardiovascular morbidity or mortality in a primary analysis, however it decreased cardiovascular in the sub analysis of prior myocardial infarction.
++ Ertugliflozin was not superior to placebo in reducing the primary composite cardiovascular endpoint.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred SGLT2 inhibitor of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents and other classes of medication (subject to clinical review).

References:

1. DeSantis A. Sodium-glucose cotransporter 2 inhibitors for the treatment of hyperglycemia in type 2 diabetes mellitus. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023

Sulfonylureas

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
glimepiride 1 mg, 2 mg, and 4 mg	glimepiride 3 mg
glipizide IR 5 mg, 10 mg	glipizide 2.5 mg, 15 mg
glipizide ER	++glyburide
glipizide/metformin	++glyburide/metformin

++Clinically Non-preferred: Glyburide is not recommended due to hypoglycemia.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of glipizide and glimepiride, as evidenced by paid claims or pharmacy printouts.
- See Preferred Dosage Form Criteria

Growth Hormone

Short Acting

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GENOTROPIN (somatropin)	HUMATROPE (somatropin)
NORDITROPIN FLEXPRO (somatropin)	OMNITROPE (somatropin)
this space intentionally left blank	SAIZEN (somatropin)
this space intentionally left blank	ZOMACTON (somatropin)

Long Acting

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
SKYTROFA (lonapegsomatropin-tcgd)	NGENLA (somatrogon-ghla)
this space intentionally left blank	SOGROYA (somapacitan-beco)

Prior Authorization Criteria

Prior Authorization Form – Growth Hormone

Initial Criteria – Approval Duration: 12 months (except 6 months if criteria met in Prader-Willi Syndrome)

- The member must have one of the following covered diagnoses (listed below):
  - Panhypopituitarism OR multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation)
  - Turner's syndrome
  - SHOX syndrome
  - Noonan syndrome
  - Chronic renal insufficiency
  - Prader–Willi syndrome
  - Endogenous growth hormone deficiency
- The requested medication must be prescribed by, or in consult annually with, an endocrinologist or nephrologist.
- The member must not have active malignancy.
- The member must not have epiphyseal closure and must still be growing, unless one of the below exceptions is present:
  - The member has a diagnosis of Prader-Willi syndrome.
  - The member has a diagnosis of endogenous growth hormone deficiency and is experiencing hypoglycemic episodes without growth hormone and growth hormone is needed to maintain proper blood glucose.
- Skytrofa and Omnitrope Only: The member must have failed a 30-day trial of Norditropin or Genotropin, as evidenced by paid claims or pharmacy printouts.
- Ngenla and Sogroya Only: The member must have failed a 30-day trial of Skytrofa and either Norditropin or Genotropin, as evidenced by paid claims or pharmacy printouts.

- All other agents: See Preferred Dosage Form Criteria

Chronic Renal Insufficiency

- The member must not have received a renal transplant.
- The member must consult with a dietitian annually to maintain a nutritious diet.

Endogenous Growth Hormone Deficiency, panhypopituitarism OR multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation)

- ONE of below criteria must be met:
  - The member has multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation) and must have an IGF-1 or IGFBP-3 level of less than SDS -1.3.
  - The member has had GH stimulation testing by at least two different stimuli (e.g., insulin, levodopa, L-arginine, propranolol, clonidine, or glucagon) with a maximum peak of < 10 ng/mL after stimulation no more than 6 months apart.
  - For infants less than 18 months old, both of the following criteria are met:
    - The member has a plasma glucose level less than 70 mg/dL
    - The member has GH level < 5 mcg/L

Prader-Willi Syndrome (PWS)

- The member must not have severe obesity (class 2) defined as ≥ 120% of the 95th percentile for age and gender
- If the member has obesity ≥ 95th percentile and < 120% of the 95th percentile for age and gender, all the following must be met (*6-month approval criteria*):
  - The prescriber must attest that member will meet with a dietician every 3 months
  - The member must have had a sleep study to rule out sleep apnea
  - The member must not have non-alcoholic fatty liver disease
  - The member must not have an A1c > 5.7%
- Vykat XR: See Medications that cost over $3000 criteria
- See covered medications for weight loss

Renewal Criteria – Approval Duration: 12 months (6 months if criteria below for PWS is met)

- The member must have been compliant with growth hormone (last 6 fills must have been on time).

Prader-Willi Syndrome

- If the member has obesity ≥ 95th percentile and < 120% of the 95th percentile for age and gender, initial criteria must be met in addition to the following *(6-month approval criteria)*:
  - The member must have met with a dietician at least 2 times in the past 6 months

References:

1. Deal et al,. Growth hormone research society workshop summary: consensus guidelines for recombinant human growth hormone therapy in Prader Will syndrome. J Clin Endocrin Metab. 2013. doi: 10.1210/jc.2012-3888

Serostim

PA REQUIRED
SEROSTIM (somatropin)

Prior Authorization Criteria

Prior Authorization Form – Growth Hormone

Initial Criteria – Approval Duration: 3 months

- The member must not have an active malignancy.
- The requested medication must be prescribed by, or in consult with, and infectious disease specialist or a specialist in the diagnosis and management of HIV infection.
- The member must be on concomitant antiretroviral therapy.
- The member must have failed a 3-month trial with megestrol, as evidenced by paid claims or pharmacy printouts.
- Lean body mass and body weight must be provided.
- Baseline physical endurance must be provided.

Renewal Criteria – Approval Duration: 8 months (one time)

- Lean body mass and body weight must have increased from baseline.
- Physical endurance must have increased from baseline.

Imcivree

PA REQUIRED
IMCIVREE (setmelanotide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 4 months (6 months for Bardet-Bidel syndrome)

- The member must have a diagnosis of obesity (BMI > 30 kg/m2 for adults or > 95th percentile using growth chart assessments for pediatric members)
- The member's weight and body mass index (BMI) must be provided within the last 60 days.
- The requested medication must be prescribed by, or in consult with, endocrinologist or medical geneticist.
- The member's obesity must be due to one of the following:
  - Genetic testing confirms one of the following variants that is pathogenic, likely pathogenic, or of unknown significance:
    - Proopiomelanocortin (POMC) deficiency
    - Proprotein convertase subtilisin/kexin type 1 (PCSK1) deficiency
    - Leptin receptor (LEPR) deficiency
  - Bardet-Biedl syndrome as evidenced by three or more of the following:

        - Rod-cone dystrophy
        - Polydactyly
        - Genital anomalies
        - Renal anomalies
        - Intellectual impairment
    - Hypothalamic obesity due to injury to the hypothalamus

Renewal Criteria – Approval Duration: 12 months

For Bardet-Biedl Syndrome

- One of the following must be met since starting treatment with Imcivree:
    - Members ≥ 18 years old:
        - First renewal – a weight reduction has been achieved or maintained.
        - Subsequent renewal – a 5% weight reduction has been achieved or maintained.
    - Members < 18 years old:
        - First renewal – a weight reduction has been achieved or maintained.
        - Subsequent renewal - a 5% reduction in BMI has been achieved or maintained.

For POMC, PCSK1, or LEPR deficiency and Hypothalamic obesity

- One of the following must be met since starting treatment with Imcivree:
    - Members ≥ 18 years old:
        - First renewal – a 5% weight reduction has been achieved or maintained.
        - Subsequent renewal – a 10% weight reduction has been achieved or maintained.
    - Members < 18 years old: a 5% reduction in BMI has been achieved or maintained.

Hypothyroidism

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
levothyroxine tablet	EUTHYROX (levothyroxine) TABLET
this space intentionally left blank	LEVO-T (levothyroxine) TABLET
this space intentionally left blank	LEVOXYL (levothyroxine) TABLET
this space intentionally left blank	SYNTHROID (levothyroxine) TABLET
this space intentionally left blank	UNITHROID (levothyroxine) TABLET

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Levothyroxine capsule only: The member must have documented celiac disease, yellow dye allergy, or lactose/milk protein allergy.
- All other agents: See Preferred Dosage Form criteria

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ERMEZA (levothyroxine) SOLUTION	THYQUIDITY (levothyroxine) ORAL SOLUTION

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- All other agents: See Preferred Dosage Form criteria

Secondary Hyperparathyroidism

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcitriol	cinacalcet
paricalcitol	doxercalciferol capsule
this space intentionally left blank	HECTOROL (doxercalciferol) CAPSULE
this space intentionally left blank	RAYALDEE ER (calcifediol)
this space intentionally left blank	ROCALTROL (calcitriol)
this space intentionally left blank	SENSIPAR (cinacalcet)
this space intentionally left blank	ZEMPLAR (paricalcitol)

++ cinacalcet is associated with hypocalcemia, increased urinary calcium excretion, and increased serum phosphate levels

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Cinacalcet only:

- If member is on chronic renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*

All other agents:

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a 30-day trial of paricalcitol, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

References:

1. Quarles LD. Management of secondary hyperparathyroidism in adult non-dialysis patients with chronic kidney disease. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023

Intravenous

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	PARSABIV (etelcalcetide) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must be on chronic renal dialysis, so Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*
- The requested medication must be prescribed by, or in consult with, an endocrinologist or nephrologist
- The member has been unable to maintain iPTH (intact parathyroid hormone) between 2-7 times ULN with previous trials of a vitamin D analog AND cinacalcet as evidenced by paid claims or pharmacy printouts

Renewal Criteria – Approval Duration: 12 months

- The member has documented one of the following:
  - At least 30% reduction from baseline in mean iPTH
  - Decreased levels of corrected total serum calcium from baseline, while levels remain ≥ 8.4 mg/dL

Subcutaneous

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	YORVIPATH (palopegteriparatide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist
- The member must have persistent hypoparathyroidism as evidenced by one of the following symptoms despite a 6-month trial of calcitriol or equivalent oral agent, as evidenced by paid claims or pharmacy printouts.:
  - Symptomatic hypocalcemia
  - Hyperphosphatemia
  - Hypercalciuria
- The member must have an albumin-corrected serum calcium concentration must be ≥ 7.8 mg/dL
- The member must have a magnesium concentration ≥ 1.3 mg/dL
- The member must have a 25 (OH) vitamin D concentration between 20 and 80 ng/mL

Renewal Criteria – Approval Duration: 12 months

- The member no longer requires active vitamin D or has experienced a significant reduction in required dosage and is still titrating Yorvipath

- The member has an albumin-corrected serum calcium in the lower-half of the normal reference range or just below the reference range (~8-9 mg/dL)

Precocious Puberty

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FENSOLVI (leuprolide) – *Medical Billing*	SUPPRELIN LA (histrelin) – *Medical Billing*
LUPRON PED DEPOT (leuprolide) – *Medical Billing*	this space intentionally left blank
SYNAREL (nafarelin)	this space intentionally left blank
TRIPTODUR (triptorelin) – *Medical Billing*	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 1 month

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

Thyroid Eye Disease

PA REQUIRED
LUMVOA (veligrotug-vvze) – *Medical Billing*
TEPEZZA (teprotumumab-trbw) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months (8 infusions per lifetime for Tepezza, 5 infusions per lifetime for Lumvoa)

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult annually with, an endocrinologist, ophthalmologist, or specialist in the treatment of Thyroid Eye Disease (TED)
- If the member is a current smoker, the member must have received smoking cessation counseling in the past year
- The member has one of the following:
  - Inflamed eyes with increasing diplopia
  - Proptosis ≥ 3 mm above ULN
  - Lid retraction of ≥ 2 mm
  - Moderate to severe-soft tissue involvement
- The provider must submit each of the following:
  - Free thyroxine (FT4) and free triiodothyronine (FT3) levels are within normal limits
  - Must have a Clinical Activity Score ≥4
- The member has failed a one-month trial of a maximally tolerated indicated dose of IV systemic glucocorticoids.
- The member has not required prior surgical ophthalmologic intervention.

Tumor-Induced Osteomalacia

PA REQUIRED
CRYSVITA (burosumab) – *Medical Billing*

Initial Criteria – Approval Duration: 12 months

- The diagnosis has been confirmed by a serum fibroblast growth factor-23 (FGF23) level > 30 pg/mL with unresectable phosphaturic mesenchymal tumor

Renewal Criteria – Approval Duration: 12 months

- The member has received a therapeutic response as evidenced by normalization of serum phosphate levels, improved ambulation, healing of bone fractures, or reduced pain.

X-linked Hypophosphatemia (XLH)

PA REQUIRED
CRYSVITA (burosumab) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, nephrologist, endocrinologist, geneticist, or specialist experienced in the treatment of metabolic bone disorders.
- The diagnosis has been confirmed by one of the following:
  - Family history of XLH, low serum phosphate, and increased alkaline phosphatase (ALP)
  - Genetic testing confirming a pathogenic mutation of the phosphate regulating gene with homology to endopeptidases on the X chromosome (PHEX gene)
  - Serum fibroblast growth factor-23 (FGF23) level > 30 pg/mL
- If the member is 18 years or older, one of the following must be met:
  - The member's epiphyseal plate has not fused
  - The member has bone fractures
  - The member has had a 3-month trial of conventional treatment with oral phosphate supplementation combined with active vitamin D (e.g., calcitriol), as evidenced by paid claims or pharmacy printouts, and continues to have significant musculoskeletal pain and limited mobility

Renewal Criteria – Approval Duration: 12 months

- For members 18 years and older: the member has received a therapeutic response as evidenced by improvement in bone pain, mobility, or healing of bone fractures) in addition to one of the following:
  - Normalization of phosphate levels
  - Normalization of bone-specific alkaline phosphatase activity
  - Normalization of tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR)
- For members younger than 18 years old: One of the following must be met:
  - Increased serum phosphate levels

- Increased tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR)
- Decreased of serum alkaline phosphatase activity

Weight Loss

Antipsychotic Induced Weight Gain

- Metformin is covered without prior authorization.
- Ozempic injection and Victoza (brand) are covered without prior authorization by submitting diagnosis code T43.505A, T43.505D, or T43.505S if being used for antipsychotic-induced weight gain

Obesity

- The following drugs are covered without prior authorization by submitting a corresponding diagnosis code for the indication:
  - phentermine, bupropion, naltrexone, topiramate

GI – Gastroenterology

Acid Blockers

Proton Pump Inhibitor

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
lansoprazole	esomeprazole magnesium	ACIPHEX (rabeprazole)
omeprazole	this space intentionally left blank	DEXILANT (dexlansoprazole)
pantoprazole	this space intentionally left blank	dexlansoprazole
rabeprazole	this space intentionally left blank	NEXIUM (esomeprazole)
this space intentionally left blank	this space intentionally left blank	omeprazole-sodium bicarbonate
this space intentionally left blank	this space intentionally left blank	PREVACID (lansoprazole)
this space intentionally left blank	this space intentionally left blank	PRILOSEC (omeprazole)
this space intentionally left blank	this space intentionally left blank	PROTONIX (pantoprazole)
this space intentionally left blank	this space intentionally left blank	ZEGERID (omeprazole/sodium bicarbonate)

Electronic Step Therapy Required

- Preferred Step 1 Agents:

- PA Not Required Criteria: A 14-day supply from at least 1 preferred agent at max dose has been paid within 365 days prior to preferred step 1 agent's date of service.
- PA Required Criteria: The member must have failed a 14-day trial from at least 1 preferred agent at max dose, as evidenced by paid claims or pharmacy printouts.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- Non-Preferred Agents Criteria – Step 2 Agents:
  - The member must have failed a 30-day trial with all preferred agents (including Step 1 Agents), as evidenced by paid claims or pharmacy printouts.

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
lansoprazole ODT	NEXIUM (esomeprazole) PACKET- *Brand Required except for 2.5 mg and 5 mg strengths are generic preferred and do not require PA for members < 1 year old)*	esomeprazole solution packet
PROTONIX (pantoprazole) PACKET – *Brand Required*	this space intentionally left blank	KONVOMEP (omeprazole/sodium bicarbonate)
this space intentionally left blank	this space intentionally left blank	omeprazole-sodium bicarbonate packet
this space intentionally left blank	this space intentionally left blank	pantoprazole packet
this space intentionally left blank	this space intentionally left blank	PREVACID (lansoprazole) SOLUTAB
this space intentionally left blank	this space intentionally left blank	PRILOSEC SUSPENSION (omeprazole)

Electronic Age Verification

- Nexium 2.5 mg and 5 mg Packet: The member must be less than 1 years old (or less than 7.5 kg)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- Non-Preferred Criteria - Step 1 Agents:
  - PA Required Criteria: The member must meet both of the following criteria:
    - The member must have failed a 14-day trial of preferred agent at max dose, as evidenced by paid claims or pharmacy printouts.
    - If member is 6 years or older, the member must meet Non-Solid Dosage Preparations criteria (clinical justification must be provided why an opened capsule can't be used).

- Non-Preferred Criteria – Step 2 Agents:
  - The member must have failed a 14-day trial with all preferred agents (including Step 1 Agents), as evidenced by paid claims or pharmacy printouts.
  - Konvomep Only: The member must be an adult and have failed a 14-day trial with omeprazole-sodium bicarbonate packet, as evidenced by paid claims or pharmacy printouts.

Therapeutic Duplication

- One strength of one medication is allowed at a time.
- Proton Pump Inhibitors is not allowed with:
  - Esomeprazole or omeprazole are not covered with clopidogrel.
    - Other PPIs such as pantoprazole are covered with clopidogrel. Clopidogrel is a substrate for 2C19 and esomeprazole and omeprazole are strong 2C19 inhibitors and can decrease effectiveness of clopidogrel.
  - Dextroamphetamine/Amphetamine ER:
    - Proton Pump Inhibitors increase blood levels and potentiate the action of amphetamine. Co-administration of Adderall XR and gastrointestinal or urinary alkalizing agents should be avoided.
  - H2 Blockers: If either of the following circumstances apply, please call for an override by calling provider relations at 1-800-755-2604:
    - The member is experiencing nocturnal symptoms after compliance with nighttime dose of proton pump inhibitor. A two-month override may be approved for concurrent H2 blocker use.
    - H2 blocker is being used concurrently with a H1 blocker for severe allergy prophylaxis, unrelated to PPI use for GI symptoms.

References

1. Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol 2013;108:308-28.
2. Fackler WK, Ours TM, Vaezi MF, Richter JE. Long-term effect of H2RA therapy on nocturnal gastric breakthrough. Gastroenterology. 2002;122:625-632.

Potassium Competitive Acid Blocker

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VOQUEZNA (vonoprazan)	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months for erosive esophagitis, 4 weeks for GERD

- The member must meet one of the following criteria (A, B, or C):
  - The member has a diagnosis of erosive esophagitis and have failed an 8-week trial of each of the following, as evidenced by paid claims or pharmacy printouts:
    - Omeprazole twice daily
    - Rabeprazole or esomeprazole daily.
  - The member has severe esophagitis (LA Grade C/D disease)

- The member must have failed a 30-day trial with all preferred proton pump inhibitors (including Step 1 Agents), as evidenced by paid claims or pharmacy printouts.

Acute Hepatic Porphyria (AHP)

PA REQUIRED
GIVLAARI (givosiran) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a geneticist, hepatologist, hematologist, gastroenterologist, or specialist in acute hepatic porphyria (AHP)
- The member must have a diagnosis of AHP (e.g., acute intermittent porphyria (AIP), porphyria cutanea tarda (PCT), erythropoietic protoporphyria (EPP)) with one of the following as defined by laboratory reference range:
  - Elevated urine porphobilinogen (PBG)
  - Genetic testing confirming a pathogenic mutation (e.g., *HMBS/PBGD*)
- The member has had two documented porphyria attacks within the past 6 months requiring hospitalization, urgent healthcare visit, or intravenous hemin administration
- The member has not had a liver transplant.
- The member has addressed identifiable lifestyle triggers (e.g., certain drugs, stress)
- If the member is a current tobacco/marijuana user, the member must have received tobacco/marijuana cessation counseling in the past year
- If the member has a history of alcohol use within the past 5 years, one of the following must be met (1, 2 or 3):
  1. The member has a carbohydrate-deficient transferrin (CDT) level < 3% within the past 3 months.
  2. The member has a phosphatidylethanol (PEth) level < 20 ng/mL.
  3. The member has submitted two negative alcohol tests with the most recent alcohol test within the past 3 months.

Renewal Criteria – Approval Duration: 12 months

- The member has had a meaningful reduction (e.g., 30%) in each of the following:
  - Number of porphyria attacks
  - Days of Hemin use
  - Reduction in *ALAS1 levels* and urinary ALA and PBG

Bowel Prep Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAVILYTE-C SOLUTION (peg3350/sod sulf,bicarb,Cl/KCl)	CLENPIQ (sod picosulf/mag ox/citric ac)
PEG 3350 – Electrolyte Solution (generic Gavilyte-N solution)	peg 3350/sod sul/NaCl/KCl/asb/C (generic Moviprep)
PEG-3350 and Electrolytes Soln (generic Golytely and Gavilyte-G solution)	SUFLAVE (peg 3350/sod sulf/chlr/pot/mag)

Sod Sul-Potass Sul-Mag Sul Sol (generic Suprep)	SUTAB (sod sulf/pot chloride/mag sulf)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 1 month

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

Cholestatic Pruritis

Alagille Syndrome (ALGS):

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED (PA REQUIRED)
BYLVAY (odevixibat)	this space intentionally left blank
LIVMARLI (maralixibat)	this space intentionally left blank

Progressive Familial Intrahepatic Cholestasis (PFIC):

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED (PA REQUIRED)
BYLVAY (odevixibat)	LIVMARLI (maralixibat)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hepatologist or gastroenterologist.
- The member is experiencing itch for greater than 6 weeks that has significantly diminished quality of life, including sleep disturbances.
- The member must have cholestasis, as evidenced by ≥ 1 of the following:
  - Serum bile acid > 3x upper limit of normal as defined by the reporting laboratory
  - Conjugated bilirubin > 1mg/dL
  - Fat soluble vitamin deficiency otherwise unexplainable
  - Gamma-glutamyl transferase > 3x the upper limit of normal
  - Intractable pruritus explainable only by liver disease
- The member must not have a history of liver transplant or decompensated cirrhosis.
- The member must not have history of biliary diversion surgery within the past 6 months.
- The member must have failed at least a 3-month trial of Ursodiol in addition to each of the following, as evidenced by paid claims or pharmacy printouts:
  - cholestyramine, rifampin, naltrexone, sertraline
- Bylvay Only:
  - ALGS:
    - Genetic testing confirms pathogenic variant (e.g., *JAG1* and *NOTCH2).*

        - The member has had a 6-month trial with Livmarli, as evidenced by paid claims or pharmacy printouts.
    - PFIC:
        - Genetic testing confirms pathogenic variant (e.g., *ATP8B1, ABCB11, ABCB4, TJP2, NR1H4, and MYO5B*).
        - Genetic testing does not indicate PFIC Type 2 with *ABCB11* variants that predict complete absence of BSEP-3 protein.
- Livmarli Only:
    - Genetic testing confirms pathogenic variant of *JAG1* or *NOTCH1*
    - PFIC Only: The member must have failed at least a 3-month trial of Bylvay, as evidenced by paid claims or pharmacy printouts

Renewal Criteria – Approval Duration: 12 months

- The member has experienced an improvement in pruritis, as evidenced by clinical documentation.
- The member must have experienced a reduction in serum bilirubin < 6.5mg/dL and bile acids < 200 micromol/L

Clostridioides difficile-associated diarrhea (CDAD)

Prevention

Fecal Microbiota

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
REBYOTA (fecal microbiota, live–jslm) SUSPENSION – *Medical Billing*	this space intentionally left blank
VOWST (fecal microbiota spores, live-brpk) CAPSULE	this space intentionally left blank

Electronic Duration Verification

- Vowst is payable every 6 months.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member has one of the following (1 or 2):
    1. The member has had at least two episodes of diarrhea with a positive stool test for *C.difficile* toxin within the last year
    2. The member has had at least one previous episodes of diarrhea with a positive stool test for *C.difficile* toxin within the last year AND one of the following
        - *C. difficile* infection was severe (defined as ZAR score ≥ 2)
        - Member is immunocompromised

Treatment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DIFICID (fidaxomicin) 40 MG/ML SUSPENSION	fidaxomicin tablet
DIFICID (fidaxomicin) TABLET – *Brand Required*	FIRVANQ (vancomycin) SOLUTION
vancomycin capsule	VANCOCIN (vancomycin) CAPSULE
vancomycin solution	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 1 month

- See Preferred Dosage Form Criteria

Crohn's Disease

Biologic Agents

α4 Integrin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	natalizumab – See Biosimilar Agents

++ Clinically Non-Preferred: Tysabri is associated with a risk of developing progressive multifocal leukoencephalopathy (PML), a rare, potentially fatal neurologic disease caused by reactivation of JC virus (JCV) infection.

A4β7 Integrin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	ENTYVIO (vedolizumab)
this space intentionally left blank	ENTYVIO (vedolizumab) – *Medical Billing*

Interleukin (IL) 12/IL-23p40 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ustekinumab - See Biosimilar Agents	this space intentionally left blank

Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TREMFYA (guselkumab)	OMVOH (mirikizumab)
TREMFYA (guselkumab) *– IV Induction Medical Billing*	OMVOH (mirikizumab) *– IV Induction Medical Billing*
this space intentionally left blank	SKYRIZI (risankizumab-rzaa)

this space intentionally left blank	SKYRIZI (risankizumab-rzaa) – *IV Induction Medical Billing*

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	CIMZIA (certolizumab) SYRINGE
infliximab - See Biosimilar Agents	CIMZIA (certolizumab) VIAL – *Medical Billing*

Janus Kinase (JAK) Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	RINVOQ ER (upadacitinib)

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must have failed all preferred agents in the same class as requested product

Cimzia Only:

- The member must have failed a 3-month trial of ustekinumab and a TNF-inhibitor, as evidenced by paid claims or pharmacy printouts

Entyvio Only:

- The member must have failed a 30-day trial with Rinvoq ER and 3-month trial of the following, as evidenced by paid claims or printouts
  - TNF inhibitor
  - Ustekinumab

Omvoh Only:

- The member has failed a 30-day trial with Rinvoq ER and 3-month trial of the following, as evidenced by paid claims or printouts:
  - Entyvio
  - TNF inhibitor
  - IL-23p19 Inhibitor
  - Ustekinumab

Rinvoq ER Only:

- The member must have failed a 3-month trial of ustekinumab, as evidenced by paid claims or pharmacy printouts
    - Ustekinumab trial may be bypassed if member has failed a 3-month trial of a TNF-inhibitor

Skyrizi Only:

- The member has failed a 30-day trial with Rinvoq ER and 3-month trial of the following, as evidenced by paid claims or printouts:
    - TNF inhibitor
    - IL-23p19 Inhibitor

Tremfya Only:

- The member has failed a 30-day trial with Rinvoq ER and 3-month trial of ustekinumab, as evidenced by paid claims or printouts
    - Ustekinumab trial may be bypassed if member has failed a 3-month trial of a TNF-inhibitor

Tysabri Only:

- The requested medication must be prescribed by, or in consult with, a gastroenterologist
- The member has failed a 30-day trial with Rinvoq ER and 3-month trial of the following, as evidenced by paid claims or printouts:
    - TNF inhibitor
    - Ustekinumab

Constipation

Therapeutic Duplication

- One medication is allowed at a time.

Chronic Idiopathic Constipation

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LINZESS (linaclotide)	AMITIZA (lubiprostone)
lubiprostone	MOTEGRITY (prucalopride)
prucalopride	this space intentionally left blank

Functional Constipation

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LINZESS (linaclotide) 72 mcg	this space intentionally left blank

Irritable Bowel Syndrome with Constipation (IBS-C)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LINZESS (linaclotide)	AMITIZA (lubiprostone)

lubiprostone	IBSRELA (tenapanor)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial with each of the following, as evidenced by paid claims or pharmacy printouts:
  - Linzess
  - lubiprostone for members assigned female at birth

Opioid-Induced Constipation

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lubiprostone	AMITIZA (lubiprostone)
SYMPROIC (naldemedine)	MOVANTIK (naloxegol)

Electronic Concurrent Medications Required

- A total of 28 days of opioid analgesics must be paid within 40 days prior to requested Movantik or Symproic's date of service.
  - Medications indicated for opioid-induced constipation should be discontinued when opioids are stopped.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have had a 30-day trial of Symproic, as evidenced by paid claims or pharmacy printouts.

Diarrhea

Irritable Bowel Syndrome

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
alosetron 0.5 mg	alosetron 1mg
antispasmotic (e.g., dicyclomine, hyoscyamine)	LOTRONEX (alosetron) 0.5 mg
loperamide	VIBERZI (eluxadoline)
LOTRONEX (alosetron) 1 mg – *Brand Required*	this space intentionally left blank
tricyclic antidepressants (e.g., amitriptyline)	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- Infectious and medication-induced etiologies of diarrhea must have been ruled out.
- The member must have failed a 30-day trial of a product in each preferred class, as evidenced by paid claims or pharmacy printouts.

HIV / AIDS

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
antimotility agent (e.g., loperamide, diphenoxylate/atropine)	MYTESI (crofelemer)
Octreotide	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- Infectious and medication-induced etiologies of diarrhea must have been ruled out.
- The member must have failed a 30-day trial of an agent in each preferred class, as evidenced by paid claims or pharmacy printouts.

Digestive Enzymes

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CREON (lipase/protease/amylase)	PERTZYE (lipase/protease/amylase)
ZENPEP (lipase/protease/amylase)	VIOKACE (lipase/protease/amylase)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- A 28-day trial of all preferred agents will be required, as evidenced by paid claims or pharmacy printouts, before a non-preferred agent will be authorized unless member stable on a pancreatic enzyme written by a gastroenterologist, cystic fibrosis, or pancreas disease specialist.

Eosinophilic Esophagitis

PA REQUIRED
DUPIXENT (dupilumab)
EOHILIA (budesonide) STICK PACKETS
fluticasone HFA

Prior Authorization Criteria

Prior Authorization Form – Eosinophilic Esophagitis

Initial Criteria – Approval Duration: 6 months (3 months for Eohilia)

- The requested medication must be prescribed by, or in consult with, an allergist or gastroenterologist.
- The member must have ≥15 intraepithelial eosinophils per high-power field (eos/hpf).
- The member must have failed an 8-week trial of twice daily proton pump inhibitors, as evidenced by paid claims or pharmacy printouts.

- Eohilia and fluticasone HFA Only: The member must have failed a 12-week trial of swallowing oral viscous budesonide nebulizer twice daily, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months (no renewal for Eohilia)

- The member has achieved a significant reduction in dysphagia symptoms since treatment initiation.
- The member must have achieved an esophageal intraepithelial eosinophil count of ≤6 eos/hp.

Ulcerative Colitis

Systemic Agents

Biologic Injectable Agents

α4β7 Integrin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	ENTYVIO (vedolizumab)
this space intentionally left blank	ENTYVIO (vedolizumab) – *Medical Billing*

Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TREMFYA (guselkumab) – *IV Induction Medical Billing*	OMVOH (mirikizumab)
TREMFYA (guselkumab)	OMVOH (mirikizumab) – *IV Induction Medical Billing*
this space intentionally left blank	SKYRIZI (risankizumab-rzaa)
this space intentionally left blank	SKYRIZI (risankizumab-rzaa) – *IV Induction Medical Billing*

Interleukin (IL) 12/IL-23p40 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ustekinumab - See Biosimilar Agents	this space intentionally left blank

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	this space intentionally left blank
infliximab - See Biosimilar Agents	this space intentionally left blank
SIMPONI (golimumab)	this space intentionally left blank

Oral Agents

Janus Kinase (JAK) Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

XELJANZ IR (tofacitinib) 5 mg – Brand Required	RINVOQ ER (upadacitinib)
XELJANZ (tofacitinib) SOLUTION – Brand Required	tofacitinib
this space intentionally left blank	XELJANZ IR (tofacitinib) 10 mg
this space intentionally left blank	XELJANZ XR (tofacitinib)

Sphingosine 1-Phosphate (S1P) Receptor Modulator

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	VELSIPITY (etrasimod)
this space intentionally left blank	ZEPOSIA (ozanimod)

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a gastroenterologist.
- The member must have failed all preferred agents in the same class as requested product
- The member must have failed a 3-month trial of infliximab and a 30-day trial with a JAK inhibitor, as evidenced by paid claims or pharmacy printouts.
- Tremfya Only: The member must have failed a 3-month trial of infliximab and Entyvio, and a 30-day trial with a JAK inhibitor as evidenced by paid claims or pharmacy printouts.
- Omvoh and Skyrizi Only: The member must have failed a 3-month trial of infliximab, Entyvio, an Interleukin (IL)-23p19 Inhibitor and a 30-day trial with a JAK inhibitor, as evidenced by paid claims or pharmacy printouts.
- Velsipity and Zeposia: The member must have had a 3-month trial of a TNF inhibitor, and 30-day trials of Xeljanz and Rinvoq ER as evidenced by paid claims or pharmacy printouts.
- Xeljanz IR 10 mg, Xeljanz XR Only: See Preferred Dosage Form criteria
- Rinvoq ER Only: The member must have failed a 3-month trial of a TNF inhibitor and a 30-day trial of Xeljanz, as evidenced by paid claims or pharmacy printouts.

Locally Acting Agents

5-Aminosalicylic Acid (5-ASA)

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
balsalazide capsule	AZULFIDINE (sulfasalazine)
DIPENTUM (olsalazine)	AZULFIDINE ENTAB (sulfasalazine)
mesalamine 1.2 mg DR tablet	LIALDA (mesalamine) TABLET
mesalamine ER 375 mg	mesalamine ER 375 mg, 500 mg ER capsule

PENTASA (mesalamine) – *Brand Required*	mesalamine 400 mg DR capsule, 800 mg DR tablet
sulfasalazine DR tablet	this space intentionally left blank
sulfasalazine tablet	this space intentionally left blank

Topical

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydrocortisone enema	budesonide rectal foam
mesalamine enema	CANASA (mesalamine) SUPPOSITORY
mesalamine rectal suppository	mesalamine enema kit
this space intentionally left blank	ROWASA (mesalamine) ENEMA KIT
this space intentionally left blank	SF ROWASA (mesalamine) ENEMA

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of mesalamine, as evidenced by paid claims or pharmacy printouts.
- Mesalamine HD: See Preferred Dosage Form criteria

Wilson's Disease

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DEPEN (penicillamine) TITRATAB – *Brand Required*	CUVRIOR (trientine tetrahydrochloride)
trientine hydrochloride 250 mg	penicillamine capsule
this space intentionally left blank	penicillamine tablet
this space intentionally left blank	trientine hydrochloride 500 mg

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Preferred Dosage Form Criteria

Genetic and Rare Disease

Amyloidosis

Polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN)

TTR-specific small interfering RNA (siRNA)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

ONPATTRO (patisiran) – *Medical Billing*	this space intentionally left blank

Transthyretin-directed small interfering RNA (siRNA)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMVUTTRA (vutrisiran) – *Medical Billing*	this space intentionally left blank

Antisense Oligonucleotide (ASO)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
WAINUA (eplontersen)	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a neurologist, geneticist, or specialist in the treatment of amyloidosis.
- The diagnosis must be confirmed by both of the following:
  - Genetic testing confirming a pathogenic TTR mutation (e.g., V30M)
  - Amyloid deposits via tissue biopsy
- One of the following must be provided:
  - Baseline polyneuropathy disability (PND) score ≤ IIIb
  - Baseline Coutinho staging system stage 1 or 2
  - Baseline Neuropathy Impairment Score [NIS] of 5–130
  - Karnofsky Performance Status score of ≥60%
- The member has not had a liver transplant.
- The member has clinical signs and symptoms of the disease (e.g., peripheral neuropathy, numbness, altered pain and temperature sensation, decreased pinprick sensation)
- The member is not receiving any other TTR reducing agent (i.e., acoramidis, tafamidis)

Renewal Criteria – Approval Duration: 12 months

- The member has received a therapeutic response as evidenced by stabilization or improvement (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.) from baseline in one of the following:
  - PND score ≤ IIIb
  - Coutinho staging system stage 1 or 2
  - Baseline Neuropathy Impairment Score [NIS] of 5–130
  - Karnofsky Performance Status score of ≥60%

Cardiomyopathy of transthyretin-mediated amyloidosis (ATTR-CM)

Transthyretin-directed small interfering RNA (siRNA)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

this space intentionally left blank	AMVUTTRA (vutrisiran) – *Medical Billing*

TTR Stabilizers

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ATTRUBY (acoramidis)	this space intentionally left blank
VYNDAQEL (tafamidis)	this space intentionally left blank
VYNDAMAX (tafamidis)	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a cardiologist, geneticist, or specialist in the treatment of amyloidosis.
- Confirmation of the diagnosis by both of the following must be provided:
  - presence of grade 2 or 3 positive bone tracer cardiac scintigraphy
  - absence of monoclonal protein confirmed by serum protein immunofixation, urine protein immunofixation, or serum free light chain ratio analysis
- The member must have heart failure class I or II with at least 1 prior hospitalization for heart failure or with symptoms of volume overload or elevated intracardiac pressures (e.g., elevated jugular venous pressure, shortness of breath or signs of pulmonary congestion on x-ray or auscultation, peripheral edema) despite 6-months of adherent use of a diuretic.
- The member has an end-diastolic interventricular septal wall thickness of at least 12 mm.
- For Attruby only: The member must not have any of the following:
  - ALT or AST > 2x ULN or Total Bilirubin >3x ULN
  - NT-proBNP level > 8500 pg/mL
- The member must not have any of the following:
  - estimated glomerular filtration rate (eGFR) < 25 mL/min/1.73m^2 or be on chronic kidney dialysis
  - NYHA class IV symptoms or severe aortic stenosis
  - Previous heart transplant or implanted cardiac mechanical assist device
  - Previous liver transplant
- Baseline 6MWT > 100 meters must be submitted.
- The member is not receiving any other TTR reducing agent (i.e., patisiran, elplontersen)

For Amvuttra Only:

- The member must have failed a 90-day trial of each Attruby and Vyndaqel/Vyndamax, as evidenced by paid claims or pharmacy printouts
- Coverage will be allowed without trial of preferred medications if the member also meets the criteria for hATTR-PN

Renewal Criteria – Approval Duration: 12 months

- For Attruby only: The member has received a therapeutic response as evidenced by stabilization or improvement from baseline in both of the following:
  - 6MWT
  - NT-proBNP level

- For Vyndaqel/Vyndamax and Amvuttra: The member has received a therapeutic response as evidenced by stabilization or improvement from baseline in both of the following:
  - 6MWT
  - NYHA class

References:

1. Ando Y, Coelho T, Berk JL, Cruz MW, Ericzon BG, Ikeda S, Lewis WD, Obici L, Planté-Bordeneuve V, Rapezzi C, Said G, Salvi F. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013 Feb 20;8:31. doi: 10.1186/1750-1172-8-31. PMID: 23425518; PMCID: PMC3584981.

Late Infantile Neuronal Ceroid Lipofuscinosis Type 2 (CLN2)

PA REQUIRED
BRINEURA (cerliponase alfa) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must be less than 16 years old.
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a metabolic specialist, geneticist, or pediatric neurologist.
- Confirmation of the diagnosis must be submitted, as evidenced by the following:
  - Molecular analysis that has detected two pathogenic variants/mutations in the TPP1 gene.
  - An enzyme assay confirming deficiency of tripeptidyl peptidase 1 (TPP1)
- The member must not have ventriculoperitoneal shunts
- Baseline results of motor and language domains of the Hamburg CLN2 Clinical Rating Scale must be submitted and meet the following parameters:
  - Results must show a combined score of less than 6 in the motor and language domains.
  - Results must show a score of at least 1 in each of these domains.

Renewal Criteria – Approval Duration: 12 months

- The member must not have acute, unresolved localized infection on or around the device insertion site or suspected or confirmed CNS infection.
- The member maintains at a score of at least 1 in the motor domain on the Hamburg CLN2 Clinical Rating Scale
- The member has responded to therapy compared to pretreatment baseline with stability/lack of decline* in motor function/milestones.

  * *Decline is defined as having an unreversed (sustained) 2-category decline or an unreversed score of 0 in the Motor domain of the CLN2 Clinical Rating Scale*

Fabry Disease

Alpha-Galactosidase A Pharmacological Chaperone

PREFERRED AGENTS (PA REQUIRED)
GALAFOLD (migalastat)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a metabolic specialist, geneticist, cardiologist, or specialist in Fabry disease.
- The member must be assigned male at birth.
- The member's diagnosis must be confirmed to be caused by a pathologic galactosidase alpha gene (GLA) variant that is amenable to treatment with Galafold interpreted from a clinical geneticist professional
- The member must have a deficiency of less than 35% of mean normal alpha-galactosidase A (α-Gal A) enzyme activity
- The medication must not be used in conjunction with enzyme replacement therapy.
- The member must not have significant renal impairment (estimated glomerular filtration rate (eGFR) <30 mL/minute/1.73 m2) or have had a kidney transplant

Renewal Criteria – Approval Duration: 12 months

- The member must have a decreased Gb3 level or GL-3 inclusions per kidney interstitial capillary (KIC) and experienced improvement in one of the following symptoms since starting treatment with requested product, subject to clinical review:
  - Acroparesthesias (burning pain in the extremities)
  - Left ventricular hypertrophy (LVH)
  - Glomerular filtration rate (GFR) and/or proteinuria

Enzyme Replacement Therapy

PA REQUIRED
ELFABRIO (pegunigalsidase alfa) – *Medical Billing*
FABRAZYME (agalsidase beta) – *Medical Billing*

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a metabolic specialist, geneticist, cardiologist, or specialist in Fabry disease.
- The member will not be concurrently treated with Galafold (migalastat)
- The member must have a diagnosis of Fabry disease with the one of the following (A or B):
  - In males assigned at birth, must meet one of the following (1 or 2):
    1. Deficiency of less than 35% of mean normal alpha-galactosidase A (α-Gal A) enzyme activity
    2. Diagnosis is confirmed to be caused by a pathologic galactosidase alpha gene (GLA)
  - In females assigned at birth, all of the following must be met:

- Diagnosis must be confirmed to be caused by a pathologic galactosidase alpha gene (GLA)
- The member is experiencing one of the following symptoms:
  - Acroparesthesias (burning pain in the extremities)
  - Impaired glomerular filtration rate (GFR) or proteinuria
  - Left ventricular hypertrophy (LVH)
  - Gastrointestinal manifestations (e.g., diarrhea, abdominal pain)
  - GL-3 deposits within the kidney

Non-Preferred Agent Criteria:

- The member must have failed a trial of each of the preferred products, as evidenced by paid claims or pharmacy printouts

Renewal Criteria – Approval Duration: 12 months

- The member must have a decreased urine or plasma Gb3 level or GL-3 inclusions per kidney interstitial capillary (KIC) and experienced improvement in one of the following symptoms since starting treatment with requested product, subject to clinical review:
  - Acroparesthesias (burning pain in the extremities)
  - Left ventricular hypertrophy (LVH)
  - Glomerular filtration rate (GFR) and/or proteinuria
  - Gastrointestinal manifestations (e.g., diarrhea, abdominal pain)

Gaucher's Disease

Enzyme Replacement Therapy

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELELYSO (taliglucerase alfa) – *Medical Billing*	CEREZYME (imiglucerase) – *Medical Billing*
this space intentionally left blank	VPRIV (velaglucerase alfa) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a geneticist, an endocrinologist, or a physician who specializes in the treatment of lysosomal storage disorders.
- The member must have a diagnosis of Gaucher disease Type I or Type III with one of the following:
  - Deficiency in glucocerebrosidase enzyme activity in peripheral leukocytes
  - Genetic testing confirming biallelic pathogenic variants in the GBA1 gene
- The member must be experiencing one or more of the following:
  - Low hemoglobin as reported by laboratory
  - Low platelet count (<120,000/mm^3)
  - Bone disease (T-score below -1.0 [DXA], height ≤ 5^{th} percentile for age and sex in children, bone pain or bone crisis, radiologic evidence of skeletal disease)
  - Hepatomegaly (liver size 1.25 or more times normal)
  - Splenomegaly (spleen size eight (8) or more times normal)

Non-Preferred Agent Criteria:

- The member must have failed a 9-month trial of Elelyso, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- The member has experienced a beneficial response to therapy as evidenced by normalization or significant improvement in one of the following symptoms:
  - Reduction in liver volume to normal size or by 10%
  - Reduction in spleen volume by 15%
  - Increase in hemoglobin levels by 1 g/dL
  - Increase in platelet levels by 15%
  - Increased T-score [DXA] by 0.3, normalized growth velocity, or decrease in bone pain or crisis

Substrate Replacement Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ZAVESCA (miglustat) – *Brand Required*	miglustat
PREFERRED AGENTS (PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
CERDELGA (eliglustat)	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Cerdelga: See Medications that cost over $3000/month criteria

Lysosomal Acid Lipase (LAL) Deficiency

PA REQUIRED
KANUMA (sebelipase alfa) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the treatment of lysosomal acid lipase (LAL) such as a lipidologist, endocrinologist, cardiologist, or hepatologist.
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming 2 mutations in the LIPA gene
  - Deficiency of the LAL in peripheral blood leukocytes, fibroblasts, or dried blood spots
- The member must have one of the following:
  - The member is ≤ 8 months old and has growth failure, severe anemia, or hepatomegaly
  - The member has an alanine aminotransferase (ALT) ≥ 1.5x upper limit of normal on 2 consecutive screenings at least one week apart.
- The member must not have had a hematopoietic stem cell or liver transplant.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, subject to clinical review, including improvement in weight for age Z-scores for individuals with growth failure, improved LDL, HDL, AST, ALT and/or triglycerides.

Hereditary Thrombotic Thrombocytopenic Purpura (hTTP) / Congenital TTP (cTTP)

AKA Congenital TTP (cTTP)

PA REQUIRED
ADZYNMA (ADAMTS13, recombinant-krhn) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: Prophylaxis: 6 months, On-Demand: 2 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist
- The diagnosis must be confirmed by both of the following:
  - genetic test confirming biallelic ADAMTS13 mutation
    - Unless member has a positive response to Adzynma inpatient and is continuing outpatient treatment, then genetic tests should be provided upon renewal
  - ADAMTS13 activity < 10% of normal with the absence of an inhibitor (i.e. ADAMTS13 autoantibodies)
- For members requesting prophylactic therapy:
  - The member must have a history of at least one of the following:
    - At least one documented TTP event
    - The member is pregnant (approval duration through 6 weeks post-partum)
  - The member must have a documented intolerance to plasma-based therapies
- For members requesting acute (On-Demand) treatment, must have an acute event defined by both of the following:
  - Platelet count < 150,000/uL or a drop in platelet count > 25% of baseline
  - Microangiopathic hemolytic anemia (LDH > 1.5 x baseline or > 1.5 x ULN)

Renewal Criteria – Approval Duration: 12 months

The member must have experienced a therapeutic response as evidenced by the following:

- For members receiving prophylaxis, any of the following:
  1. Decreased number of acute and subacute TTP events
  2. Increased platelet counts (within 25% of baseline or > 150,000/uL
  3. Decreased microangiopathic hemolytic anemia episodes (defined as LDH < 1.5 x baseline or < 1.5 x ULN)
- For members receiving On-Demand treatment, both of the following:
  1. Increased platelet counts (within 25% of baseline or >150,000/uL, whichever occurs first)
  2. Decreased microangiopathic hemolytic anemia (defined as LDH < 1.5 x baseline or < 1.5 x ULN)

Alpha-Mannosidosis

PA REQUIRED
LAMZEDE (velmanase alfa-tycv) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Confirmation of the member's diagnosis must be submitted, as evidenced by one of the following:
  - Deficiency of alpha-mannosidase activity in leukocytes or fibroblasts < 10% of normal activity
  - Detection of biallelic pathogenic variants in the *MAN2B1* gene by molecular genetic testing
- The requested medication must be prescribed by, or in consult with, a neurologist, pulmonologist, geneticist or another prescriber specializing in lysosomal storage diseases.
- The member must not have had a hematopoietic stem cell transplant.
- All of the following must be submitted:
  - Non-central nervous system manifestations (e.g., progressive motor function disturbances, physical disability, hearing and speech impairment, skeletal abnormalities, and immune deficiency)
  - Elevated level of serum oligosaccharide concentration, as defined by being above the upper limit of normal by the laboratory reference range
  - If 3 years of age or older, must be able to walk without support
  - Motor function as measured by one of the following:
    - 6-minute walk test (6-MWT)
    - 3-minute stair climb test
    - Forced Vital Capacity (FVC) via Pulmonary Function Test

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced clinical benefit since starting treatment with the requested medication, subject to clinical review, by both of the following:
  - Reduction in serum oligosaccharide concentration
  - Stability or improvement in the one of the following scores and symptoms:
    - 6-MWT
    - 3-minute stair climb test
    - FVC via Pulmonary Function Test

Metachromatic Leukodystrophy (MLD)

Cell-based Gene Therapy

PA REQUIRED
LENMELDY (atidarsagene autotemcel) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member has a diagnosis of Metachromatic Leukodystrophy (MLD), confirmed by all the following:
  - Genetic testing for biallelic ARSA pathogenic variants
  - Deficient ARSA enzyme activity in leukocytes
  - Elevated urinary excretion of sulfatides
- The member must be a child with one of the following:
  - Pre-symptomatic late infantile (PSLI) onset defined as the absence of neurological signs and symptoms of MLD
  - Pre-symptomatic early juvenile (PSEJ) onset defined as the absence of neurological signs and symptoms of MLD, or physical exam findings limited to abnormal reflexes and/or clonus
  - Early symptomatic early-juvenile (ESEJ) onset disease defined as walking independently (GMFC-MLD Level 0 with ataxia or GMFC-MLD Level 1) and IQ ≥ 85
- The member does not have human immunodeficiency virus type 1 or 2 (HIV-1 and HIV-2), human T-lymphotropic virus type 1 or 2 (HTLV-1 and HTLV-2), hepatitis B virus (HBV), or hepatitis C (HCV)
- The member must not be a recipient of a previous allogeneic transplant or gene therapy

Mucopolysaccharidosis I (MPS I)

PA REQUIRED
ALDURAZYME (laronidase) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a geneticist, metabolic specialist, or specialist in mucopolysaccharidoses (MPS)
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming biallelic pathogenic mutations in the IDUA gene
  - Deficiency in activity of the lysosomal enzyme α-L-iduronidase (IDUA) in fibroblast or leukocyte < 10% of normal activity
- The member must not have had a hematopoietic stem cell transplant.
- If 3 years of age or older, must be able to walk without support
- The member's current motor function must be submitted, as evidenced by scores from the following assessments:
  - 6-minute walk test (6MWT)
  - Forced Vital Capacity (FVC) via Pulmonary Function Test greater than 30%

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, subject to clinical review, including improvement in the following scores and symptoms:

- 6-minute walk test (6MWT)
- Forced Vital Capacity (FVC) via Pulmonary Function Test

Mucopolysaccharidosis II (MPS II) – Hunter Syndrome

PA REQUIRED
AVLAYAH (tividenofusp alfa-eknm) – *Medical Billing*
ELAPRASE (idursulfase) – *Medical Billing*

Therapeutic Duplication

- One strength of one medication is allowed at a time.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency in iduronate-2sulfatase (I2S) enzyme activity of ≤ 10% of the lower limit of normal in white cells, fibroblasts, or plasma in the presence of normal activity of at least one other sulfatase
  - Genetic testing confirming pathogenic mutations in the IDS gene that leaves the Fragile X Messenger Ribonucleoprotein genes (FMR1, *FMR2*) intact
- The requested medication must be prescribed by, or in consult with, a geneticist, metabolic specialist, or specialist in mucopolysaccharidoses (MPS)
- Urinary glycosaminoglycan (uGAG) levels must be elevated as defined by laboratory reference range
- For Avlayah only, both of the following must be submitted:
  - Baseline description of current neurologic manifestations (including mean hearing score)
  - Hepatomegaly (liver size 1.25 or more times normal)
- For Elaprase only, one of the following must be submitted:
  - 6-minute walk test (6MWT)
  - Hepatomegaly (liver size 1.25 or more times normal)
  - Splenomegaly (spleen size five (5) or more times normal)

Renewal Criteria – Approval Duration: 12 months

- Urinary glycosaminoglycan (uGAG) levels normalization defined by laboratory reference range
- For Avlayah only: The member must have experienced
  - Improvement in one or more neurologic manifestations or has continued to be asymptomatic as reported by prescriber attestation
- For Elaprase only, the member must have had a therapeutic response as evidenced by improvement of one of the following:
  - 6-minute walk test (6MWT) increase
  - Reduction in liver volume to normal size or by 10%
  - Reduction in spleen volume by 15%

Mucopolysaccharidosis IVA (MPS IVA) – Morquio A syndrome

PA REQUIRED
VIMIZIM (elosulfase alfa) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: *6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming biallelic pathogenic mutations in the GALNS gene
  - Deficiency in activity of the n N-acetylgalactosamine 6-sulfatase (GALNS) enzyme
- The requested medication must be prescribed by, or in consult with, a geneticist, metabolic specialist, or specialist in mucopolysaccharidoses (MPS)
- The member must not have had a hematopoietic stem cell transplant.
- If 3 years of age or older, must be able to walk without support
- Baseline Urine Keratan Sulfate (KS) levels must be submitted
- One of the following must be submitted:
  - Forced Vital Capacity (FVC) via Pulmonary Function Test
  - 6-minute walk test (6MWT)
  - 3-minute stair climb test (3-MSCT)

Renewal Criteria – Approval Duration: *12 months*

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, subject to clinical review, by one of the following scores:
  - Forced Vital Capacity (FVC) via Pulmonary Function Test
  - 6-minute walk test (6MWT)
  - 3-minute stair climb test (3-MSCT)
  - Reduced Urine Keratan Sulfate (KS) levels

Mucopolysaccharidosis VI (MPS VI) – Maroteaux-Lamy syndrome

PA REQUIRED
NAGLAZYME (galsulfase) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: *6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency of N-acetylgalactosamine 4-sufatase (arylsulfatase B or ASB) enzyme activity of <10% of the lower limit of normal
  - Detection of pathogenic variants in the ARSB gene by molecular genetic testing
- The requested medication must be prescribed by, or in consult with, an expert in lysosomal storage diseases.
- Both of the following must be submitted:

- Elevated level of urinary excretion of glycosaminoglycans (GAGs) such as chondroitin sulfate and dermatan sulfate, as defined by being above the upper limit of normal by the laboratory reference range
- Motor function as measured by one of the following:
  - 6 or 12-minute walk test (6-MWT or 12-MWT)
  - 3-minute stair climb test
  - Forced Vital Capacity (FVC) via Pulmonary Function Test

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced clinical benefit since starting treatment with the requested medication, subject to clinical review, including improvement in the one of the following scores and symptoms:
  - Reduction in urinary excretion of glycosaminoglycans (GAGs)
  - Stability or improvement in 6 or 12-minute walk test (6-MWT or 12-MWT)
  - Stability or improvement in 3-minute stair climb test
  - Stability or improvement in Forced Vital Capacity (FVC) via Pulmonary Function Test

Mucopolysaccharidosis VII (MPS VII) – Sly Syndrome

PA REQUIRED
MEPSEVII (vestronidase alfa-vjbk) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency of beta-glucuronidase enzyme
  - Detection of pathogenic variants in the GUSB gene by molecular genetic testing.
- The requested medication must be prescribed by, or in consult with, an expert in lysosomal storage diseases.
- The member must not have had a hematopoietic stem cell transplant.
- If 3 years of age or older, must be able to walk without support
- One or more of the following must be submitted:
  - Elevated level of urinary excretion of glycosaminoglycans (GAGs) such as chondroitin sulfate and dermatan sulfate, as defined by being 2 or more times normal
  - Hepatomegaly (liver size 1.25 or more times normal)
  - Splenomegaly (spleen size 5 or more times normal)
  - 6-minute walk test (6MWT)
  - Forced Vital Capacity (FVC) via Pulmonary Function Test

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced clinical benefit since starting treatment with the requested medication, subject to clinical review, including improvement in the one of the following scores and symptoms:
  - Urinary glycosaminoglycan (uGAG) levels normalization defined by laboratory reference range
  - Reduction in liver volume to normal size or by 10%

- Reduction in spleen volume by 15%
- Improvement in 6-minute walk test (6MWT)
- Improvement in Forced Vital Capacity (FVC) via Pulmonary Function Test

Niemann-Pick Type C

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AQNEURSA (levacetylleucine)	MIPLYFFA (arimoclomol)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a geneticist, neurologist or other specialist with treatment of NPC
- The member is symptomatic with neurological manifestations associated with NPC such as gait problems, ataxia, cognitive deterioration, or vertical gaze palsy (chart notes must be submitted)
- Confirmation of the diagnosis must be submitted, as evidenced by one of the following:
  - Confirmation by genetic testing identifying disease-causing mutations in both alleles of NPC1 or NPC2
  - Confirmation by genetic testing identifying disease-causing mutation in one allele of NPC1 or NPC2 AND either a positive filipin-staining or elevated cholestane triol/oxysterols (> 2x the upper limit of normal)
- For Aqneursa only: The member must weigh ≥ 15 kg
- For Miplyffa only:
  - The member must weigh ≥ 8 kg
  - The member must be ≥ 2 years of age
  - The member must not have significant renal impairment (estimated glomerular filtration rate (eGFR) < 15 mL/min) or be on chronic renal dialysis.

Non-Preferred Agents Criteria:

- The member must have failed a 3-month trial of the preferred agent, as evidenced by paid claims or pharmacy printouts

Renewal Criteria – Approval Duration: 12 months

- The member demonstrates a positive response with a slowed progression or decrease in neurological symptoms compared to baseline

Phenylketonuria (PKU)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
JAVYGTOR (sapropterin)	KUVAN (sapropterin)
sapropterin	PALYNZIQ (pegvaliase-pqpz)
this space intentionally left blank	SEPHIENCE (sepiapterin)
this space intentionally left blank	ZELVYSIA (sapropterin)

Underutilization

- Sapropterin and Palynziq must be used adherently and will reject on point of sale for late fill

Prior Authorization Criteria

Prior Authorization Form – Phenylketonuria

Initial Criteria – Approval Duration: 2 months (sapropterin and Sephience); 12 months (Palynziq)

- The member must have been compliant with a PHE restricted diet for past 6 months
- The requested medication must be prescribed by, or in consult with, a geneticist or endocrinologist.
- Current PHE levels must meet one of the following:
  - For members of childbearing potential or children ≤ 12 years old: PHE levels must be above 360 µmoles/liter (6 mg/dL)
  - For members without childbearing potential, or children > 12 years old: PHE levels must be above 600 µmoles/liter or 10 mg/dL)
- Sapropterin Only:
  - The member's weight must be provided. Requested initial dose must be 10 mg/kg.
  - The member does not have two null mutations in trans
- Palynziq and Sephience Only:
  - One of the following must be met (A or B):
    A. The member is known to have two null mutations in trans
    B. PHE levels must be attached documenting the member was unable to achieve a PHE level less than 600 µmoles/liter (10 mg/dL) despite a 2-month trial of 20 mg/kg dose of sapropterin with good compliance, as evidenced by paid claims or pharmacy printouts.
  - Sephience Only: One of the following must apply:
    - The member's weight must be provided and must be less than 16 kg.
    - PHE levels must be attached documenting the member was unable to achieve a PHE level less than 600 µmoles/liter (10 mg/dL) or less than 360 µmoles/liter (6 mg/dL) if childbearing potential or child ≤ 12 years old, despite a 4-month trial of 60 mg per day of Palynziq with good compliance, as evidenced by paid claims or pharmacy printouts.
  - Palynziq Only: Requested initial dose must be 20 mg
    - 40 mg: PHE levels must be attached documenting the member was unable to achieve a PHE level less than 600 µmoles/liter (10 mg/dL) or less than 360 µmoles/liter (6 mg/dL) if childbearing potential or child ≤ 12 years old, despite a 6-month trial of 20 mg per day of Palynziq with good compliance, as evidenced by paid claims or pharmacy printouts.
    - 60 mg: PHE levels must be attached documenting the member was unable to achieve a PHE level less than 600 µmoles/liter (10 mg/dL) or less than 360 µmoles/liter (6 mg/dL) if childbearing potential or child ≤ 12 years old, despite a 4-month trial of 40 mg per day of Palynziq with good compliance, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- For same or reduced dose from previous trial:
  Approval Duration: 12 months – if dose is the same or less than previous trial
  - PHE level must be between 60 and 600 µmoles per liter
  - Sapropterin Only: The member's weight must be provided.

- <u>For a dose increase from previous trial</u>
  Approval Duration: 4 months – for a dose increase from previous trial
  - PHE level must be attached that were taken after previous trial (1 month for Kuvan, 4 months for Palynziq/Sephience)
    - For members of childbearing potential or children ≤ 12 years old: PHE levels must be above 360 µmoles/liter (6mg/dL)
    - For members without childbearing potential, or children > 12 years old: PHE levels must be above 600 µmoles/liter 10mg/dL)
  - Sapropterin Only: The member's weight must be provided.

Pompe Disease

PREFFERED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LUMIZYME (alglucosidase alpha) – *Medical Billing*	OPFOLDA (miglustat) *does not require PA
NEXVIAZYME (avalglucosidase alfa-ngpt) – *Medical Billing*	POMBILITI (cipaglucosidase alfa-atga) – *Medical Billing*

Prior Authorization Criteria

<u>Initial Criteria – Approval Duration:</u> 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency of acid alpha-glucosidase enzyme activity in blood-based assay or fibroblasts
    - 2% to 40% of the lab specific normal mean value partial deficiency of GAA (associated with non-classic infantile forms or late onset forms)
    - ≤ 1 % of the lab specific normal mean value partial deficiency of GAA (associated with infantile forms)
  - Detection of two pathogenic variants in the GAA gene by molecular genetic testing.
- The requested medication must be prescribed by, or in consult with, a cardiologist, neurologist or geneticist or specialist in Pompe disease.
- The member must not have ventilation support for > 6 hours/day while awake

Infantile Onset

- The member must be less than 12 months old
- The member must have cardiomyopathy

Late Onset

- The member has measurable signs of Pompe disease, such as impairment in pulmonary function or motor weakness
- Ages 5 years and older: The member's current motor function must be submitted, as evidenced by scores from at least two of the following assessments:
  a. 6-minute walk test (6MWT) ≥ 40 meters
  b. Forced Vital Capacity (FVC) via Pulmonary Function Test ≥ 30% of the predicted value for healthy adults
- Ages under 5 years The member's current motor function must be submitted, as evidenced by scores from at least two of the following assessments:
  A. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND)

B. Hammersmith Infant Neurological Examination (HINE) Section 2 motor milestone score
C. Hammersmith Functional Motor Scale Expanded (HFMSE)
D. Motor Function Measure – 32 items (MFM-32)
E. Revised Upper Limb Module (RULM)
F. 6-minute walk test (6MWT)

- Pombiliti Only:
  - The member must have failed a 6-month trial of Lumizyme and/or Nexviazyme, as evidenced by paid claims or pharmacy printouts.
  - Opfolda and Pombiliti must be taken concurrently

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by stabilization or improvement of the following (subject to clinical review):
  - Ages 5 years and older:
    - 6MWT and/or FVC
  - Ages under 5 years:
    - CHOP-INTEND, HINE, HFMSE, MFM-32, RULM or 6MWT scores

Urea Cycle Agents

Hyperammonemia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BUPHENYL (sodium phenylbutyrate) – *Brand Required*	sodium phenylbutyrate
PREFERRED AGENTS (PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
PHEBURANE (sodium phenylbutyrate)	glycerol phenylbutyrate
this space intentionally left blank	OLPRUVA (sodium phenylbutyrate)
this space intentionally left blank	RAVICTI (glycerol phenylbutyrate) – *Brand Required*

N-acetylglutamate synthase (NAGS) deficiency

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CARBAGLU (carglumic acid) – *Brand Required*	carglumic acid

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Medications that cost over $3000/month criteria.

Non-Preferred Agents Criteria:

- *Ravicti Only:* One of the following apply:
  - The member is unable to tolerate sodium phenylbutyrate due to sodium content or GI distress.
  - The member has failed a 30-day trial of Pheburane
- All other agents: See Preferred Dosage Form criteria.

Therapeutic Duplication

- One strength of one medication is allowed at a time.

Hematology/Oncology

Anemia

Disease-Modifying Agents

Pyruvate Kinase Activator

PA REQUIRED
AQVESME (mitapivat)

Initial Criteria – Approval Duration: 6 months
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have a documented diagnosis of thalassemia (β-thalassemia with or without α-globin gene mutations, hemoglobin E (HbE)/β-thalassemia, or α-thalassemia/hemoglobin H (HbH) disease) based on Hb electrophoresis, Hb high-performance liquid chromatography (HPLC), and/or deoxyribonucleic acid (DNA) analysis
- The requested medication must be prescribed by, or in consult with, a hematologist or oncologist, or prescriber specializing in the treatment of thalassemia
- The member must not have a diagnosis of cirrhosis (Child Pugh Class A, B, or C)
- The member must meet one of the following:
  - The member has transfusion-dependent thalassemia, defined as 6 to 20 red blood cell (RBC) units transfused over a 24-week period
  - The member has non-transfusion-dependent thalassemia, defined as ≤ 5 red blood cell units over a 24-week period and an average baseline Hb concentration ≤10.0 g/dL

Renewal Criteria – Approval Duration: 12 months
- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication including:
  - For transfusion-dependent thalassemia, a reduction in transfusion requirements from pretreatment baseline achieving one of the following:
    - At least 2 units packed red blood cells in any consecutive 12 weeks
    - By one-half from baseline
  - For non-transfusion-dependent thalassemia, both of the following:

- An increase in average Hb level ≥ 1 g/dL
- An attestation of decreased fatigue-related symptoms from baseline

Telomerase Inhibitor

PA REQUIRED
RYTELO (imetelstat) – *Medical Billing*

Initial Criteria – Approval Duration: 6 months
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or oncologist, or prescriber specializing in the treatment of beta thalassemia or myelodysplastic syndrome/myeloproliferative neoplasm.
- The member must not have deletion 5q cytogenetic abnormality
- The member meets the guidelines for low- to intermediate-1 risk myelodysplastic syndrome, defined as an IPSS-R score ≤ 3.5 points *without TP53* mutation
- The member has transfusion-dependent anemia, defined as requiring transfusion of ≥ 4 red blood cell units over an 8-week period despite a 3-month trial with an erythropoiesis-stimulating agent (ESA), as evidenced by claims history or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months
- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication including:
  - Reduction in transfusion requirements from pretreatment baseline achieving one of the following:
    - At least 2 units packed red blood cells
    - By one-half from baseline
    - Complete transfusion independence

TGF-Beta Signaling Modulator

PREFERRED AGENTS (PA REQUIRED)
REBLOZYL (luspatercept) – *Medical Billing*

Initial Criteria – Approval Duration: 6 months
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or oncologist, or prescriber specializing in the treatment of beta thalassemia or myelodysplastic syndrome/myeloproliferative neoplasm.
- The member must not have deletion 5q cytogenetic abnormality
- Other causes of anemia (e.g., hemolysis, bleeding, recent major surgery, vitamin deficiency, etc.) have been ruled out.

For anemia due to myelodysplastic syndrome/myeloproliferative neoplasm:
- The member must require 2 or more RBC units over an 8-week period in the past 3 months

- The member has ring sideroblasts ≥ 5% or a mutated SF3B1 gene
- The member meets the guidelines for low- to intermediate-1 risk myelodysplastic syndrome, defined as an IPSS-R score ≤ 3.5 points *without TP53* mutation
- The member must meet one of the following:
  - Serum erythropoietin greater than 200 mU/mL
  - Serum erythropoietin less than or equal to 200 mU/mL with an inadequate response to ESA (defined as hemoglobin of less than 11 g/dL or continued need for transfusions) despite a 3-month trial with an erythropoiesis-stimulating agent (ESA), as evidenced by claims history or pharmacy printouts.

For anemia due to beta thalassemia:

- The member must not be a recipient of a previous allogeneic transplant or gene therapy
- The member has required at least 6 red blood cell (RBC) transfusions in the previous 24 weeks.
- The member has not had a transfusion-free period for ≥ 35 days during the most recent 24 weeks.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication including:
  - Reduction in transfusion requirements from pretreatment baseline achieving one of the following:
    - At least 2 units packed red blood cells
    - By one-half
    - Complete transfusions independence
- Dose will be increased to 1.25 mg/kg daily if renewal criteria has not been met.

Cell-based Gene Therapy

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CASGEVY (exagamglogene autotemcel) – *Medical Billing*	ZYNTEGLO (betibeglogene autotemcel) – *Medical Billing*

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or prescriber specializing in the treatment of beta thalassemia
- For members older than 35 years old, clinical justification must be provided (including ability to provide minimum cells required for manufacturing), subject to clinical review.
- Diagnosis should be confirmed with a non-ß0/ß0 or ß0/ß0 genotype via genetic testing
- The member must have a transfusion-dependent beta thalassemia requiring one of the following:
  - At least 100 mL/kg/year of packed red blood cells (pRBCs) in the preceding 2 years
  - At least 8 transfusions of pRBCs per year in the preceding 2 years
- Other causes of anemia (e.g., hemolysis, bleeding, recent major surgery, vitamin deficiency, etc.) have been ruled out.
- The member must not be a recipient of a previous allogeneic transplant or gene therapy
- The member must not have a matched allogeneic transplant donor.
- Member must not have any of the following:

- Severely elevated iron in the heart as evidenced by any of the following:
  - Cardiac T2* < 10 msec by MRI
  - LVEF < 45%
- Advanced liver disease as evidenced by any of the following:
  - AST or ALT > 3 times the upper limit of normal
  - Direct bilirubin value > 2.5 times the upper limit of normal
  - Liver iron content ≥ 15 mg/g (per MRI) with liver biopsy, VCTE, ELF, or MRE demonstrating bridging fibrosis or cirrhosis

Zynteglo Only:

- The member must not have received and must not be a candidate for Casgevy (subject to clinical review)

Chelating Agents

Iron Chelators

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
deferasirox tablet for suspension	EXJADE (deferasirox tablet for suspension)
deferasirox tablet	deferasirox sprinkle
deferoxamine mesylate vial – *Medical Billing*	DESFERAL (deferoxamine) MESYLATE VIAL – *Medical Billing*
this space intentionally left blank	FERRIPROX (deferiprone)
this space intentionally left blank	JADENU (deferasirox) SPRINKLE
this space intentionally left blank	JADENU (deferasirox) TABLET

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a trial duration of 30 days (or less if duration is FDA approved) of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

Cold Agglutin Disease (CAD)

Anti-B-cell Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rituximab - See Biosimilar Agents	this space intentionally left blank

Anti-Complement Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	ENJAYMO (sutimlimab-jome) – *Medical Billing*

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a hematologist or specialist in cold agglutinin disease (CAD)
- The member must have all of the following:
  - Evidence of chronic hemolysis (e.g., high lactated dehydrogenase [LDH], low haptoglobin, high reticulocyte count)
  - Direct antiglobin (Coombs) test is positive for C3d
  - Cold agglutinin titer ≥ 64 at 4°C
- Cold agglutinin syndrome secondary to other factors has been ruled out (e.g., infection, rheumatologic disease, systemic lupus erythematosus, or overt hematologic malignancy)
- The member has a baseline hemoglobin level ≤ 10 g/dL
- The member has a baseline bilirubin level above normal reference range of the reporting laboratory
- The member has one or more of the following symptoms:
  - Symptomatic anemia
  - Acrocyanosis
  - Raynaud's phenomenon
  - Hemoglobinuria
  - Disabling circulatory symptoms
  - Major adverse vascular event
- The member must have been unresponsive to previous rituximab-based therapy or one of the following must be documented:
  - The member has a medical reason why rituximab-based therapy is not appropriate or is contraindicated.
  - The member has severe anemia or acute exacerbations of hemolysis and needs a bridge therapy awaiting the effects of a rituximab-based therapy.

Renewal Criteria – Approval Duration: 12 months

- The member must have had a therapeutic response to therapy from baseline as shown by one or more of the following:
  - Decrease in transfusions from baseline
  - Increase in hemoglobin (Hgb) by ≥ 2 g/dL from baseline or Hgb level ≥ 12 g/dL
  - Normalization of bilirubin levels to less than 1.2 mg/dL
- Therapy continues to be necessary due to ongoing cold agglutinin production and inability to use rituximab.

Chronic Graft vs Host Disease (cGvHD)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
JAKAFI (ruxolitinib)	REZUROCK (belumosudil)
JAKAFI XR (ruxolitinib ER)	NIKTIMVO (axatilimab-csfr) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, an oncologist, or other specialist involved in the organ care for cGvHD
- The member must have life expectancy > 6 months
- The member must have failed a 3-month trial of Jakafi WITH concurrent corticosteroids or corticosteroid taper following NCCN treatment guidelines
- Request must include all affected organs or sites of involvement and current scoring per Chronic GVHD: Grading in the NCCN guidelines

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced improvement in at least 1 organ or site without progression in any other organ or site as evidenced by current scoring per Chronic GVHD: Grading in the NCCN guidelines

Hemophagocytic Lymphohistiocytosis (HLH)

PREFERRED AGENTS (PA REQUIRED)
GAMIFANT (emapalumab-lzsg) – *Medical Billing*

Initial Criteria – Approval Duration: 3 months or up to the hematopoietic stem cell transplantation (HSCT) date

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist, oncologist, immunologist, or transplant specialist.
- The member has refractory, recurrent or progressive disease or intolerance with conventional HLH therapy (i.e., etoposide + dexamethasone, cyclosporine A, or Anti-thymocyte globulin)
- The member must be a candidate for stem cell transplant.
- Confirmation of the diagnosis must be submitted, as evidenced by the following:
  - Confirmation of a gene mutation known to cause primary HLH (e.g., PRF1, UNC13D, STX11 RAB27A, STXBP2)
  - Confirmation of 5 of the following clinical characteristics:
    - Fever ≥ 101.3F for over 7 days
    - Splenomegaly
    - Two of the following cytopenias in the peripheral blood:
      - Hemoglobin < 9 g/dL (or < 10 g/dL in infants less than 4 weeks of age)
      - Platelet count < 100,000/microL
      - ANC <1000/microL
    - One of the following:
      - Hypertriglyceridemia defined as fasting triglycerides ≥ 265 mg/dL (2 mmol/L)
      - Hypofibrinogenemia defined as fibrinogen ≤ 1.5 g/L

    - Hemophagocytosis in bone marrow or spleen or lymph nodes with no evidence of malignancy
    - Low or absent natural killer cell activity
    - Ferritin ≥ 500 mg/L
    - Soluble CD25 (i.e., soluble IL-2 receptor) ≥ 2,400 U/mL
- The requested medication must be administered with dexamethasone as part of the induction or maintenance phase of stem cell transplant, which is to be discontinued at the initiation of conditioning for stem cell transplant.

Renewal Criteria – Approval Duration: 3 months or up to the HSCT date

- At least 3 HLH abnormalities must be improved by at least 50% from baseline.

Hemophilia

Clotting Factor Products

Hemophilia A

Factor VIII – Non-Extended Half Life

Plasma Derived

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPHANATE (antihemophilic factor/Von Willebrand Factor Complex (Human))	HEMOFIL M (factor VIII plasma derived; mAb-purified)
this space intentionally left blank	HUMATE-P (factor VIII/von Willebrand Factor (human))
this space intentionally left blank	KOATE (factor VIII plasma derived, chromatography purified)
this space intentionally left blank	WILATE (factor VIII/von Willebrand Factor (human))

First Generation – Recombinant

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	RECOMBINATE (factor VIII recombinant)

Second Generation – Recombinant

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	KOGENATE FS (factor VIII recombinant)

Third Generation – Recombinant

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NOVOEIGHT (factor VIII recombinant)	ADVATE (factor VIII recombinant)
KOVALTRY (factor VIII recombinant)	this space intentionally left blank
XYNTHA (factor VIII recombinant)	this space intentionally left blank
XYNTHA SOLOFUSE (factor VIII recombinant)	this space intentionally left blank

Fourth Generation – Recombinant

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AFSTYLA (factor VIII recombinant, single chain)	this space intentionally left blank
NUWIQ (factor VIII recombinant)	this space intentionally left blank

Factor VIII Extended Half Life

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ADYNOVATE (factor VIII recombinant, PEGylated)	ELOCTATE (factor VIII recombinant, Fc fusion protein)
ALTUVIIIO (antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl)	ESPEROCT (factor VIII recombinant, glycoPEGylated – exei)
JIVI (factor VIII recombinant, pegylated-aucl)	this space intentionally left blank

Recombinant humanized bispecific monoclonal antibody

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HEMLIBRA (emicizumab-kxwh)	this space intentionally left blank

Procoagulant (TFPI inhibitors/Antithrombin inhibitors)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HYMPAVZI (marstacimab-hncq)	ALHEMO (concizumab-mtci)
this space intentionally left blank	QFITLIA (fitusiran)

Factor VII deficiency or Hemophilia A and B with Inhibitors

Factor VIIa

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NOVOSEVEN RT (coagulation Factor VIIa recombinant)	this space intentionally left blank
SEVENFACT (coagulation Factor VIIa recombinant)	this space intentionally left blank

B domain-deleted porcine – Recombinant

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OBIZUR (recombinant, B domain-deleted porcine (pig) factor VIII)	this space intentionally left blank

Hemophilia B

Factor IX – Non-Extended Half Life

Plasma Derived

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPHANINE SD (factor IX, plasma-derived)	this space intentionally left blank
MONONINE (factor IX, plasma-derived mAb purified)	this space intentionally left blank

Recombinant

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

BENEFIX (factor IX recombinant)	IXINITY (factor IX recombinant)
this space intentionally left blank	RIXUBIS (factor IX recombinant)

Factor IX – Extended Half Life

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPROLIX (factor IX recombinant, Fc fusion)	IDELVION (factor IX recombinant, albumin fusion)
REBINYN (factor IX recombinant, glycol-PEGylated)	this space intentionally left blank

Procoagulant (TFPI inhibitors/Antithrombin inhibitors)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HYMPAVZI (marstacimab-hncq)	ALHEMO (concizumab-mtci)
this space intentionally left blank	QFITLIA (fitusiran)

Prothrombin Complex Concentrates

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FEIBA NF (Anti-Inhibitor coagulant complex)	KCENTRA (hum prothrombin cplx(PCC)4fact)
PROFILNINE (factor IX cplx(pcc)no4,3factor)	this space intentionally left blank

Von Willebrand disease

Factor VIII/vWF

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPHANATE (antihemophilic factor/Von Willebrand Factor Complex (Human))	HUMATE-P (factor VIII/von Willebrand Factor (human))
this space intentionally left blank	WILATE (factor VIII/von Willebrand Factor (human))

Von Willebrand Factor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VONVENDI (recombinant human vWF)	this space intentionally left blank

Factor X Deficiency

Factor X – Plasma Derived

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COAGADEX (coagulation factor X (human))	this space intentionally left blank

Factor XIII Deficiency

Factor XIII – Plasma Derived

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CORIFACT (factor XIII concentrate (human))	this space intentionally left blank

Factor XIII A – Subunit, Recombinant

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRETTEN (Factor XIII A-Subunit, recombinant)	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The date of the member's last appointment with a Hemophilia Treatment Center must be within the past year.
- The contact information for Hemophilia Treatment Center must be provided.

Non-Preferred Agents Criteria:

- Clinical justification must be provided explaining why the member is unable to use a preferred agent (subject to clinical review).
- The member may qualify for non-preferred product if they are stable on current therapy (have had a paid claim for requested therapy in the past 45 days)
- *Alhemo and Qfitlia only*:
  - The member must have one of the following:
    - A diagnosis of Hemophilia A with inhibitors AND has failed a 6-month trial with Hemlibra
    - A diagnosis of Hemophilia A without inhibitors AND has failed a 6-month trial with Hemlibra and Hympavzi
    - A diagnosis of Hemophilia B with inhibitors
    - A diagnosis of Hemophilia B without inhibitors AND has failed a 6-month trial with Hympavzi
- *Hympavzi only*:
  - The member must have one of the following:
    - A diagnosis of Hemophilia A without inhibitors AND has failed a 6-month trial with Hemlibra
    - A diagnosis of Hemophilia B without inhibitors
- *Obizur only*:
  - The member must have anti-porcine Factor VIII inhibitors noted by prescriber attestation

Gene Therapy

PA REQUIRED
HEMGENIX (etranacogene dezaparvovec) – *Medical Benefit Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The Medicaid Member must meet FDA-approved label for use
- The member has completed Factor IX inhibitor testing demonstrating the absence of a Factor IX inhibitor
- The member has completed liver health assessment including all of the following:
  - Enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin

- Hepatic ultrasound and elastography
- In case of patients with either radiological liver abnormalities or sustained liver enzyme elevations, a consulting hepatologist has assessed that the member is eligible to receive the gene therapy

Hematopoietic, Colony Stimulating Factors

Filgrastim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
filgrastim – See Biosimilar Agents	this space intentionally left blank

Pegfilgrastim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pegfilgrastim – See Biosimilar Agents	this space intentionally left blank

Sargramostim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LEUKINE (sargramostim)	this space intentionally left blank
LEUKINE (sargramostim) – *Medical Billing*	this space intentionally left blank

Efbemalenograstim alfa-vuxw

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	RYZNEUTA (efbemalenograstim alfa-vuxw) – *Medical Billing*

Eflapegrastim-xnst

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	ROLVEDON (eflapegrastim-xnst)
this space intentionally left blank	ROLVEDON (eflapegrastim-xnst) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Preferred Dosage Form criteria.

Nausea/Vomiting

Chemo-Induced

NK1 Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
aprepitant tripack	AKYNZEO (netupitant/palonosetron) CAPSULE
EMEND (aprepitant) SUSPENSION	aprepitant capsules
this space intentionally left blank	EMEND (aprepitant) 125 MG-80 MG CAPSULE TRIPACK
this space intentionally left blank	EMEND (aprepitant) CAPSULES

5-HT3 Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
granisetron tablet	AKYNZEO (netupitant/palonosetron) CAPSULE
granisetron vial – *Medical Billing*	SANCUSO (granisetron) PATCH
ondansetron	ZOFRAN (ondansetron)
SUSTOL (granisetron) SYRINGE – *Medical Billing*	this space intentionally left blank

Cannabinoids

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dronabinol capsule	MARINOL (dronabinol) CAPSULE

Electronic Diagnosis Verification

- Dronabinol Only: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months or until last day of chemotherapy

- The requested medication must be prescribed by, or in consult with, an oncologist.
- The member must be receiving a moderately or highly emetogenic chemotherapy.
- The final date of chemotherapy treatment must be provided with the request.
- The member must have failed a 3-day trial of each preferred product(s) in the same class within the last 6 months, as evidenced by paid claims or pharmacy printouts.
- The member must not have failed preferred chemical entity with same active ingredient as requested product due to side effects.

Paroxysmal Nocturnal Hemoglobinuria (PNH)

C5 inhibitors

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ULTOMIRIS (ravulizumab)	eculizumab - See Biosimilar Agents
ULTOMIRIS (ravulizumab) – *Medical Billing*	PIASKY (crovalimab-akkz) – *Medical Billing*

C3 Inhibitors

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EMPAVELI (pegcetacoplan)	

Factor B Inhibitors

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	FABHALTA (iptacopan)

Factor D Inhibitors

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	VOYDEYA (danicopan)

Prior Authorization Criteria

Prior Authorization Form – Paroxysmal Nocturnal Hemoglobinuria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a hematologist.
- Diagnosis must be confirmed by flow cytometry demonstrating that the member's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) – linked proteins (e.g., CD55, CD59)
- One of the following criteria must be met (A or B):
  - The member has had at least 1 transfusion in the past 6 months
  - The member has symptoms of PNH (e.g., abdominal pain, anemia, shortness of breath, hemolysis, organ dysfunction, debilitating fatigue) and one of the following:
    - granulocyte PNH clone size > 10%
    - hemoglobin < 10 g/dL
    - LDH level of 1.5 times the upper limit of normal (must include at least 2 different reagents tested on at least 2 cell lineages)

Non-Preferred Agent Criteria:

Fabhalta Only:

- The member must have failed a 6-month trial with Empaveli, as evidenced by paid claims or printouts, with one of the following criteria being met (A or B):
  - The member has had at least 1 transfusion in the past 6 months
  - The member has symptoms of PNH (e.g., abdominal pain, anemia, shortness of breath, hemolysis, organ dysfunction, debilitating fatigue) and one of the following:
    - granulocyte PNH clone size > 10%
    - hemoglobin < 10 g/dL
    - LDH level of 1.5 times the upper limit of normal (must include at least 2 different reagents tested on at least 2 cell lineages)

Voydeya Only:
- The member must have failed a 6-month trial with Ultomiris, with at least one transfusion, persistent anemia (Hb < 9.5 g/dL) and absolute reticulocyte count ≥ 120 × 109 /L, as evidenced by paid claims or printouts.

Piasky and Eculizumab Only:
- The member must have failed a 6-month trial with Ultomiris with Voydeya, as evidenced by paid claims or printouts, with at least one transfusion, persistent anemia (Hb < 9.5 g/dL) and absolute reticulocyte count ≥ 120 × 109 /L, as evidenced by paid claims or printouts.

Renewal Criteria – Approval Duration: 12 months
- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by one of the following:
  - Member has not required transfusion in the past 6 months
  - Increase in hemoglobin by ≥ 2 g/dL from baseline
  - Normal LDH levels ≤ 280 U/L

Fabhalta Only:

- The member must have experienced one of the clinical benefit metrics defined in the renewal criteria that was not met with Empaveli.

Voydeya Only:

- The member must have experienced one of the clinical benefit metrics defined in the renewal criteria that was not met with Ultomiris.

Piasky and Eculizumab Only:

- The member must have experienced one of the clinical benefit metrics defined in the renewal criteria that was not met Ultomiris with Voydeya

References:

1. Parker, Charles J. “Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria.” Hematology 2014, the American Society of Hematology Education Program Book 2016.1 (2016): 208-216.

Plasminogen Deficiency Type 1 (Hypoplasminogenemia)

PA REQUIRED
RYPLAZIM (plasminogen, human-tvmh) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or specialist in treated condition
- Confirmation of the diagnosis must be submitted, as evidenced by the following:
  - Baseline plasminogen activity level ≤ 45% *(If the patient is receiving plasminogen supplementation with fresh frozen plasma, allow for a 7-day washout period before obtaining baseline plasminogen activity level.)*
  - Documented history of lesions (e.g., ligneous conjunctivitis, ligneous gingivitis, occlusive hydrocephalus, abnormal wound healing)
  - Genetic testing to confirm biallelic pathogenic *PLG* mutation

Renewal Criteria – Approval Duration: 12 months, a one-time 6-month approval for dose adjustment allowed for members not meeting renewal criteria upon request

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, subject to clinical review, including the following:
  - The member has demonstrated a 50% resolution of lesions, with no active or recurrent lesions.
  - Trough plasminogen activity levels are >10% above baseline.

Sickle Cell Disease

Disease-Modifying Agents

First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydroxyurea capsule	SIKLOS (hydroxyurea) tablet

Second Line Agents

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENDARI (glutamine) – *Brand Required*	+ADAKVEO (crizanlizumab-tmca) – *Medical Billing*
this space intentionally left blank	L-glutamine

+ Based on results of the STAND clinical trial, the efficacy of Adakveo in the prevention of vaso-occlusive crisis (VOC) is unclear.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a hematologist, oncologist, or immunology specialist.

- The member has experienced at least one sickle cell-related VOC within past 12 months while adherent with hydroxyurea (documentation required) at the maximum (35 mg/kg/day) or maximally tolerated dose (mild myelosuppression is expected), as evidenced by paid claims or pharmacy printouts.
- Adakveo Only:
  - The member must have had a 30-day trial of Endari, as evidenced by paid claims or pharmacy printouts.
- Siklos Only:
  - Baseline hemoglobin (Hb) ≤ 10.5 g/dL
  - See Preferred Dosage Form Criteria

Renewal Criteria – Approval Duration: 12 months

- Adakveo Only:
  - The member must have experienced and/or maintained clinical benefit since starting treatment with the requested product, subject to clinical review, by the reduction in sickle cell-related VOCs
- All Other Products:
  - The member must have experienced and/or maintained clinical benefit since starting treatment with the requested product, subject to clinical review, by one of the following:
    - Increase in hemoglobin (Hb) by ≥ 1 g/dL from baseline
    - Decrease in indirect bilirubin from baseline
    - Decrease in percent reticulocyte count from baseline
    - Reduction in sickle cell-related vaso-occlusive crisis

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XROMI (hydroxyurea)	this space intentionally left blank

Cell-based Gene Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CASGEVY (exagamglogene autotemcel) *– Medical Billing*	LYFGENIA (lovotibeglogene autotemcel) *– Medical Billing*

Initial Criteria – Approval Duration: 12 months

- The member is ≥ 12 and ≤ 50 years of age
- The member has a diagnosis of sickle cell disease (SCD), with either βS/βS or βS/β0 or βS/β+ genotype
- The member has experienced at least four (4) sickle cell-related VOCs or priapism within past 24 months that required pain medications or RBC transfusion at a medical facility while on hydroxyurea at the maximum (35 mg/kg/day) or maximally tolerated dose (mild myelosuppression is expected), as evidenced by paid claims or pharmacy printouts.

- The member does not have human immunodeficiency virus type 1 or 2 (HIV-1 and HIV-2), hepatitis B virus (HBV), or hepatitis C (HCV)
- The member does not have inadequate bone marrow function, as defined by an absolute neutrophil count of < 1000/µL (< 500/µL for members on hydroxyurea treatment) or a platelet count < 100,000/µL
- The member must not be a recipient of a previous allogeneic transplant or gene therapy
- The member must not have a matched allogeneic transplant donor.

Lyfgenia Only:

- The member must not have more than two α-globin gene deletions (−α3.7/−α3.7)
- The member must not have received and must not be a candidate for Casgevy (subject to clinical review)

Thrombocytopenia

Immune Thrombocytopenic Purpura (ITP)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
eltrombopag powder pack	ALVAIZ (eltrombopag choline)
NPLATE (romiplostim)	DOPTELET (avatrombopag)
PROMACTA (eltrombopag) – *Brand Required*	DOPTELET (avatrombopag) SPRINKLE CAP
this space intentionally left blank	eltrombopag
this space intentionally left blank	PROMACTA (eltrombopag) POWDER PACK
this space intentionally left blank	TAVALISSE (fostamatinib)
this space intentionally left blank	WAYRILZ (rilzabrutinib)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 4 months

- The member has diagnosis of immune thrombocytopenic purpura (ITP) lasting >3 months.
- The member has a platelet count of less than 30 x 10^9/L
- The member must have experienced an inadequate response after one of the following (A, B or C):
  A. The member must have failed a trial of appropriate duration of a corticosteroid or immunoglobulins, as evidenced by paid claims or pharmacy printouts.
  B. Rituximab
  C. The member must have undergone a splenectomy.

Non-Preferred Agents Criteria:

- The member must have failed trials with eltrombopag (at the recommended dose and duration) with each preferred agent, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- The member has a platelet count greater than or equal to 50 x 10^9/L

References:

1. Neunert, Cindy, et al. “American Society of Hematology 2019 guidelines for immune thrombocytopenia.” *Blood advances* 3.23 (2019): 3829-3866.

Chronic Liver Disease-Associated Thrombocytopenia

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DOPTELET (avatrombopag)	MULPLETA (lusutrombopag)
this space intentionally left blank	DOPTELET (avatrombopag) SPRINKLE CAP

Prior Authorization Criteria

Initial Criteria – Approval Duration: The 2 weeks prior to procedure

- The member must have platelet count of less than 50 x 10^9/L
- The member must be scheduled to undergo a procedure that puts the member at risk of bleeding
- The scheduled date of procedure, and date therapy will be initiated and discontinued has been submitted:
  - Doptelet: Member must undergo procedure 5-8 days after last dose.
  - Mulpleta: Member must undergo procedure 2-8 days after last dose.

Non-Preferred Agents Criteria:

- The member must have failed trials with the preferred agent (at the recommended dose and duration) with each preferred agent, as evidenced by paid claims or pharmacy printouts.

Chronic Hepatitis C Infection-Associated Thrombocytopenia

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
eltrombopag powder pack	ALVAIZ (eltrombopag choline)
PROMACTA (eltrombopag) – *Brand Required*	eltrombopag
this space intentionally left blank	PROMACTA (eltrombopag) POWDER PACK

Prior Authorization Criteria

Initial Criteria – Approval Duration: 4 months

- The member is unable to receive direct acting antivirals for hepatitis C.
- The member’s degree of thrombocytopenia must prevent initiation or continuation of interferon-based therapy.

Renewal Criteria – Approval Duration: 12 months

- The member has a platelet count greater than or equal to 50 x 10^9/L
- The member is currently receiving interferon-based therapy.

Aplastic Anemia

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
eltrombopag powder pack	ALVAIZ (eltrombopag choline)
PROMACTA (eltrombopag) – *Brand Required*	eltrombopag

this space intentionally left blank	PROMACTA (eltrombopag) POWDER PACK

Prior Authorization Criteria

Initial Criteria – Approval Duration: 4 months
- The member must have platelet count of less than 30 x 10^9/L
- The member must have failed therapy or be receiving concurrent therapy with immunosuppressive therapy (e.g., corticosteroid, Atgam, cyclosporine)

Renewal Criteria – Approval Duration: 12 months
- The member has a platelet count greater than or equal to 50 x 10^9/L

Hepatology

Metabolic Dysfunction-Associated Steatohepatitis (MASH)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OZEMPIC (semaglutide) injection	liraglutide
VICTOZA (liraglutide) – *Brand Required*	REZDIFFRA (resmetirom)
this space intentionally left blank	WEGOVY (semaglutide) injection

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months
- The requested medication must be prescribed by, or in consult with, an endocrinologist, gastroenterologist or hepatologist.
- The member has moderate to severe fibrosis (F2 or F3) as determined by one of the following (1-5):
  1. Biopsy
  2. Liver Stiffness Measurement (e.g. VCTE; Fibroscan)
  3. Enhanced Liver Fibrosis (ELF)
  4. Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF).
  5. Magnetic resonance elastography (MRE)
- If the member has a history of alcohol use within the past 5 years, one of the following must be met:
  1. The member has a phosphatidylethanol (PEth) level < 20 ng/mL.
  2. The member has submitted two negative alcohol tests with the most recent alcohol test within the past 3 months.
- The member must not have a concomitant terminal diagnosis where life expectancy is less than 1 year.
- Rezdiffra Only:
  - If concurrent Type 2 DM diagnosis, the member has failed a 6-month trial of semaglutide combined with pioglitazone as evidenced by paid claims or pharmacy printouts
  - If no concurrent Type 2 DM diagnosis, the member has failed a 6-month trial of semaglutide as evidenced by paid claims or pharmacy printouts.
- Wegovy Only:

- If the member qualifies for Wegovy, a dose escalation to 2mg weekly of Ozempic injection (semaglutide) must be tolerated before Wegovy will be authorized.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced one of the following (1-3):
  1. Resolution of steatohepatitis AND no worsening of liver fibrosis
  2. Improvement of liver fibrosis greater than or equal to one stage AND no worsening of steatohepatitis
  3. Both resolution of steatohepatitis AND improvement in fibrosis.
- Fibrosis and steatosis are measured by one of the following (1-5):
  1. Biopsy
  2. Liver Stiffness Measurement (e.g. VCTE; Fibroscan)Enhanced Liver Fibrosis (ELF)
  3. Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF)
  4. Magnetic resonance elastography (MRE)

Primary Biliary Cholangitis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ursodiol tablets	IQIRVO (elafibranor)
this space intentionally left blank	LIVDELZI (seldelpar lysine)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in cons ult with, a hepatologist or a gastroenterologist
- The diagnosis must be confirmed by liver biopsy
- The member must not have a concomitant terminal diagnosis where life expectancy is less than 1 year.
- The member must not have a history of decompensated cirrhosis
- The member must have failed at least a 6-month trial of ursodiol, as evidenced by paid claims or pharmacy printouts, as evidenced by one of the following
  - ALP > 1.67 x Upper Limits of Normal (ULN) as defined by reporting laboratory
  - Bilirubin > ULN
- If the member has a history of alcohol use within the past 5 years, one of the following must be met (1, 2 or 3):
  1. The member has a carbohydrate-deficient transferrin (CDT) level < 3% within the past 3 months.
  2. The member has a phosphatidylethanol (PEth) level < 20 ng/mL.
  3. The member has submitted two negative alcohol tests with the most recent alcohol test within the past 3 months.

Renewal Criteria – Approval Duration: 12 months

- The member has experienced a therapeutic response as evidenced by one of the following (A or B):
  A. Both of the following (1 or 2):
     1. ALP < 1.67 x ULN OR > 15% decrease in ALP from baseline
     2. Total bilirubin is less than ULN
- The member is currently on Livdelzi and is receiving itch benefit and has had previous trials of cholestyramine, rifampin, and naltrexone that did not provide itch relief.

Infectious Disease

Anti-infectives – Resistance Prevention

Antifungals – Aspergillus and Candidiasis Infections

Solid Dosage Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clotrimazole	CRESEMBA (isavuconazonium)
clotrimazole troche	DIFLUCAN (fluconazole)
fluconazole	flucytosine
itraconazole	NOXAFIL (posaconazole)
nystatin	SPORANOX (itraconazole)
ORAVIG (miconazole)	VFEND (voriconazole)
posaconazole	this space intentionally left blank
terbinafine	this space intentionally left blank
voriconazole	this space intentionally left blank

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluconazole suspension	DIFLUCAN (fluconazole) SUSPENSION
itraconazole solution	NOXAFIL (posaconazole) POWDERMIX SUSPENSION
NOXAFIL (posaconazole) SUSPENSION	SPORANOX (itraconazole) SOLUTION
voriconazole suspension	TOLSURA (itraconazole) DISPERSE CAPSULE
this space intentionally left blank	VFEND (voriconazole) suspension
this space intentionally left blank	voriconazole 200 mg/20 mL suspension

Community-Acquired Pneumonia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amoxicillin	BAXDELA (delafloxacin)
amoxicillin-clavulanate	FACTIVE (gemifloxacin)
azithromycin	XENLETA (lefamulin)

cefpodoxime	this space intentionally left blank
cefuroxime	this space intentionally left blank
clarithromycin	this space intentionally left blank
doxycycline	this space intentionally left blank
levofloxacin	this space intentionally left blank
linezolid	this space intentionally left blank
moxifloxacin	this space intentionally left blank

Complicated Intra-abdominal Infections (cIAI)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	EMBLAVEO (aztreonam-avibactam) – *Medical Billing*

Cytomegalovirus infection

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
valganciclovir	LIVTENCITY (maribavir)

Methicillin-Resistant *Staphylococcus aureus* (MRSA):

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clindamycin	BAXDELA (delafloxacin)
doxycycline	NUZYRA (omadacycline)
linezolid	SIVEXTRO (tedizolid)
minocycline	this space intentionally left blank
trimethoprim-sulfamethoxazole	this space intentionally left blank

Helicobacter pylori

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lansoprazole/amoxicillin/clarithromycin	bismuth subcitrate potassium/metronidazole/tetracycline
PYLERA (bismuth subcitrate potassium/metronidazole/tetracycline) – *Brand Required*	OMECLAMOX-PAK (omeprazole/clarithromycin/amoxicillin)
this space intentionally left blank	TALICIA (omeprazole/amoxicillin/rifabutin)
this space intentionally left blank	VOQUEZNA DUAL PAK (vonoprazan/amoxicillin)
this space intentionally left blank	VOQUEZNA TRIPLE PAK (vonoprazan/amoxicillin/clarithromycin)

Tuberculosis

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ethambutol	isoniazid	cycloserine
PRIFTIN (rifapentine)	this space intentionally left blank	RIFADIN (rifampin)
pyrazinamide	this space intentionally left blank	SIRTURO (bedaquiline)
rifabutin	this space intentionally left blank	this space intentionally left blank

Uncomplicated Urogenital Gonorrhea

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	BLUJEPA (gepotidacin)

Urinary Tract Infection

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	BLUJEPA (gepotidacin)
this space intentionally left blank	CONTEPO (fosfomycin)
this space intentionally left blank	FETROJA (cefiderocol)
this space intentionally left blank	ORLYNVAH (sulopenem etzadroxil and probenecid)
this space intentionally left blank	PIVYA (pivmecillinam)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 5 days or as supported in compendia for indication

- The requested medication must be prescribed by, or in consult with, an infection disease specialist, an antibiotic/antifungal stewardship program, or protocol.
- Diagnosis must be proven to be caused by a susceptible microorganism by culture and susceptibility testing
  - For Voquezna Dual or Triple Pak – member must have a clarithromycin or amoxicillin resistant strain of *H. Pylori*)
- One of the following criteria must be met (A or B):
  A. The member is continuing treatment upon discharge from an acute care facility.
  B. Clinical justification must be provided explaining why the preferred antibiotics/antifungals are not an option due to susceptibility, previous failed trials, or other contraindications (subject to clinical review)

Tuberculosis Only:

- Isoniazid: The ND Division of Disease Control Tuberculosis Prevention and Control program provides isoniazid for no cost through the UND Center for Family Medicine Pharmacy. Please contact 701-328-2378 to obtain supply.

Renewal Criteria – Approval Duration: 5 days

- It is medically necessary to continue treatment course after re-evaluation of the member's condition.
- The total requested duration of use must not be greater than manufacturer labeling or treatment guideline recommendations (whichever is greater).

COVID-19

Antiviral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PAXLOVID (nirmatrelvir/ritonavir)	VEKLURY (remdesivir) – *Medical Billing*

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

Prior Authorization Criteria

- The member must be at risk for hospitalization due to COVID-19 following a 5-day course of Paxlovid during the same infection.

IL-6 Receptor antagonist

PREFERRED AGENTS (PA REQUIRED)
tocilizumab - See Biosimilar Agents

Prior Authorization Criteria

- This medication is not covered for outpatient use since it is indicated for inpatient use only

Human Immunodeficiency Virus (HIV)

Antiretrovirals – Pre-exposure Prophylaxis (PrEP)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APRETUDE (cabotegravir) – *Medical billing*	TRUVADA (emtricitabine/tenofovir disoproxil fumarate)
DESCOVY (emtricitabine/tenofovir alafenamide)	this space intentionally left blank
emtricitabine/tenofovir disoproxil fumarate	this space intentionally left blank
YEZTUGO TABLETS (lenacapavir)	this space intentionally left blank
YEZTUGO INJECTION (lenacapavir) – *Medical billing*	this space intentionally left blank

Antiretrovirals – Treatment

References:

Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf Accessed (October 9, 2020)

Integrase Strand Transfer Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BIKTARVY (bictegravir/emtricitabine/tenofovir)	JULUCA (dolutegravir/rilpivirine)
CABENUVA (cabotegravir/rilprivirine) – *Medical Billing*	this space intentionally left blank
DOVATO (dolutegravir/lamivudine)	this space intentionally left blank
GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	this space intentionally left blank
ISENTRESS (raltegravir)	this space intentionally left blank
STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	this space intentionally left blank
TIVICAY (dolutegravir)	this space intentionally left blank
TRIUMEQ (abacavir/dolutegravir/lamivudine)	this space intentionally left blank
TRIUMEQ PD (abacavir/dolutegravir/lamivudine)	this space intentionally left blank

Non-Nucleoside Reverse Transcriptase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COMPLERA (emtricitabine/rilpivirine/tenofovir) – Brand Required	ATRIPLA (efavirenz/emtricitabine/tenofovir)
efavirenz	EDURANT (rilpivirine)
efavirenz/emtricitabine/tenofovir	EDURANT PED (rilpivirine)
IDVYNSO (doravirine/islatravir)	efavirenz/lamivudine/tenofovir
ODEFSEY (emtricitabine/rilpivirine/tenofovir)	emtricitabine/rilpivirine/tenofovir
PIFELTRO (doravirine)	JULUCA (dolutegravir/rilpivirine)
SYMFI (efavirenz/lamivudine/tenofovir) – *Brand Required*	rilpivirine
SYMFI LO (efavirenz/lamivudine/tenofovir) – *Brand Required*	this space intentionally left blank
Not Recommended for First Line Use	
etravirine	INTELENCE (etravirine)
nevirapine	nevirapine ER

- Etravirine – Guidelines do not recommend for treatment-naïve members due to insufficient data. FDA indication is for treatment experienced members and so should be reserved for salvage therapy, pretreated members with NNRTI resistance and PI exposure or who have ongoing adverse effects with first line therapies.

- Nevirapine – Guidelines no longer recommend nevirapine for initial treatment of HIV infection in treatment-naïve members. In resource limited settings, it can be considered as a third agent. Nevirapine demonstrated inferiority relative to efavirenz and is associated with serious and fatal hepatic and rash events.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- See Preferred Dosage Form criteria

Nucleoside Reverse Transcriptase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
abacavir	ATRIPLA (efavirenz/emtricitabine/tenofovir)
abacavir/lamivudine	efavirenz/lamivudine/tenofovir
BIKTARVY (bictegravir/emtricitabine/tenofovir)	emtricitabine capsule
CIMDUO (lamivudine/tenofovir)	emtricitabine/rilpivirine/tenofovir
COMPLERA (emtricitabine/rilpivirine/tenofovir) – Brand Required	EMTRIVA (emtricitabine) CAPSULE
DELSTRIGO (doravirine/lamivudine/tenofovir)	EPIVIR (lamivudine)
DESCOVY (emtricitabine/tenofovir alafenamide)	lamivudine
efavirenz/emtricitabine/tenofovir	TRIZIVIR (abacavir/lamivudine)
emtricitabine solution	TRUVADA (emtricitabine/tenofovir disoproxil fumarate)
emtricitabine/tenofovir disoproxil fumarate	VIREAD (tenofovir)
GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	ZIAGEN (abacavir)
IDVYNSO (doravirine/islatravir)	this space intentionally left blank
ODEFSEY (emtricitabine/rilpivirine/tenofovir)	this space intentionally left blank
SYMFI (efavirenz/lamivudine/tenofovir) – *Brand Required*	this space intentionally left blank
SYMFI LO (efavirenz/lamivudine/tenofovir) – *Brand Required*	this space intentionally left blank
STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	this space intentionally left blank
SYMTUZA (darumavir/cobicistat/emtricitabine/tenofovir)	this space intentionally left blank
tenofovir	this space intentionally left blank
TEMIXYS (lamivudine/tenofovir)	this space intentionally left blank
TRIUMEQ (abacavir/dolutegravir/lamivudine)	this space intentionally left blank
TRIUMEQ PD (abacavir/dolutegravir/lamivudine)	this space intentionally left blank
Not Recommended for First Line Use	
abacavir/lamivudine/zidovudine	RETROVIR (zidovudine)
didanosine	TRIZIVIR (abacavir/lamivudine/zidovudine)
lamivudine/zidovudine	ZERIT (stavudine) CAPSULE
stavudine	zidovudine capsule and tablet
zidovudine syrup	this space intentionally left blank

- abacavir/lamivudine/zidovudine – Guidelines do not recommend ABC/3TC/ZDU (as either a triple-NRTI combination regimen or in combination with tenofovir (TDF) as a quadruple-NRTI combination regimen) due to inferior virologic efficacy.
- didanosine – Guidelines do not recommend ddI/3TC or ddI/FTC regimens due to inferior virologic efficacy, limited trial experience in ART-naïve members, and ddI toxicities (including pancreatitis and peripheral neuropathy). Ddi/TDF regimens are not recommended due to high rate of early virologic failure, rapid selection of resistance mutations, potential for immunologic nonresponse/CD4 cell decline, and increased ddI drug exposure and toxicities.
- lamivudine/zidovudine – Guidelines do not recommend ZDV/3TC due to greater toxicities than recommended NRTIs (including bone marrow suppression, GI toxicities, skeletal muscle myopathy, cardiomyopathy, and mitochondrial toxicities such as lipoatrophy, lactic acidosis and hepatic steatosis).
- stavudine – Guidelines do not recommend d4T/3TC due to significant toxicities (including lipoatrophy, peripheral neuropathy) and hyperlactatemia (including symptomatic and life-threatening lactic acidosis, hepatic steatosis, and pancreatitis)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- See Preferred Dosage Form criteria

Post-Attachment Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ROKOBIA (fostemsavir)	this space intentionally left blank
TROGARZO (Ibalizumab-uiyk)	this space intentionally left blank

Protease Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atazanavir	NORVIR (ritonavir)
darunavir	PREZISTA (darunavir)
EVOTAZ (atazanavir/cobicistat)	REYATAZ (atazanavir)
NORVIR (ritonavir) POWDER PACKET	this space intentionally left blank
PREZCOBIX (darunavir/cobicistat)	this space intentionally left blank
REYATAZ (atazanavir) POWDER PACK	this space intentionally left blank
ritonavir	this space intentionally left blank
SYMTUZA (darumavir/cobicistat/emtricitabine/tenofovir)	this space intentionally left blank
Not Recommended for First Line Use	
APTIVUS (tipranavir)	KALETRA (lopinavir/ritonavir)
fosamprenavir	this space intentionally left blank
INVIRASE (saquinavir)	this space intentionally left blank
lopinavir/ritonavir	this space intentionally left blank
VIRACEPT (nelfinavir)	this space intentionally left blank

- Fosamprenavir – Guidelines do not recommend use of unboosted FPV or FPV/r due to virologic failure with unboosted FPV-based regimens that may result in selection of mutations that confer

resistance to FPV and DRV. There is also less clinical trial data for FPV/r than other RTV-boosted Pis.

- Lopinavir/ritonavir – Guidelines do not recommend LPV/r due to GI intolerance, higher pill burden and higher RTV dose than other PI-based regimens
- Nelfinavir – Guidelines do not recommend use of NFV due to inferior virologic efficacy and diarrhea.
- Saqinavir – Guidelines do not recommend use of unboosted SQV due to inadequate bioavailability and inferior virologic efficacy or SQV/r due to high bill burden and QT and PR prolongation.
- Tipranavir – Guidelines do not recommend TPV/r due to inferior virologic efficacy, higher dose of RTV and higher rate of adverse events than other RTV-boosted Pis.

Capsid Function Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Not Recommended for First Line Use	
SUNLENCA (lenacapavir) INJECTION – *Medical Billing*	this space intentionally left blank
SUNLENCA (lenacapavir) TABLET	this space intentionally left blank

- lenacapavir – SUNLENCA, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (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.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Not Recommended for First Line Use	
FUZEON (enfuvirtide)	this space intentionally left blank
SELZENTRY (maraviroc)	this space intentionally left blank

- Enfuvirtide (Fusion Inhibitor)– Guidelines do not recommend T20 for initial therapy due to twice daily injections, high rate of injection site reactions, and it has only been studied in members with virologic failure
- Maraviroc (CCR5 Antagonist) – Guidelines do not recommend MVC for initial therapy due to twice daily dosing, no virologic benefit compared to recommended regimens, and required CCR5 tropism testing.

Diarrhea

Mytesi – See Diarrhea criteria

Wasting Cachexia

Serostim: See Growth Hormone criteria

Hepatitis C Antiviral Treatments

Direct Acting Antivirals

Solid Dosage Forms

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
sofosbuvir/velpatasvir	EPCLUSA (sofosbuvir/velpatasvir)
this space intentionally left blank	HARVONI (ledipasvir/sofosbuvir)
this space intentionally left blank	ledipasvir/sofosbuvir 90mg/400mg tablet
this space intentionally left blank	MAVYRET (glecaprevir/pibrentasvir)
this space intentionally left blank	SOVALDI (sofosbuvir)

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MAVYRET PELLET PACKET (glecaprevir/pibrentasvir)	EPCLUSA PALLET PACKET (sofosbuvir/velpatasvir)
this space intentionally left blank	HARVONI PALLET PACKET (ledipasvir/sofosbuvir)
this space intentionally left blank	SOVALDI PALLET PACKET (sofosbuvir)

Electronic Age Verification

- Mavyret Pellet Packet:
  - PA Not Required Criteria: The member is 9 years old or less.
  - PA Required Criteria: The member must meet Non-Solid Dosage Preparations criteria in addition to Hepatitis C criteria

Electronic Concurrent Medication Required

- Epclusa (and its generic): A total of 84 days of ribavirin must be billed within the previous 14 days of a sofosbuvir/velpatasvir claim if member has decompensated cirrhosis (Child Pugh B or C).

First Fill

- Epclusa (and its generic) and Vosevi: The entire treatment course must be dispensed at the initial fill.
  - Please call pharmacy provider relations (1-701-328-4086) if a member has already partially completed their treatment course and needs less than a full course of therapy for their current fill.

Prior Authorization Criteria

Prior Authorization Form – Hepatitis C

Initial Criteria – Approval Duration: Based on label recommendations

- The member must have life expectancy greater than 12 months.
- One of the following must be met (1-4):
  1. The member has no history of alcohol use disorder or IV illicit drug use.
  2. The member has maintained sobriety for the past 12 months.
  3. The member has completed or be currently enrolled in a treatment program within the past 12 months.
  4. The Disease Prevention Program Participation Attestation Form is attached indicating one of the following (a or b):
     a. The member participates in a Syringe Service Program
     b. The member participates in at least 2 Disease Prevention Pathway appointments as defined in Appendix D (may be completed by any qualified healthcare provider)

Non-Solid Dosage Form Agents Criteria:

- Epclusa, Harvoni, and Sovaldi pellets: All of the following are met (A or B)
  A. The member must meet Non-Solid Dosage Preparations criteria in addition to Hepatitis C criteria
  B. The member is unable to use Mavyret pellets (subject to clinical justification)

Non-Preferred Agents Criteria:

- Clinical justification must be provided explaining why the member is unable to use the preferred product (subject to clinical review).

For FIRST TIME or RE-INFECTION Treatment with Direct Acting Antivirals or incomplete therapy after receiving < 28 days:

- Chronic Hepatitis C must be documented by one of the following (most recent test within the last 24 months):
  - No liver fibrosis or unknown (one of the following):
    - 2 positive HCV RNA levels at least 3 months apart
    - 1 positive HCV RNA test with the last likely HCV exposure occurring at least 6 months before the most recent positive test
  - Liver fibrosis or cirrhosis:1 positive HCV RNA test
- For incomplete therapy, the following criteria is met:

Due to incomplete therapy (defined as a medication possession ratio (MPR) of less than 80%)	The member has participated in 1 visit focused on addressing adherence barriers within the past 180 days. Adherence education may be provided by a pharmacist (may be billed through the MTM program) or clinic-based E&M billed service (provided by a nurse or independent practitioner).

For RE-TREATMENT after Direct Acting Antiviral failure or incomplete therapy after receiving ≥ 28 days:

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

ribavirin	MAVYRET (glecaprevir/pibrentasvir)
VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)	SOVALDI (sofosbuvir) 400MG TABLET

- The requested medication must be prescribed by, or in consult with, a hepatology, gastroenterology, or infectious disease specialist (including via Project ECHO)
- Chronic Hepatitis C must be documented by 1 HCV RNA test since most recent DAA treatment (HCV RNA level must be within the last 24 months)
- The following criteria is met (as applicable due to reason for retreatment):

Reason For Retreatment	Criteria
Due to incomplete therapy (defined as a medication possession ratio (MPR) of less than 80%)	The member has participated in 1 visit focused on addressing adherence barriers within the past 180 days. Adherence education may be provided by a pharmacist (may be billed through the MTM program) or clinic-based E&M billed service (provided by a nurse or independent practitioner).
Resistance	• **FIRST TIME treatment with Direct Acting Antivirals** criteria must be met

Non-Preferred Agents Criteria:

- The member has had a failed treatment course with Vosevi.

Influenza

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
oseltamivir	TAMIFLU (oseltamivir)
this space intentionally left blank	XOFLUZA (baloxavir marboxil)

Electronic Age Verification

- Xofluza: The member must be 5 years of age or older

Prior Authorization Criteria

Initial Criteria – Approval Duration: 5 days

- The member must have failed a 5-day trial of oseltamivir, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred product (subject to clinical review).

Malaria

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
chloroquine	atovaquone/proguanil
hydroxychloroquine	COARTEM (artemether/lumefantrine)
quinine	KRINTAFEL (tafenoquine)
this space intentionally left blank	MALARONE (atovaquone/proguanil)
this space intentionally left blank	mefloquine

this space intentionally left blank	primaquine
this space intentionally left blank	SOVUNA (hydroxychloroquine)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 7 days

- The request must be for treatment of malaria (*NOT covered for prophylaxis)*
- One of the following criteria must be met (A or B):
  A. The member is continuing treatment upon discharge from an acute care facility.
  B. The requested medication must be prescribed by, or in consult with, an infection disease specialist and clinical justification has been provided explaining why the preferred agents are not an option due to susceptibility, previous failed trials, or other contraindications (subject to clinical review)

Renewal Criteria – Approval Duration: 5 days

- It is medically necessary to continue treatment course after re-evaluation of the member's condition.
- The total requested duration of use must not be greater than manufacturer labeling or treatment guideline recommendations (whichever is greater).

Nephrology/Urology

Anemia

Hematopoietic, Erythropoiesis Stimulating Agents

Pharmacy Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ARANESP (darbepoetin alfa)	MIRCERA (methoxy polyethylene glycol-epoetin beta)
EPOGEN (epoetin alfa)	PROCRIT (epoetin alfa)
RETACRIT (epoetin alfa – epbx) – Labeler 00069	RETACRIT (epoetin alfa – epbx) – Labelers 59353

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have had a 4-week trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- If member is on chronic renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.

Medical Billing

PREFERRED AGENTS (PA REQUIRED)
J0604 - Cinacalcet, oral, 1 mg, (for ESRD on dialysis)
J0882 - Injection, darbepoetin alfa, 1 microgram (for ESRD on dialysis)
Q4081 - Injection, epoetin alfa, 100 units (for ESRD on dialysis) (for renal dialysis facilities and hospital use)
J0887 - Injection, epoetin beta, 1 microgram, (for ESRD on dialysis)
Q0139 - Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (for ESRD on dialysis)
J0879 - Injection, difelikefalin, 0.1 microgram, (for ESRD on dialysis)
Q5105 - Injection, epoetin alfa-epbx, biosimilar, (retacrit) (for ESRD on dialysis), 100 units
J3591 - Unclassified drug or biological used for ESRD on dialysis

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3-month approval if member has diagnosis of End Stage Renal Disease

- If member is on chronic renal dialysis, Medicare eligibility must be ruled out
- If member does not have End Stage Renal Disease diagnosis, non-ESRD HCPCS code should be used or ESRD should be added as a diagnosis (as appropriate).

HIF-PHIs (Hypoxia-Inducible Factor-Prolyl Hydroxylase Inhibitors)

PREFERRED AGENTS (PA REQUIRED)
VAFSEO (vadadustat)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- If member is on chronic renal dialysis, Medicare eligibility must be ruled out (6-month approval may be allowed to determine eligibility).

Benign Prostatic Hyperplasia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
alfuzosin ER	CARDURA (doxazosin)
doxazosin	CARDURA XL (doxazosin)
dutasteride	dutasteride/tamsulosin
finasteride	PROSCAR (finasteride)
prazosin	RAPAFLO (silodosin)
tamsulosin	sildenafil
terazosin	silodosin
this space intentionally left blank	tadalafil
this space intentionally left blank	TEZRULY (terazosin) ORAL SOLUTION

Electronic Diagnosis Verification

- Finasteride, sildenafil, and tadalafil: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Cardura XL:
  - The member must have failed a 30-day trial of doxazosin, as evidenced by paid claims or pharmacy printouts.
- Silodosin:
  - The member must have failed a 30-day trial of tamsulosin, as evidenced by paid claims or pharmacy printouts.
- Sildenafil/tadalafil:
  - The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
  - Documentation (e.g., chart notes) must be provided confirming the diagnosis.
- Tezruly: Must meet Non-Solid Dosage Forms criteria

Complement-mediated Thrombotic Microangiopathy (TMA) / Complement-mediated Hemolytic Uremic Syndrome

PA REQUIRED
eculizumab - See Biosimilar Agents
ULTOMIRIS (ravulizumab-cwvz)
ULTOMIRIS (ravulizumab-cwvz) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or nephrologist.
- The member has all the following:
  - Low platelet count, as defined by laboratory reference range or member requires dialysis.
  - Evidence of hemolysis such as an elevation in serum lactate dehydrogenase (LDH), elevated indirect bilirubin, reduced haptoglobin, or increased reticulocyte, as defined by laboratory reference range or member requires dialysis.
  - Serum creatinine above the upper limits of normal, as defined by laboratory reference range or member requires dialysis.
- The member does not have bloody diarrhea.

- If member is on chronic renal dialysis (for at least 3 months), Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.

Renewal Criteria – Approval Duration: 12 months
- The member must have experienced clinical benefit since starting treatment with the requested medication, subject to clinical review, including one of the following scores and symptoms:
  - Normalization of platelet count, as defined by laboratory reference range.
  - Normalization of lactate dehydrogenase (LDH), as defined by laboratory reference range.
  - ≥ 25% improvement in serum creatinine from baseline or ability to discontinue dialysis.

Chronic Kidney Disease

Kappa-opioid agonist

PA REQUIRED
KORSUVA (difelikefalin) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months (one time)
- The member must be on chronic renal dialysis.
- Medicare eligibility must be ruled out (6-month approval may be allowed to determine eligibility).
- The member must have failed a 60-day trial of pregabalin or gabapentin in addition to an oral antihistamine, as evidenced by paid claims or pharmacy printouts

Vasopressin V2-receptor (V2R) Antagonist

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tolvaptan	JYNARQUE (tolvaptan)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- The member has autosomal dominant polycystic kidney disease.
- The member must not be on chronic renal dialysis or have a kidney transplant
- The requested medication must be prescribed by, or in consult with, a nephrologist.
- The member does not have liver disease.
- The member has estimated glomerular filtration rate (eGFR) ≥ 25
- The prescriber has provided clinical justification that the member is at high risk of kidney progression by submitting one of the following (subject to clinical review):
  - Autosomal dominant polycystic kidney disease mayo classes 1C, 1D, or 1E
  - Kidney length > 16.5 cm (by ultrasound, MRI, or CT scan) for patients aged < 50 years
  - An annual eGFR decline of at least 3 mL/min/1.73 m2 per year over a period of five years
  - Total kidney volume > 750 mL and age < 51

- Prognostic Tools - PROPKD Score | ADPKDSim > 6

Sodium/Hydrogen Exchanger 3 (NHE3)

PA REQUIRED
XPHOZAH (tenapanor)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months (one time)

- The member must be on chronic renal dialysis
- Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have failed 30-day trials of sevelamer carbonate and sucroferric oxyhydroxide, as evidenced by paid claims or pharmacy printouts.

References:

1. Stevens, Paul E., et al. "KDIGO 2024 Clinical practice guideline for the evaluation and management of chronic kidney disease." Kidney international 105.4 (2024): S117-S314.

C3 Glomerulopathy (C3G)

Therapeutic Duplication

- Medication classes not payable together:
  - Empaveli and Fabhalta are not allowed together

C3 Inhibitors

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EMPAVELI (pegcetacoplan)	this space intentionally left blank

Factor B Inhibitors

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	FABHALTA (iptacopan)

Renin-Angiotensin-Aldosterone System (RAAS) Inhibitors

NO PA REQUIRED
ACE (angiotensin-converting enzyme) inhibitors – all oral agents preferred
ARBs (angiotensin receptor blockers) – all oral agents preferred

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- If member is post kidney transplant, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have estimated glomerular filtration rate (eGFR) ≥ 30 and must not be on chronic kidney dialysis.
- The member must be experiencing proteinuria > 1 g/day or UPCR ≥ 1 g/g despite a 3-month trial with good compliance with an ACE inhibitor or an ARB at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts.

Empaveli Only:

- The member must have a diagnosis of native kidney or post-kidney transplant recurrent C3 glomerulopathy (C3G) or native kidney primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN)

Fabhalta Only

- The member must also have failed a 6-month trial of Empaveli, as evidenced by paid claims or pharmacy printouts and proteinuria > 1 g/day or UPCR ≥ 1 g/g

Renewal Criteria – Approval Duration: 12 months (clinical justification required for treatment longer than 1.5 years such as relapse upon discontinuation – subject to clinical review)

- If member is on chronic renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by both of the following (A or B):
    A. A stable or improved eGFR
    B. A reduction of proteinuria or UPCR of 30% from baseline proteinuria <0.5 g/day or UPCR < 0.5 g/g or reduction of 30% from baseline.

Diabetic Kidney Disease

GLP-1 receptor agonist

NO PA REQUIRED
OZEMPIC (semaglutide) injection

Non-steroidal selective mineralocorticoid receptor antagonist (MRA)

PA REQUIRED
KERENDIA (finerenone)

Renin-Angiotensin-Aldosterone System (RAAS) Inhibitors

NO PA REQUIRED

ACE (angiotensin-converting enzyme) inhibitors – all oral agents preferred
ARBs (angiotensin receptor blockers) – all oral agents preferred
TEKTURNA (aliskiren)

SGLT-2 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dapagliflozin	FARXIGA (dapagliflozin)
JARDIANCE (empagliflozin)	INVOKANA (canagliflozin)
this space intentionally left blank	INVOKAMET (canagliflozin/metformin)
this space intentionally left blank	INVOKAMET XR (canagliflozin/metformin)

SGLT-1/SGLT-2 Inhibitor

PA REQUIRED
INPEFA (sotagliflozin)

Prior Authorization Criteria

<u>Initial Criteria – Approval Duration:</u> 6 months

Kerendia Only

- The member must have type 2 diabetes and chronic kidney disease.
- The member must be on the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - An ACE-inhibitor or an ARB
  - A SGLT-2 inhibitor
- The member has an estimated glomerular filtration rate (eGFR) ≥ 25 mL/min/1.73 m^2 and is not on chronic kidney dialysis.
- If member is post-kidney transplant, Medicare eligibility must be ruled out (6-month approval may be allowed to determine eligibility).
- The member has one of the following (1 or 2) despite a 6-month trial with an ACE inhibitor or ARB in combination with a SGLT-2 inhibitor and a GLP1-agonist, as evidenced by paid claims or pharmacy printouts:
  1. urinary albumin-to-creatinine ratio (UACR) ≥ 30 mg/g (≥3 mg/mmol)
  2. albuminuria ≥ 300 mg/day

Inpefa Only:

- The requested medication must be prescribed by, or in consult with, a cardiologist or nephrologist.
- If member is on chronic renal dialysis, Medicare eligibility must be ruled out. *(6-month approval allowed to determine eligibility)*
- The member has type 2 diabetes and chronic kidney disease.
- The member has a history of a cardiovascular event (e.g., heart failure, myocardial infarction, cerebrovascular event) or two or more risk factors (e.g., elevated cardiac and inflammatory biomarker, obesity, hyperlipidemia, hypertension)

- The member is receiving concurrent Entresto, a beta-blocker, a GLP-1 agonist, and a mineralocorticoid receptor antagonist.

Renewal Criteria – Approval Duration: 12 months
- If member is on chronic renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.

Kerendia Only:
- The member has experienced a stabilization in eGFR or one of the following:
  - albuminuria <0.3 g/day or reduction of 30% from baseline
  - UACR < 0.3 g/g or reduction of 30% from baseline

References:

1. de Boer, Ian H., et al. "Diabetes management in chronic kidney disease: a consensus report by the American Diabetes Association (ADA) and Kidney Disease: Improving Global Outcomes (KDIGO)." *Diabetes care* 45.12 (2022): 3075-3090.

IgA Nephropathy

Electronic Duration Verification:

- Tarpeyo is payable for 9 months every 3 years.

Therapeutic Duplication

- Medication classes not payable together:
  - Filspari, ACE Inhibitors, ARBs, and Renin Inhibitors are not allowed with each other.
  - Fabhalta Filspari, Vanrafia and Voyxact and are not allowed together

APRIL inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VOYXACT (sibeprenlimab-szsi)	this space intentionally left blank

Dual endothelin angiotensin receptor antagonist

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FILSPARI (sparsentan)	this space intentionally left blank

Endothelin receptor antagonist

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	VANRAFIA (atrasentan)

Factor B Inhibitors

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	FABHALTA (iptacopan)

Renin-Angiotensin-Aldosterone System (RAAS) Inhibitors

NO PA REQUIRED
ACE (angiotensin-converting enzyme) inhibitors – all oral agents preferred
ARBs (angiotensin receptor blockers) – all oral agents preferred

SGLT-2 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dapagliflozin	FARXIGA (dapagliflozin)
JARDIANCE (empagliflozin)	INVOKANA (canagliflozin)
this space intentionally left blank	INVOKAMET (canagliflozin/metformin)
this space intentionally left blank	INVOKAMET XR (canagliflozin/metformin)

Systemic Corticosteroids

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methylprednisolone	TARPEYO (budesonide-targeted release)
prednisone	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have estimated glomerular filtration (eGFR ≥ 30) and not be on chronic kidney dialysis
- If member is post-kidney transplant, Medicare eligibility must be ruled out (6-month approval may be allowed to determine eligibility).
- The member must biopsy-proven IgA Nephropathy
- The member must be experiencing proteinuria > 0.5 g/day or UPCR ≥ 0.5 g/g despite a 3-month trial of a combination of (ACE inhibitor or an ARB + SGLT-2 inhibitor) with good compliance of the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts

Fabhalta Only

- The member must also have failed a 6-month trial of Tarpeyo and mycophenolate mofetil (MMF), as evidenced by paid claims or pharmacy printouts and proteinuria > 0.5 g/day or UPCR ≥ 0.5 g/g

Vanrafia Only

- The member must also have failed a 6-month trial of Filspari, as evidenced by paid claims or pharmacy printouts and proteinuria > 0.5 g/day or UPCR ≥ 0.5 g/g

Renewal Criteria – Approval Duration: 12 months
- The member has experienced one of the following:
  - proteinuria <0.5 g/day or reduction of 30% from baseline
  - UPCR < 0.5 g/g or reduction of 30% from baseline

References:

- Stevens, Paul E., et al. "KDIGO 2025 Clinical practice guideline for the management of Immunoglobulin A Nepropathy (igAN) and Immunogobulin A Vasculitis (IgAV)." Kidney International (2025) 108 (Suppl 4S), S1–S71

Hematopoietic Syndrome of Acute Radiation Syndrome

PREFERRED AGENTS (PA REQUIRED)
NPLATE (romiplostim)

Prior Authorization Criteria

Initial Criteria – Approval Duration: treatment plan must be documented in request
- The requested medication must be prescribed by, or in consult with, a hematologist or oncologist.
- The member meets one of the following:
  - The member has had a ≥ 2 gray exposure to radiation
  - The member has had exposure to radiation and experiencing one of the following:
    - Gross blood loss
    - > 10% decrease in hemoglobin
    - Platelet count < 50,000/microL
    - Absolute neutrophil count < 1000 cells/microL
    - Absolute lymphocyte count < 1000 cells/microL

Hyperkalemia (Chronic)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LOKELMA (sodium zirconium cyclosilicate)	VELTASSA (patiromer)
SPS (sodium polystyrene sulfonate) SUSPENSION+	this space intentionally left blank

+ SPS can cause intestinal necrosis which may be fatal. Concomitant use of additional sorbitol is not recommended.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months
- The requested medication must be prescribed by, or in consult with, a nephrologist or cardiologist.

- If member is on chronic renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member's current serum potassium level must be exceeding the upper limit of normal, as evidenced by at least two separate lab values, submitted with the request.
- The member must have failed 30-day trials with at least two of the following products, as evidenced by paid claims or pharmacy printouts:
  - bumetanide, chlorothiazide, fludrocortisone, furosemide, hydrochlorothiazide, indapamide, metolazone, torsemide
- The member must not be receiving nonsteroidal anti-inflammatory drugs (NSAIDs)

Non-Preferred Agent Criteria:

- The member must have failed a 30-day trial with Lokelma, as evidenced with paid claims or pharmacy print outs.

Renewal Criteria – Approval Duration: 12 months

- The member's current serum potassium level is within normal limits or has been significantly reduced from baseline

Reference:

1. Rossing, Peter, et al. "KDIGO 2022 clinical practice guideline for diabetes management in chronic kidney disease." *Kidney International* 102.5 (2022): S1-S127.

Primary Hyperoxaluria Type 1 (PH1)

RNA interference (RNAi)

PA REQUIRED
OXLUMO (lumasiran) – *Medical Billing*
RIVFLOZA (nedosiran)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a nephrologist, urologist or geneticist
- The member's diagnosis must be documented by one of the following:
  - Mutation in the alanine: glyoxylate aminotransferase (AGXT) gene confirmed by genetic testing
  - Liver enzyme analysis confirming absent or significant deficiency in alanine: glyoxylate aminotransferase (AGT) activity
- The member has a failed to achieve at least a 30% reduction in urinary oxalate excretion after a 90-day trial of pyridoxine (vitamin B6) of maximally tolerated doses (maximum dose, 20 mg/kg per day), as evidenced by paid claims or pharmacy printouts.
- The member has not received a liver transplant
- One of the following must be submitted:
  - Elevated urinary oxalate excretion > 1 mmol/1.73 m^2 per day or 90 mg/1.73 m^2 per day

- Elevated urinary oxalate: creatinine ratio as defined by age defined laboratory reference range

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, (subject to clinical review) including one of the following scores and symptoms:
  - Reduced signs and symptoms of PH1 (e.g., nephrocalcinosis, formation of renal stones, renal impairment)
  - Decrease of 30% from baseline or normalization of urinary oxalate excretion
  - Decreased or normalized urinary oxalate: creatinine ratio relative to normative values for age

Lupus Nephritis

First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
cyclophosphamide	this space intentionally left blank
mycophenolate	this space intentionally left blank
systemic oral corticosteroids	this space intentionally left blank

Anti-CD20 Monoclonal Antibodies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAZYVA (obinutuzumab) – *Medical Billing*	this space intentionally left blank
rituximab - See Biosimilar Agents	this space intentionally left blank

B-Lymphocyte Stimulator (BlyS) – Specific Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BENLYSTA (belimumab) – *Medical Billing*	this space intentionally left blank

Calcineurin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
cyclosporine	LUPKYNIS (voclosporin)
tacrolimus	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a nephrologist or rheumatologist
- The member has an estimated glomerular filtration rate (eGFR) > 45 and is not on chronic kidney dialysis.

- The member must be using concurrently with mycophenolate and a systemic corticosteroid for 3 months, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months
- The member has experienced a therapeutic response since starting treatment, as evidenced by one of the following:
  - Improvement of proteinuria (UPCR decreased by 50% and/or below 0.5 g/day)
  - Improvement of serum creatinine (SCr ≤ 1.4 mg/dl)
  - Chronic steroid use to ≤ 7.5 mg/day

Overactive Bladder

Solid Dosage Formulations

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
flavoxate	darifenacin ER	GEMTESA (vibegron)
oxybutynin ER	fesoterodine ER	mirabegron ER
oxybutynin tablet	MYRBETRIQ (mirabegron) – *Brand Required*	TOVIAZ ER (fesoterodine)
solifenacin	this space intentionally left blank	trospium ER
tamsulosin	this space intentionally left blank	VESICARE (solifenacin)
tolterodine	this space intentionally left blank	this space intentionally left blank
trospium	this space intentionally left blank	this space intentionally left blank
tolterodine ER	this space intentionally left blank	this space intentionally left blank

Therapeutic Duplication

- One strength of one of the following medications is allowed at a time: dutasteride, dutasteride/tamsulosin, or finasteride
- Non-selective alpha 1 blockers (doxazosin, prazosin, and terazosin) are not allowed with carvedilol or labetalol
  - Carvedilol and labetalol are non-selective beta blockers with alpha 1 blocking activity

Electronic Step Therapy Required

- Preferred Step 1 Agents:
  - PA Not Required Criteria: A 60-day supply of a preferred agent at max dose has been paid within 100 days prior to step 1 agent's date of service.
  - PA Required Criteria: The member must have failed A 30-day trial of a preferred agent, as evidenced by paid claims or pharmacy printouts.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have had three 30-day trials of preferred medications including Myrbetriq, as evidenced by paid claims or pharmacy printouts.
    - Note: trospium and darifenacin have less central nervous system penetration and should be trialed if experiencing antimuscarinic side effects with other antimuscarinic medications

Non-Solid Dosage Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
oxybutynin syrup	MYRBETRIQ (mirabegron) SUSPENSION – *Brand Required*
OXYTROL (oxybutynin) PATCH	mirabegron suspension

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have had a 60-day trial of a preferred agent, as evidenced by paid claims or pharmacy printouts.
- Must meet Non-Solid Dosage Forms criteria

Therapeutic Duplication

- Anticholinergic medications (tolterodine, oxybutynin, trospium, fesoterodine) are not covered with Acetylcholinesterase Inhibitors.
    - The effects of an anticholinergic (blocks the effect of acetylcholine) and acetylcholinesterase inhibitors (prevents breakdown of acetylcholine) oppose each other, and the therapeutic effect of both products is diminished.

Phosphate Binders

Solid Dosage Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcium acetate	AURYXIA (ferric citrate) TABLET
sevelamer carbonate tablet	ferric citrate tablet
this space intentionally left blank	RENVELA (sevelamer carbonate) TABLET
this space intentionally left blank	sevelamer HCl

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- If member is on chronic renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have failed a 30-day trial of sevelamer carbonate, as evidenced by paid claims or pharmacy printouts.

Non-Solid Dosage Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
sevelamer carbonate powder pack	FOSRENOL (lanthanum) CHEWABLE TABLET
this space intentionally left blank	FOSRENOL (lanthanum) POWDER PACK
this space intentionally left blank	lanthanum chew tab
this space intentionally left blank	RENVELA (sevelamer carbonate) POWDER PACK
this space intentionally left blank	VELPHORO (sucroferric oxyhydroxide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- If member is on chronic renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility).*
- The member must have failed a 30-day trial of sevelamer carbonate, as evidenced by paid claims or pharmacy printouts.
- Must meet Preferred Dosage Forms criteria
- Must meet Non-Solid Dosage Forms criteria

Neurology

Alzheimer's Disease

Cholinesterase Inhibitors

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
donepezil 5 mg, 10 mg tablet	ARICEPT (donepezil)
galantamine tablet	donepezil 23 mg tablet
galantamine ER	donepezil ODT
rivastigmine capsule	RAZADYNE (galantamine)
this space intentionally left blank	RAZADYNE ER (galantamine)
this space intentionally left blank	ZUNVEYL (benzgalantamine)

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EXELON (rivastigmine) PATCH – *Brand Required*	ADLARITY (donepezil) PATCH
this space intentionally left blank	galantamine oral solution
this space intentionally left blank	rivastigmine patch

NMDA Receptor Antagonists

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
memantine	NAMENDA (memantine)

Non-Solid Dosage Forms

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
memantine ER capsule sprinkle	memantine oral solution
this space intentionally left blank	NAMENDA XR (memantine) CAPSULE SPRINKLE

Cholinesterase Inhibitors / NMDA Receptor Antagonist Combinations

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	memantine/donepezil
this space intentionally left blank	NAMZARIC (memantine/donepezil)

Therapeutic Duplication

- One memantine medication is allowed at a time

Drug-Drug Interaction

- Anticholinergic medications are not covered with acetylcholinesterase inhibitors (e.g., donepezil, rivastigmine, galantamine, benzgalantamine).
  - The effects of an anticholinergic (blocks the effect of acetylcholine) and acetylcholinesterase inhibitors (prevents breakdown of acetylcholine) oppose each other, and the therapeutic effect of both products is diminished.

Electronic Diagnosis Verification

- Memantine: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

Electronic Age Verification

- Submit chart notes to verify diagnosis for members less than 30 years old

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.
- Zunveyl Only:
  - The member must have experienced gastrointestinal side effects with galantamine (lasting longer than 6 days after dose increase) that were unable to be mitigated despite gradual titration, adequate fluid intake, and being taken with meals.
  - Clinical justification must be provided explaining why the member is unable to use another preferred products (subject to clinical review).
- Donepezil 23 mg Only:
  - Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).
  - The member must not reside in facility where medications are managed such as skilled nursing care.
- Extended release and non-solid dosage forms:
  - The member must not reside in facility where medications are managed such as skilled nursing care.
- Non-solid dosage forms: Must meet Non-Solid Dosage Forms criteria

Amyloid Beta-Directed Monoclonal Antibody

PA REQUIRED
KISUNLA (donanemab-azbt) – *Medical Billing*
LEQEMBI (lecanemab-irmb) – *Medical Billing*
LEQEMBI IQLIK (lecanemab-irmb)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a neurologist, geriatric psychiatrist, or geriatrician specializing in dementia.
- The member must have been diagnosed with mild cognitive impairment or mild dementia due to Alzheimer's disease as evidenced by both of the following (1 and 2):
  1. beta-amyloid plaque on the brain by amyloid PET scan or presence of AD biomarkers in the cerebrospinal fluid.
  2. One of the following scores (a, b, c or d):
     a. Mini-Mental State Examination (MMSE) score ≤ 24 and ≥ 20
     b. Montreal Cognitive Assessment (MoCA) score ≤ 25 and ≥ 18
     c. St. Louis University Mental Status Exam (SLUMS) score ≤ 26 and ≥ 18
     d. Clinical Demetia Rating of 0.5 or 1
- The member must have been receiving treatment with donepezil, galatamine, or rivastigmine for the past 2 months, as evidenced by paid claims or pharmacy print outs.
- The member must not be receiving treatment with memantine, as evidenced by paid claims.

Renewal Criteria – Approval Duration: 6 months

- The member continues to show positive clinical response, such as stable or slowed decline as evidenced by one of the following scores (a, b, c or d):
  a. Mini-Mental State Examination (MMSE) score ≥ 20
  b. Montreal Cognitive Assessment (MoCA) score ≥ 18

c. St. Louis University Mental Status Exam (SLUMS) score of ≥ 18
d. Clinical Demetia Rating of 0.5 or 1

- The member must not be receiving treatment with memantine.

Amyotrophic Lateral Sclerosis (ALS)

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
riluzole tablet	edaravone – *Medical Billing*	RILUTEK (riluzole) TABLET
this space intentionally left blank	EXSERVAN (riluzole) FILM	this space intentionally left blank
this space intentionally left blank	QALSODY (tofersen) + – *Medical Billing*	this space intentionally left blank
this space intentionally left blank	RADICAVA (edaravone) – *Medical Billing*	this space intentionally left blank
this space intentionally left blank	RADICAVA ORS (edaravone)	this space intentionally left blank
this space intentionally left blank	TIGLUTIK (riluzole) ORAL SUSPENSION	this space intentionally left blank

+ Qalsody failed to demonstrate statistically significant benefit over placebo on the primary efficacy endpoint, the change from baseline to Week 28 in the Amyotrophic Lateral Sclerosis Functional Rating Scale – Revised (ALSFS-R) in the Phase 3 VALOR trial (NCT02623699 or clinical secondary endpoints. Continued approval of Qalsody for this indication may be contingent upon verification of clinical benefit in the ATLAS study (NCT04856982).

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a neurologist or neuromuscular specialist.
- The member has had ALS symptoms present for less than 2 years.
- The member must have both of the following:
  - Forced vital capacity (FVC) > 80 percent of predicted.
  - ALS Function Rating Scale-Revised (ALSFRS-R) with a score of 2 or greater on each individual item of the scale
- The member must not have permanent invasive ventilation.

Exservan and Tiglutik Only:

- Must meet Non-Solid Dosage Forms criteria

Renewal Criteria – Approval Duration: 12 months

- The member must have both of the following:
  - Forced Vital Capacity (FVC) > 60 percent of predicted
  - The member has received a therapeutic response (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.) from baseline as evidenced by a score decline of less than 6 on the ALSFRS-R.

Anticonvulsants

Anticonvulsant Prevention

Narrow Spectrum:

Carbamazepine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
carbamazepine 100 mg chewable tablet	carbamazepine 200 mg chewable tablet
carbamazepine 100 mg ER capsule	CARBATROL 100 MG (carbamazepine) CAPSULE
carbamazepine oral suspension	carbamazepine ER 200 mg, 300 mg capsule
carbamazepine tablet	carbamazepine XR tablet
CARBATROL 200 MG, 300 MG (carbamazepine) CAPSULE – *Brand Required*	EPITOL (carbamazepine)
EQUETRO (carbamazepine)	TEGRETOL (carbamazepine oral suspension)
TEGRETOL XR (carbamazepine) – *Brand Required*	TEGRETOL (carbamazepine)

Ethosuximide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ethosuximide capsule	ZARONTIN (ethosuximide)
ethosuximide oral solution	ZARONTIN (ethosuximide) ORAL SOLUTION

Gabapentin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
gabapentin capsule	NEURONTIN (gabapentin) CAPSULE
gabapentin oral solution	NEURONTIN (gabapentin) ORAL SOLUTION
gabapentin tablet	NEURONTIN (gabapentin) TABLET

Lacosamide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lacosamide oral solution	MOTPOLY XR (lacosamide) CAPSULE
lacosamide tablet	VIMPAT (lacosamide) ORAL SOLUTION
this space intentionally left blank	VIMPAT (lacosamide) TABLET

Oxcarbazepine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
oxcarbazepine oral solution	oxcarbazepine ER
oxcarbazepine tablet	OXTELLAR XR (oxcarbazepine) – *Brand Required*
this space intentionally left blank	TRILEPTAL (oxcarbazepine)
this space intentionally left blank	TRILEPTAL (oxcarbazepine) ORAL SUSPENSION

Pregabalin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pregabalin	LYRICA (pregabalin)
pregabalin oral solution	LYRICA (pregabalin) ORAL SOLUTION
this space intentionally left blank	LYRICA CR (pregabalin)
this space intentionally left blank	pregabalin ER

Phenytoin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
phenytoin chewable tablet	DILANTIN (phenytoin) CHEWABLE TABLET
phenytoin sodium ER	DILANTIN (phenytoin) ORAL SUSPENSION
phenytoin suspension	DILANTIN ER (phenytoin)
this space intentionally left blank	PHENYTEK (phenytoin)

Primidone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
primidone	this space intentionally left blank

Tiagabine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tiagabine	this space intentionally left blank

Vigabatrin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
SABRIL (vigabatrin) TABLET – *Brand Required*	SABRIL (vigabatrin) POWDER PACK
vigabatrin powder pack	vigabatrin tablet
this space intentionally left blank	VIGADRONE (vigabatrin)
this space intentionally left blank	VIGAFYDE (vigabatrin)

Other

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CELONTIN (methsuximide) – *Brand Required*	APTIOM (eslicarbazepine)
DIACOMIT (stiripentol)	methsuximide
EPIDIOLEX (cannabidiol)	this space intentionally left blank
eslicarbazepine	this space intentionally left blank
FINTEPLA (fenfluramine) ORAL SOLUTION	this space intentionally left blank
phenobarbital elixir	this space intentionally left blank
phenobarbital tablet	this space intentionally left blank
XCOPRI (cenobamate)	this space intentionally left blank
ZTALMY (ganaxolone) SUSPENSION	this space intentionally left blank

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale for Diacomit, Epidiolex, and Fentepla

Electronic Concurrent Medications Required

- A total of 28 days of clobazam must be paid within 45 days prior to Diacomit.

- Diacomit is FDA approved to be used in combination with clobazam.

Quantity Limit Override

- Gabapentin: 2400 mg max dose per day

Please call for an override by calling provider relations at 1-800-755-2604 if dose exceeds 2400 mg per day and the indication is adjuvant seizure (if monotherapy, please send chart notes to verify indication)

Prior Authorization Criteria:

- See Preferred Dosage Form Criteria

Therapeutic Duplication

- One Vimpat strength is allowed at a time
- Lyrica and gabapentin are not allowed together.
- Lyrica and gabapentin oral solutions are not allowed with benzodiazepines, muscle relaxants (except baclofen), or narcotic solid dosage forms. If a member can swallow, they should be transitioned to a solid dosage form.

Please call for an override by calling provider relations at 1-800-755-2604 if the member's medications are dispensed in solid formulations are being crushed or opened to administer because member is unable to swallow

Broad Spectrum:

Clobazam

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clobazam	ONFI (clobazam)
clobazam oral suspension	ONFI (clobazam) ORAL SUSPENSION
this space intentionally left blank	SYMPAZAN (clobazam) FILM

Divalproex/Valproic Acid

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
divalproex sodium ER	DEPAKOTE SPRINKLE (divalproex sodium)
divalproex sodium sprinkle	DEPAKOTE (divalproex sodium) TABLET
divalproex sodium tablet	DEPAKOTE ER (divalproex sodium)
valproic acid capsule	this space intentionally left blank
valproic acid oral solution	this space intentionally left blank

Felbamate

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
felbamate oral suspension	felbamate tablet
FELBATOL (felbamate) TABLET– *Brand Required*	this space intentionally left blank

Lamotrigine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lamotrigine chewable tablet	LAMICTAL (lamotrigine) CHEWABLE TABLET
lamotrigine ER	LAMICTAL (lamotrigine) DOSE PACK
lamotrigine ODT	LAMICTAL (lamotrigine) TABLET
lamotrigine tablet	lamotrigine dose pack
SUBVENITE (lamotrigine)	lamotrigine ODT dose pack
this space intentionally left blank	LAMICTAL ODT (lamotrigine)
this space intentionally left blank	LAMICTAL ODT (lamotrigine) DOSE PACK
this space intentionally left blank	LAMICTAL XR (lamotrigine)
this space intentionally left blank	LAMICTAL XR (lamotrigine) DOSE PACK
this space intentionally left blank	SUBVENITE (lamotrigine) DOSE PACK
this space intentionally left blank	SUBVENITE (lamotrigine) ORAL SUSPENSION

Levetiracetam

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
levetiracetam ER	ELEPSIA XR (levetiracetam)
levetiracetam oral solution	KEPPRA (levetiracetam)
levetiracetam tablet	KEPPRA (levetiracetam) ORAL SOLUTION
this space intentionally left blank	KEPPRA XR (levetiracetam)
this space intentionally left blank	levetiracetam tablet for suspension
this space intentionally left blank	SPRITAM (levetiracetam) TAB FOR SUSPENSION

Rufinamide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rufinamide suspension	BANZEL (rufinamide) TABLET
rufinamide tablet	BANZEL (rufinamide) ORAL SUSPENSION

Topiramate

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EPRONTIA (topiramate) SOLUTION – *Brand Required*	TOPAMAX (topiramate)
topiramate ER sprinkle cap	TOPAMAX (topiramate) SPRINKLE CAPSULE
topiramate sprinkle capsule	topiramate solution
topiramate tablet	topiramate ER capsule
TROKENDI XR (topiramate) – *Brand Required*	this space intentionally left blank

Other

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
brivaracetam	BRIVIACT (brivaracetam)
brivaracetam oral solution	BRIVIACT (brivaracetam) ORAL SOLUTION
FYCOMPA (perampanel) – *Brand Required*	perampanel oral suspension
FYCOMPA (perampanel) ORAL SUSPENSION – *Brand Required*	perampanel tablet
zonisamide	this space intentionally left blank
zonisamide oral suspension	this space intentionally left blank

Anticonvulsant Rescue Therapies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diazepam rectal gel	this space intentionally left blank
NAYZILAM (midazolam) NASAL SPRAY	this space intentionally left blank
VALTOCO (diazepam) NASAL SPRAY	this space intentionally left blank

Electronic Duration Verification

- 5 doses are covered every 75 days without an override

If one of the following criteria are met (A or B), please request an override by calling provider relations at 1-800-755-2604 or emailing medicaidpharmacy@nd.gov:

A. The previous dose has expired
B. The dose was used by member for a seizure (in this case, it is recommended to follow up with prescriber to discuss frequency of use and potential regimen review/adjustments)

Prior Authorization Criteria:

- See Preferred Dosage Form criteria

Duchenne Muscular Dystrophy

Corticosteroids

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EMFLAZA (deflazacort) – *Brand Required*	AGAMREE (vamorolone)
this space intentionally left blank	deflazacort
this space intentionally left blank	PYQUVI (deflazacort)

Prior Authorization Criteria

Prior Authorization Form – Duchenne Muscular Dystrophy

Initial Criteria – Approval Duration: 6 months
(approval may be granted for tapering if all initial criteria are not met)

- Diagnosis must be confirmed by the presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene (must be confirmed in addition to a positive newborn screening)
- The requested medication must be prescribed by, or in consult with, a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- Onset of weakness must have occurred before 2 years of age
- The member must have serum creatinine kinase activity of at least 10 times the upper limit of normal (ULN) prior to initiating treatment
- The member must have failed a 6-month trial of prednisone, as evidenced by paid claims or pharmacy printouts

- The provider must submit baseline assessment results from the following assessments (the member does not have to meet all of these parameters, but each assessment must be submitted, and provider must indicate which parameters are met and being preserved, must be at least one):
    - Stable cardiac function LVEF > 40% by echo
    - Scoliosis not requiring surgery
    - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
    - The provider must submit baseline motor milestone score results from at least ONE the following assessments:
        - 6-minute walk test (6MWT)
        - North Star Ambulatory Assessment (NSAA)
        - Motor Function Measure (MFM)
        - Hammersmith Functional Motor Scale (HFMS)
        - Performance of Upper Limb (PUL)
        - 4 stair climb (4SC)
- The member must have ONE of the following significant intolerable adverse effects to prednisone supported by documentation:
    i. Cushingoid appearance
    ii. Central (truncal) obesity
    iii. Severe behavioral adverse effect
    iv. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
    v. Diabetes and/or hypertension that is difficult to manage

Non-Preferred Agent Criteria:

- Please provide explanation with the request why the preferred agent cannot be used (subject to clinical review)

<u>Renewal Criteria – Approval Duration:</u> 12 months

- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, including the following assessments (the member does not have to meet all of these parameters, but each assessment must be submitted, and provider must indicate which parameters are met and being preserved, must be at least one):
    - Stable cardiac function LVEF > 40% by ECHO
    - Scoliosis not requiring surgery
    - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
    - Motor function assessment
        - 6MWT – improvement of 35 meters from baseline
        - NSAA – improvement of 2 points from baseline
        - MFM – improvement of 2 points from baseline
        - HFMS – improvement of 2 points from baseline
        - PUL – improvement of 4 points from baseline
        - 4SC – improvement of 1 second from baseline
- The member must have had improvement of adverse effects experienced on prednisone supported by documentation:
    i. Cushingoid appearance
    ii. Central (truncal) obesity
    iii. Severe behavioral adverse effect
    iv. Undesirable weight gain (>10% of body weight gain increase over 6-month period)

v. Diabetes and/or hypertension that is difficult to manage

References:

1. Muntoni, Francesco, et al. "Meaningful changes in motor function in Duchenne muscular dystrophy (DMD): A multi-center study." *PloS one* 19.7 (2024): e0304984.

Histone Deacetylase Inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUVYZAT (givinostat)	this space intentionally left blank

Prior Authorization Criteria

Prior Authorization Form – Duchenne Muscular Dystrophy

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders.
- The member must be assigned male at birth.
- The diagnosis must be confirmed by the presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene (must be confirmed in addition to a positive newborn screening).
- The member must have a baseline 6-Minute Walk Time (6MWT) ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
- Weight and calculated dose must be provided consistent with approved FDA dose.
- The provider must submit baseline motor milestone score results from at least ONE the following assessments:
  - North Star Ambulatory Assessment (NSAA)
  - 4-stair claim (4SC)
- The member is on a stable dose of corticosteroids for the past 3 months, as evidenced by paid claims or pharmacy print outs.

Renewal Criteria – Approval Duration: 12 months

- The member must have maintained a 6MWT ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, subject to clinical review, including:
  - North Star Ambulatory Assessment (NSAA)
  - 4-stair claim (4SC)

Genetic Therapies

Adeno-Associate Virus Vector

PA REQUIRED
ELEVIDYS (delandistrogene moxeparvovec-rokl) – *Medical Billing*

Exon 45 Skipping

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMONDYS 45 (casimersen) – *Medical Billing*	this space intentionally left blank

Exon 51 Skipping

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EXONDYS 51 (eteplirsen) – *Medical Billing*	this space intentionally left blank

Exon 53 Skipping

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VILTEPSO (viltolarsen) – *Medical Billing*	VYONDYS 53 (golodirsen) – *Medical Billing*

High-Cost Drug:

Amondys 45, Exondys 51, and Vyondys 53 cost $758,000 per year for a 30 kg child.
Viltepso cost $733,200 per year for a 30 kg child.
Elevidys is a once-per-lifetime treatment that costs > $3 million.

- Amondys 45 is awaiting verification of clinical benefit in confirmatory trials. In Study 1 (NCT02500381), individuals treated with Amondys 45 observed an increase in mean dystrophin protein levels of 0.81%, while the placebo arm observed a mean increase of 0.22%.
- Exondys 51 is awaiting verification of clinical benefit in confirmatory trials. In Study 1, there was no significant difference in change in 6MWD in patients treated with Exondys 51 and placebo. All 12 individuals enrolled in Study 1, continued treatment with open-label Exondys 51 and were compared to an external control group. Study 2 failed to provide evidence of a clinical benefit of Exondys 51 compared to the external control group. In Study 3, the median increase in dystrophin level was 0.1% in 12 evaluable individuals receiving open-label Exondys 51.
- Viltepso is awaiting verification of clinical benefit in confirmatory trials. In Study 1 (NCT02740972), 8 individuals treated with Viltepso observed a mean increase in dystrophin of 5.3% of normal levels.
- Vyondys 53 is awaiting verification of clinical benefit in confirmatory trials. In Study 1 (NCT02310906), 25 individuals treated with Vyondys 53 observed a mean increase in dystropin of 0.92% of normal levels.
- Elevidys is awaiting verification of clinical benefit in confirmatory trials. This gene therapy received traditional approval for ambulatory patients aged 4 years and older, and accelerated approval for non-ambulatory patients in the same age group. However, this decision was made despite the drug failing to meet its primary endpoint in a pivotal Phase III clinical trial. Consider also: administering adeno-associated virus (AAV) vector therapy to patients may prevent them from accessing future, potentially more effective gene therapies, as it can lead to the development of neutralizing antibodies against the viral vector.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 8 weeks

- Clinical justification must be provided explaining the expected benefit given the evidence of safety and efficacy for the requested product (subject to clinical review).

Elevidys only

- The member must be assigned male at birth and be between the ages of 4 and 7
- The requested medication must be prescribed by, or in consult with, a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- Diagnosis must be confirmed by the presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene (must be confirmed in addition to a positive newborn screening)
- The member cannot have any deletion in exon 8 and/or exon 9 in the DMD gene
- The member does not have an elevated anti-AAVrh74 total binding antibody titer ≥ 1:400
- The member must be ambulatory as confirmed by the North Star Ambulatory Assessment (NSAA) scale (score of ≥ 1)
- The member is not on concomitant therapy with DMD-directed antisense oligonucleotides (e.g., golodirsen, casimersen, viltolarsen, eteplirsen)

All Other Agents

- The member must be assigned male at birth and be between ages of 4 and 19 years old
- Diagnosis must be confirmed by the presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene (must be confirmed in addition to a positive newborn screening)
- The requested medication must be prescribed by, or in consult with, a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- The member has had an inadequate treatment response with standard corticosteroid therapy for a minimum of 6 months with adherence, as evidenced by paid claims or pharmacy printouts
- The member must meet the following parameters:
    - A baseline 6-Minute Walk Time (6MWT) ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
    - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
    - Stable cardiac function – LVEF > 40 % by ECHO
- Weight and calculated dose must be provided consistent with approved FDA dose
- The member must not be taking any other RNA antisense agent or any other gene therapy, including Elevidys

Non-Preferred Agent Criteria

- Please provide explanation with the request why the preferred agent cannot be used (subject to clinical review)

<u>Renewal Criteria – Approval Duration:</u> 12 months (Elevidys is for one-time use only and will not be renewed)

- The member must meet the following parameters:
    - A 6MWT ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
    - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
    - Stable cardiac function – LVEF > 40 % by ECHO

Huntington's Disease

PA REQUIRED

AUSTEDO (deutetrabenazine)
AUSTEDO XR (deutetrabenazine)
INGREZZA (valbenazine)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a neurologist or psychiatrist.
- The member must have failed a 3-month trial of tetrabenazine, as evidenced by paid claims or pharmacy printouts.

Hypersomnolence (Narcolepsy and Idiopathic Hypersomnia)

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED AGENTS (PA REQUIRED)
armodafinil	SUNOSI (solriamfetol)	NUVIGIL (armodafinil)
modafinil	XYREM (sodium oxybate) *– Brand Required*	PROVIGIL (modafinil)
this space intentionally left blank	this space intentionally left blank	sodium oxybate
this space intentionally left blank	this space intentionally left blank	WAKIX (pitolisant)
this space intentionally left blank	this space intentionally left blank	XYWAV (sodium, calcium, magnesium, potassium oxybate)

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Electronic Step Therapy Required

- Sunosi and Xyrem:
  - PA Not Required Criteria: A 30-day supply of armodafinil or modafinil has been paid within 60 days prior to preferred step 1 agent's date of service.
  - PA Required Criteria: The member must have failed a 30-day trial of armodafinil or modafinil, as evidenced by paid claims or pharmacy printouts.
- Wakix requires titration to 17.8 mg dose with 4.45 mg tablets.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed 30-day trials of each preferred agent (except Sunosi for idiopathic hypersomnia) and at least 1 additional CNS stimulant indicated for treatment of narcolepsy, as evidenced by paid claims or pharmacy printouts
- Documentation of each treatment failure must be provided, as evidenced by one of the following:
  - Multiple Sleep Latency Test (MSLT) <8 minutes
  - EPWORTH sleepiness scale score ≥10
- Xywav Only:

- The member must have failed a 30-day trial with Wakix, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to Xyrem due to sodium content (subject to clinical review).

Renewal Criteria – Approval Duration: 12 months

- The member must have received a therapeutic response, as evidenced by one of the following, while on prior treatments:
  - Multiple Sleep Latency Test (MSLT) < 8 minutes
  - EPWORTH sleepiness scale score ≥10

Therapeutic Duplication

- Sunosi and Wakix are not allowed together.
- Provigil and Nuvigil are not allowed together.
- Xyrem and Xywav are not allowed with each other, sleeping medication or benzodiazepines.

Underutilization

- Wakix, Sunosi, and Xywav must be used adherently and will reject on point of sale for late fill.

Migraine

Prophylaxis of Episodic Migraine

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

PREFERRED AGENTS (PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AIMOVIG (erenumab-aooe)	NURTEC ODT (rimegepant) TABLETS	QULIPTA (atogepant) TABLETS
AJOVY (fremanezumab-vfrm)	this space intentionally left blank	VYEPTI (eptinezumab-jjmr) – *Medical Billing*
EMGALITY (galcanazumab-gnlm)	this space intentionally left blank	this space intentionally left blank

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 6 months

- The member must experience 3 or more migraine days per month.
- The member must have failed 2-month trials of at least two of the following agents from different therapeutic classes, as evidenced by paid claims or pharmacy printouts:
  - amitriptyline, atenolol, candesartan, divalproex sodium, metoprolol, nadolol, propranolol, topiramate, venlafaxine, zonisamide

- *Nurtec ODT Only:*
    - The member must have failed a 3-month trial of Ajovy and Emgality, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agents Criteria:

- *Qulipta Only:*
    - The member must have failed a 3-month trial of Ajovy, Emgality, Aimovig, and Nurtec ODT, as evidenced by paid claims or pharmacy printouts.
- *Vyepti Only:*
    - The member must have failed a 3-month trial of Ajovy, Emgality, Aimovig, Qulipta and Nurtec ODT, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced at least a 50% reduction in migraine frequency, pain intensity, or duration from baseline.

Prophylaxis of Chronic Migraine

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AIMOVIG (erenumab-aooe)	QULIPTA (atogepant) TABLETS
AJOVY (fremanezumab-vfrm)	VYEPTI (eptinezumab-jjmr) – *Medical Billing*
EMGALITY (galcanazumab-gnlm)	this space intentionally left blank

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 6 months

- The member must experience 3 or more migraine days per month.
- The member must have failed a 2-month trial of at least two of the following agents from different therapeutic classes, as evidenced by paid claims or pharmacy printouts:
    - amitriptyline, atenolol, candesartan, divalproex sodium, metoprolol, nadolol, propranolol, topiramate, venlafaxine, zonisamide

Non-Preferred Agents Criteria:

- *Qulipta Only:*
    - The member must have failed a 3-month trial of Ajovy, Emgality, and Aimovig, as evidenced by paid claims or pharmacy printouts.
- *Vyepti Only:*
    - The member must have failed a 3-month trial of Ajovy, Emgality, Aimovig, and Qulipta, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced at least a 50% reduction in migraine frequency, pain intensity, or duration from baseline.

Treatment of Migraine

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

Therapeutic Duplication

- One strength of one medication for treatment of migraine is allowed at a time.

Oral

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NURTEC ODT (rimegepant)	this space intentionally left blank
UBRELVY (ubrogepant)	this space intentionally left blank

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 3 months

- The member must have failed a 30-day trial of two triptans (5HT-1 Agonists) of unique ingredients, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agents Criteria:

- The member must have failed a 30-day trial of the preferred agent, as evidenced by paid claims or pharmacy printouts.

Nasal

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	ZAVZPRET NASAL SPRAY (zavegepant)

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 3 months

- The member must have failed each of the following:
  - a 30-day trial of two oral triptans (5HT-1 Agonists) of unique ingredients, two nasal triptans of unique ingredients, and an injectable triptan, as evidenced by paid claims or pharmacy printouts.a 30-day trial of Nurtec ODT and Ubrelvy, as evidenced by paid claims or pharmacy printouts.

Non-Steroidal Anti-inflammatory Drugs (NSAIDS)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NSAIDS	diclofenac potassium powder packet (generic Cambia)

this space intentionally left blank	ELYXYB (celecoxib)

Prior Authorization Criteria:

- See Preferred Dosage Form criteria

Ergot Alkaloids

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dihydroergotamine nasal spray	BREKIYA (dihydroergotamine) INJECTION
ERGOMAR (ergotamine) SL TABLET	dihydroergotamine injection
this space intentionally left blank	MIGERGOT (ergotamine/caffeine) RECTAL SUPPOSITORY

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 3 months

- The member must have failed a 30-day trial of two triptans (5HT-1 Agonists) of unique ingredients, as evidenced by paid claims or pharmacy printouts.
- The member must have failed a 30-day trial of a treatment CGRP receptor agonist, as evidenced by paid claims or pharmacy printouts.

Migergot rectal suppository and dihydroergotamine injection only:

- The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.

Bekiya injection only:

- The member must have failed a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
    - Dihydroergotamine nasal spray
    - Ergomar SL tablet
    - dihydroergotamine injection
    - Migergot rectal suppository

Therapeutic Duplication

- One strength of one medication for treatment of migraine is allowed at a time

Triptans (5HT-1 Agonists)

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
RELPAX (eletriptan) – *Brand Required*	FROVA (frovatriptan) TABLET – *Brand Required*	almotriptan tablet
rizatriptan tablet	naratriptan tablet	eletriptan tablet
sumatriptan tablet	zolmitriptan tablet	frovatriptan tablet
this space intentionally left blank	this space intentionally left blank	IMITREX (sumatriptan) TABLET
this space intentionally left blank	this space intentionally left blank	MAXALT (rizatriptan) TABLET
this space intentionally left blank	this space intentionally left blank	sumatriptan/naproxen tablet
this space intentionally left blank	this space intentionally left blank	SYMBRAVO (rizatriptan/meloxicam) TABLET
this space intentionally left blank	this space intentionally left blank	ZOMIG (zolmitriptan) TABLET

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Non-Preferred Step 1 Agents:

- The member must have failed a 30-day trial of rizatriptan, as evidenced by paid claims or pharmacy printouts.
- Members over 18 years old: The member must also have failed a 30-day trial of sumatriptan and eletriptan, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Step 2 Agents:

- The member must have failed a 30-day trial of each available preferred and non-preferred step 1 triptan agents, as evidenced by paid claims or pharmacy printouts
- For Symbravo: Clinical justification must be provided explaining why the member cannot use individual preferred products separately or preferred agent.

Therapeutic Duplication

- One strength of one medication for treatment of migraine is allowed at a time

Non-Solid Oral Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rizatriptan ODT	MAXALT MLT (rizatriptan)
this space intentionally left blank	zolmitriptan ODT

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of rizatriptan ODT, as evidenced by paid claims or pharmacy printouts.

Therapeutic Duplication

- One strength of one medication for treatment of migraine is allowed at a time

Nasal Spray

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
zolmitriptan spray	sumatriptan spray
this space intentionally left blank	TOSYMRA (sumatriptan) NASAL SPRAY
this space intentionally left blank	ZOMIG (zolmitriptan) NASAL SPRAY

Injectable

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
sumatriptan injectable	IMITREX (sumatriptan) INJECTABLE
this space intentionally left blank	ZEMBRACE SYMTOUCH (sumatriptan)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must be unable to take oral medications or experience nausea/emesis with oral triptans (subject to clinical review).
- Sumatriptan 6 mg Injectable and Nasal Spray Only:
    - The member must have failed a 30-day trial with zolmitriptan nasal spray, as evidenced by paid claims or pharmacy printouts.
- Sumatriptan 4 mg and Zembrance Symtouch Injectable Only:
    - The member must have failed a 30-day trial with each of the following: zolmitriptan nasal spray, sumatriptan 6 mg injectable and nasal spray, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agent Criteria:

- See Preferred Dosage Form criteria

Therapeutic Duplication

- One strength of one medication for treatment of migraine is allowed at a time

Cluster Headache

Cluster Headache Prevention

PA REQUIRED
EMGALITY (galcanazumab-gnlm)

- Emgality is to be used as preventative treatment during episodic cluster headache episodes (cluster periods usually last between 2 weeks and 3 months with pain-free periods lasting at least 3 months), as it is not indicated for chronic use

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 3 months

- The member has had at least five attacks fulfilling criteria A-D
  - A. Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting at least 15 minutes
  - B. Occurring with a frequency of at least every other day
  - C. At least two cluster periods lasting longer than one month and separated by pain-free remission periods of at least three months.
  - D. The member must have at least one of the following:
    - A sense of restlessness or agitation
    - Any of the following symptoms or signs, ipsilateral to the headache:
      - Conjunctival injection and/or lacrimation
      - Nasal congestion and/or rhinorrhea
      - Eyelid edema
      - Forehead and facial swelling
      - Miosis and/or ptosis
- The member must have had 2-month trials with each of the following, as evidenced by paid claims or pharmacy printouts:
  - Topiramate
  - Verapamil

Myasthenia Gravis

Glucocorticoid-Sparing Therapy

Oral Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine	this space intentionally left blank
cyclosporine	this space intentionally left blank
mycophenolate mofetil	this space intentionally left blank
tacrolimus	this space intentionally left blank

Biologic Agents

Acetylcholine Receptor (AChR) Antibody Positive

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rituximab - See Biosimilar Agents	eculizumab - See Biosimilar Agents
PREFERRED AGENTS (PA REQUIRED)	this space intentionally left blank
IMAAVY (nipocalimab-aahu) – *Medical Billing*	this space intentionally left blank
RYSTIGGO (rozanolixizumab-noli) – *Medical Billing*	this space intentionally left blank
UPLIZNA (inebilizumab) – *Medical Billing*	this space intentionally left blank
ULTOMIRIS (ravulizumab-cwvz) – *Medical Billing*	this space intentionally left blank
VYVGART (ergartigimod alfa) – *Medical Billing*	this space intentionally left blank
VYVGART HYTRULO (efgartigimod alfa/hyaluronidase) syringes	this space intentionally left blank
VYVGART HYTRULO (efgartigimod alfa/hyaluronidase) – *Medical Billing*	this space intentionally left blank
ZILBRYSQ (zilucoplan)	this space intentionally left blank

Muscle Specific Kinase (MuSK) Positive

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rituximab - See Biosimilar Agents	IMAAVY (nipocalimab-aahu) – *Medical Billing*
this space intentionally left blank	RYSTIGGO (rozanolixizumab-noli) – *Medical Billing*
PREFERRED AGENTS (PA REQUIRED)	UPLIZNA (inebilizumab) – *Medical Billing*
VYVGART (ergartigimod alfa) – *Medical Billing*	this space intentionally left blank
VYVGART HYTRULO (efgartigimod alfa/hyaluronidase) syringes	this space intentionally left blank
VYVGART HYTRULO (efgartigimod alfa/hyaluronidase) – *Medical Billing*	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months (1 year total for bridge therapy)

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, a neurologist or neuromuscular specialist.
- The member must have all of the following:
  - Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II, III, or IV
  - Positive serological lab test for one of the following (A or B):
    A. Anti-AchR antibodies
    B. Anti-MuSK antibodies
- The member must have Myasthenia Gravis-specific Activities of Daily Living (MG-ADL) total score of one of the following:
  - For Zilbrysq (zilucoplan), eculizumab, Imaavy (nipocalimab-aahu), Uplizna (inebilizumab-cdon), or Ultomiris (ravulizumab-cwvz) requests: ≥ 6

- For Vyvgart (efgartigimod alfa-fcab) or Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) requests: ≥ 5
- For Rystiggo (rozanolixizumab-noli) requests: ≥ 3 (with at least 3 points from non-ocular symptoms)

Acetylcholine Receptor (AChR) Antibody Positive

- One of the following (A or B):
  A. The member is unable to complete glucocorticoid bridge therapy (e.g., diabetes) while waiting for efficacy of oral immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus)
  B. The member required chronic intravenous immunoglobulin (IVIG) or chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control), despite a 12-month trial (total duration) of immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus), as evidenced by paid claims or pharmacy printouts.
- Soliris Only:
  - The member required chronic intravenous immunoglobulin (IVIG) or chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control), despite a 90-day trial or recommended cycle duration of each of the following, as evidenced by paid claims or pharmacy printouts:
    A. Rituximab
    B. Ultomiris
    C. Vyvgart or Rystiggo

Muscle Specific Kinase (MuSK) Positive

- The member required chronic intravenous immunoglobulin (IVIG) or chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control), despite a 90-day trial of rituximab and Vyvgart, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by one of the following scores and symptoms (subject to clinical review):
  - Decreased rate of Myasthenia Gravis exacerbations
  - A 2-point improvement in the member's total MG-ADL score

Multiple Sclerosis

Injectable Agents

B-cell and T-cell Therapies

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BRIUMVI (ublituximab-xiiy) – *Medical Billing*	(natalizumab) – See Biosimilar Agents	cladribine tablets

KESIMPTA (ofatumumab)	LEMTRADA (alemtuzumab) – *Medical Billing*	MAVENCLAD (cladribine) – *Brand Required*
OCREVUS (ocrelizumab) – *Medical Billing*	this space intentionally left blank	this space intentionally left blank
OCREVUS ZUNOVO (ocrelizumab) – *Medical Billing*	this space intentionally left blank	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Natalizumab and Lemtrada Only:

- The requested medication must be prescribed by, or in consult with, a neurologist

Cladribine Only:

- The member must have failed a 3-month trial of Briumvi, Kesimpta, and Ocrevus, as evidenced by paid claims or pharmacy print outs.
- One of the following must be met:
  - The member must have failed 3-month trials of natalizumab and alemtuzumab, as evidenced by paid claims or pharmacy print outs.
  - Clinical justification must be provided why the member can't trial natalizumab or alemtuzumab (subject to clinical review).

Interferons:

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVONEX (interferon beta-1A)	BETASERON (interferon beta-1B)
this space intentionally left blank	REBIF (interferon beta-1A)
this space intentionally left blank	PLEGRIDY (peginterferon beta-1A)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of the preferred agent in the class of the requested product, as evidenced by paid claims or pharmacy print outs.
- Plegridy Only: The member must have failed a 3-month trial of Rebif, as evidenced by paid claims or pharmacy printouts.

Non-Interferons

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COPAXONE (glatiramer) 20 MG/ML – *Brand Required*	COPAXONE (glatiramer) 40 MG/ML
this space intentionally left blank	glatiramer 20 mg/ml
this space intentionally left blank	glatiramer 40 mg/ml
this space intentionally left blank	GLATOPA (glatiramer)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Copaxone: See Preferred Dosage Form criteria

Oral Agents

Fumerates

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dimethyl fumarate	BAFIERTAM (monomethyl fumarate)
this space intentionally left blank	TECFIDERA (dimethyl fumarate)
this space intentionally left blank	VUMERITY (diroximel fumarate)

Pyrimidine Synthesis Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
teriflunomide	AUBAGIO (teriflunomide)

Sphingosine 1-Phosphate (S1P) Receptor Modulators

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fingolimod 0.5 mg	GILENYA (fingolimod) 0.5 MG
GILENYA (fingolimod) 0.25 MG	MAYZENT (siponimod)
TASCENSO ODT (fingolimod)*Requires PA	PONVORY (ponesimod)
this space intentionally left blank	ZEPOSIA (ozanimod)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of all oral preferred agents of an unique ingredient, as evidenced by paid claims or pharmacy print outs.
- Mayzent: The member must have failed a 3-month trial of Zeposia, as evidenced by paid claims or pharmacy print outs.
- Ponvory: The member must have failed a 3-month trial of Zeposia and Mayzent, as evidenced by paid claims or pharmacy print outs.
- Tascenso ODT: See Non-Solid Dosage Forms

Neuromyelitis Optica Spectrum Disorder

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rituximab - See Biosimilar Agents	ENSPRYNG (satralizumab-mwge)	eculizumab - See Biosimilar Agents

this space intentionally left blank	ULTOMIRIS (ravulizumab-cwvz) – *Medical Billing*	this space intentionally left blank
this space intentionally left blank	UPLIZNA (inebilizumab) – *Medical Billing*	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, a neurologist
- The member has a positive serologic test for aquaporin-4 (AQP4)-Immunoglobulin G (IgG) antibodies
- The member must have one of the core clinical characteristics from the following:
  - Optic neuritis
  - Acute myelitis
  - Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
  - Acute brainstem syndrome
  - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

Non-Preferred Agents Criteria

- The member must have failed a 3-month trial with Enspryng, Ultomiris and Uplizna, as evidenced by paid claims or pharmacy print outs:

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, subject to clinical review, including:
  - Reduction in relapse rate
  - Reduction in symptoms (such as pain, fatigue, motor function)

Pseudobulbar Affect (PBA)

PA REQUIRED
NUEDEXTA (dextromethorphan/quinidine)

Prior Authorization Criteria

Prior Authorization Form – Nuedexta

Initial Criteria – Approval Duration: 3 months

- The member must not have a diagnosis of any of the following: prolonged QT interval, heart failure, or complete atrioventricular (AV) block.
- The following must be provided:
  - Baseline Center for Neurological Studies lability (CNS-LS) score
  - Baseline weekly PBA episode count

- The member must have diagnosis of pseudobulbar affect (PBA) due to one of the following neurologic conditions and meet additional criteria for diagnosis:
    - Amytrophic Lateral Sclerosis (ALS)
    - Multiple Sclerosis (MS)
    - Alzheimer's Disease
    - Parkinson's Disease
    - Stroke
    - Traumatic Brain Injury (TBI)
- For diagnosis of PBA secondary to a neurological condition *other than* Amytrophic Lateral Sclerosis or Multiple Sclerosis:
    - Neurologic condition must have been stable for at least 3 months
    - Member must have failed a 3-month trial of at least one medication from each of the following classes, as evidenced by paid claims or pharmacy print outs:
        - SSRIs: sertraline, fluoxetine, citalopram and paroxetine
        - Tricyclic Antidepressants: nortriptyline and amitriptyline
    - Documentation of each treatment failure of SSRI and tricyclic antidepressant must be provided, as evidenced by a PBA episode count and CNS-LS score before and after each trial showing one of the following:
        - PBA count has not decreased by more than 75 percent from baseline
        - CNS-LS score has not decreased by more than 7 points from baseline

Renewal Criteria – Approval Duration: 6 months

- Benefit of continued therapy must be assessed.
    - Spontaneous improvement of PBA occurs and should be ruled out periodically before continuing medication.
- For diagnosis of PBA secondary to a neurological condition other than Amytrophic Lateral Sclerosis or Multiple Sclerosis:
    - Current CNS-LS score must be reduced by at least 30% from baseline
- For all other indications:
    - Current PBA episode must be reduced by at least 75% from baseline

Parkinson's disease

Parkinson's Agents – First Line Therapy

Parkinson's Agents – Levodopa

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
carbidopa-levodopa-entacapone 25 mg/100 mg, 37.5 mg/150 mg, 50 mg/200 mg	carbidopa-levodopa ER capsule
carbidopa-levodopa	carbidopa-levodopa-entacapone 12.5 mg/50 mg, 18.75 mg/75 mg, 31.25 mg/125 mg
carbidopa-levodopa ER	CREXONT (carbidopa-levodopa ER)
carbidopa-levodopa ODT	DHIVY (carbidopa-levodopa)
RYTARY (carbidopa-levodopa) ER CAPSULE – *Brand Required*	SINEMET (carbidopa-levodopa) TABLET

this space intentionally left blank	STALEVO (carbidopa-levodopa-entacapone)

Prior Authorization Criteria

- See Preferred Dosage Form criteria

Parkinson's Agents – Adjunctive Therapy

Parkinson's Agents – Adenosine Receptor Agonists

Oral

PA REQUIRED
NOURIANZ (Istradefylline)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months
- The requested medication must be prescribed by, or in consult with, a neurologist
- The member has a minimum of 3 hours of "off" time per day despite a 3-month trial at least 1 g/day or frequency of 5x per day of levodopa/carbidopa in combination with at least one of the following: a dopamine agonist, a COMT inhibitor, a MOA-B inhibitor, and amantadine, as evidenced by paid claims or pharmacy printouts.
- The member has had a previous response to levodopa.

Renewal Criteria – Approval Duration: 12 months
- The member has had either a 50% reduction or 3-hour reduction in hours per day of "off" time.

Parkinson's Agents - Amantadine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amantadine IR capsule	amantadine IR tablet
amantadine solution	GOCOVRI (amantadine ER)
this space intentionally left blank	OSMOLEX ER (amantadine ER)

Electronic Age Verification:

- Amantadine: Member must be 18 years old or older

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- The member must not reside in facility where medications are managed such as skilled nursing care.
- See Preferred Dosage Form Criteria

Parkinson's Agents – Anticholinergics

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
benztropine	COGENTIN (benztropine)
trihexyphenidyl	this space intentionally left blank

Parkinson's Agents – COMT inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
entacapone	COMTAN (entacapone)
this space intentionally left blank	ONGENTYS (opicapone)
this space intentionally left blank	tolcapone

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each of the preferred agents, as evidenced by paid claims or pharmacy printouts.

Parkinson's Agents – Ergot Dopamine Receptor Agonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Bromocriptine	PARLODEL (bromocriptine)

Parkinson's Agents – MAO-B Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Rasagiline	AZILECT (rasagiline)
selegiline	EMSAM (selegiline) PATCH
ZALAPAR ODT (selegiline)	XADAGO (safinamide)

Prior Authorization Criteria

Emsam Only:

- See Preferred Dosage Form and Non-Solid Oral Dosage form criteria

Xadago Only:

- *Initial Criteria – Approval Duration: 3 months*
  - The requested medication must be prescribed by, or in consult with, a neurologist
  - The member has a minimum of 3 hours of "off" time per day despite a 3-month trial at least 1 g/day or frequency of 5x per day of levodopa/carbidopa in combination with at least one of the following: a dopamine agonist, a COMT inhibitor, a MOA-B inhibitor, and amantadine, as evidenced by paid claims or pharmacy printouts.
  - The member has had a previous response to levodopa.
- *Renewal Criteria – Approval Duration: 12 months*

- The member has had either a 50% reduction or 3-hour reduction in hours per day of “off” time.

Parkinson’s Agents – Non-ergot Dopamine Receptor Agonists

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pramipexole IR	MIRAPEX (pramipexole)
ropinirole IR	MIRAPEX ER (pramipexole)
ropinirole ER	pramipexole ER
this space intentionally left blank	REQUIP (ropinirole)

Topical

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	NEUPRO (rotigotine) PATCH

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must not reside in facility where medications are managed such as skilled nursing care.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).
- Pramipexole ER: See Preferred Dosage Form criteria

Parkinson’s Agents – Device-Assisted Refractory Therapies

Enteral Suspension

PA REQUIRED
DUOPA (levodopa/carbidopa)

Subcutaneous

PA REQUIRED
ONAPGO (apomorphine)
VYALEV (foscarbidopa/foslevodopa)
VYALEV (foscarbidopa/foslevodopa) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, a neurologist
- The member has a minimum of 3 hours of “off” time per day despite a 3-month trial at least 1 g/day or frequency of 5x per day of levodopa/carbidopa in combination with at least one of the following: a dopamine agonist, a COMT inhibitor, a MOA-B inhibitor, and amantadine, as evidenced by paid claims or pharmacy printouts.
- The member has had a previous response to levodopa.

Renewal Criteria – Approval Duration: 12 months

- The member has had either a 50% reduction or 3-hour reduction in hours per day of "off" time.

Parkinson's Agents – On-Demand Rescue for "Off" Episodes

Subcutaneous

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APOKYN (apomorphine) – *Brand Required*	apomorphine

Inhalation

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
INBRIJA (levodopa)	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a neurologist
- The member must be currently taking carbidopa – levodopa, as evidenced by paid claims or pharmacy printouts, and will continue taking carbidopa – levodopa concurrently with requested agent
- The number and frequency of intermittent hypomobility or off episodes must be provided.
- At least one of the following criteria must be met:
  - The member is experiencing unpredictable off periods, morning off, delayed on, no on or failure of on response
  - The member is experiencing wearing off episodes or other levodopa dose cycle related dystonias or akathisias, and a treatment adjustment plan is attached (e.g., levodopa dose and interval adjustments, bedtime dose of CR or ER levodopa/ carbidopa, addition of adjunctive therapy)

Spinal Muscular Atrophy (SMA)

SMN2 Gene Splicing Modifiers

PA REQUIRED
EVRYSDI (risdiplam)
SPINRAZA (nusinersen) – *Medical Billing*

Prior Authorization Criteria

Prior Authorization Form – Evrysdi

Initial Criteria – Approval Duration: 12 months

- The member must have a diagnosis of spinal muscular atrophy (SMA) with each of the following:
  - Bi-allelic deletions or mutations of SMN1 as confirmed by genetic testing, reported as one of the following:
    - Homozygous deletions of exon 7

        - Compound heterozygous mutations
    - One of the following:
        - The member has number of SMN2 gene copies ≥ 1 but ≤ 4 as confirmed by genetic testing
        - The member is symptomatic (e.g., loss of reflexes, motor delay, motor weakness, abnormal EMG/neuromuscular ultrasound)
- The requested medication must be prescribed by, or in consult with, a neuromuscular neurologist or neuromuscular physiatrist (medical geneticist may be allowed for initial request)
- The member must visit with a neuromuscular clinic - clinic name and contact information and date of last visit must be provided, and date of last visit must be within the last year (short term 6-month bypass of this criteria may be granted to allow time for appointment scheduling if genetic test showing 0 copies of SMN1 and SMN2 gene copies ≥ 1 but ≤ 4 is provided):
- The member must not require continuous intubation > 3 weeks
- The member must not have received gene therapy (i.e., Zolgensma)
- The member's weight and prescribed dose must be provided and within dosing recommendations per the manufacturer label
- The member's baseline motor milestone score results must be provided from at least two of the following assessments (short term 6-month bypass of this criteria may be granted to allow time for appointment scheduling if genetic test showing 0 copies of SMN1 and SMN2 gene copies ≥ 1 but ≤ 4 is provided):
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND)
    - Hammersmith Infant Neurological Examination (HINE) Section 2 motor milestone score
    - Hammersmith Functional Motor Scale Expanded (HFMSE)
    - Motor Function Measure – 32 items (MFM-32)
    - Revised Upper Limb Module (RULM)
    - 6-minute walk test (6MWT)
    - Forced Vital Capacity (FVC and FEV1) via Pulmonary Function Test

Renewal Criteria – Approval Duration: 12 months

- The member's weight and prescribed dose must be provided and within dosing recommendations per the manufacturer label
- The member must visit with a neuromuscular clinic - clinic name, contact information, and date of last visit must be provided, and date of last visit must be within the last year
- The provider must submit motor milestone score results showing that the member has experienced clinical benefit (defined as maintenance of baseline motor function or significant slowed rate of decline vs expected natural course of the disease) since starting treatment, as evidenced by one of the following:
    - Current Forced Vital capacity (FVC and FEV1) via Pulmonary Function Test
    - CHOP-INTEND, HINE, HFMSE, MFM-32, 6MWT, or RULM scores

Gene Therapy

PREFERRED AGENTS (PA REQUIRED)
ITVISMA (onasemnogene abeparvovec-brve) – *Medical Billing*
ZOLGENSMA (onasemnogene abeparvovec-xioi) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 1 month (Approval is limited to a single intravenous infusion per lifetime)

- Itvisma only:
  - The member is 2 years of age or older.
  - The diagnosis is spinal muscular atrophy (SMA) with genetic testing confirming bi-allelic deletions or mutations in *SMN1* gene
  - The prescriber is a neurologist specialized in neuromuscular disorders or is a medical geneticist in consult with a neurologist specialized in neuromuscular disorders.
  - The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
  - The member is able to sit independently
  - The member is unable to walk independently.
  - The member must not have complete paralysis of limbs
  - The member must not require invasive ventilation, awake noninvasive ventilation for > 6 hours during a 24-hour period, noninvasive ventilation for > 12 hours during a 24-hour period or require tracheostomy
  - Baseline confirmation must be submitted of anti-adeno-associated virus serotype 9 (anti-AAV9) antibody titer is ≤ 1:50 measured by Enzyme-linked Immunosorbent Assay (ELISA) binding immunoassay
- Zolgensma only:
  - The member is less than 2 years of age
  - The diagnosis is spinal muscular atrophy (SMA) with genetic testing confirming bi-allelic deletions or mutations in the *SMN1 gene*
  - The medication is prescribed per the dosing guidelines in the package insert (recommended dose is 1.1×10^{14} vector genomes per kilogram)
  - Baseline confirmation must be submitted of anti-adeno-associated virus serotype 9 (anti-AAV9) antibody titer is ≤ 1:50 measured by Enzyme-linked Immunosorbent Assay (ELISA) binding immunoassay
  - The member must not have advanced SMA evidenced by one of the following
    - Complete paralysis of limbs
    - Permanent ventilator dependence (defined as requiring invasive ventilation (tracheostomy) or respiratory assistance for 16 or more hours per day (including noninvasive ventilatory support) continuously for 14 or more days in the absence of an acute reversible illness, excluding perioperative ventilation.

Tardive Dyskinesia

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AUSTEDO (deutetrabenazine)	this space intentionally left blank
AUSTEDO XR (deutetrabenazine)	this space intentionally left blank
INGREZZA (valbenazine)	this space intentionally left blank

Electronic Step Therapy Required

- The Initiation Pack or 40 mg x 7 days is required for titration to 80 mg capsules.

Prior Authorization Criteria

Prior Authorization Form – Tardive Dyskinesia

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a psychiatric or neurology specialist.
  The member must have a history of treatment with a dopamine receptor blocking agent (DRBA) or dopamine receptor modifier that reduces dopaminergic tone (i.e., a partial agonist).
- The member must have a total AIMS score (items 1-7) of ≥ 6 or AIMS score on item 8 or item 9 ≥ 3

Renewal Criteria – Approval Duration: 12 months

- The member must have had improvement in AIMS score from baseline

Obstetrics/Gynecology

Endometriosis Pain

PA REQUIRED
MYFEMBREE (relugolix, estradiol, and norethindrone acetate)
ORILISSA (elagolix)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts:
  A. A 3-menstrual cycle trial of mefenamic acid or meclofenamate, celecoxib, ibuprofen 1800 mg/day or equivalent high dose NSAID
  B. A 3-menstrual cycle trial of an oral estrogen-progestin or progestin contraceptives

Renewal Criteria – Approval Duration: 18 months

- The member must have received therapeutic response, as evidenced by improvement in pain score from baseline

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Estrogens

Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DELESTROGEN (estradiol valerate) INJECTION *– Brand Required*	estradiol valerate injection
DEPO-ESTRADIOL (estradiol cypionate) INJECTION	this space intentionally left blank

PREMARIN (estrogens, conjugated) INJECTION	this space intentionally left blank

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABIGALE LO (estradiol/norethindrone)	BIJUVA (estradiol-progesterone) CAPSULE
ACTIVELLA (estradiol-norethindrone) TABLET	estrogens, conjugated tablet
estradiol tablet	FYAVOLV (norethindrone-ethinyl estradiol) TABLET
estradiol-norethindrone tablet	JINTELI (norethindrone-ethinyl estradiol) TABLET
norethindrone-ethinyl estradiol tablet	MENEST (estrogens, esterified) TABLET
PREMARIN (estrogens, conjugated) TABLET – *Brand Required*	MIMVEY (estradiol-norgestimate) TABLET
PREMPHASE (estrogen, conj. M-progest) TABLET	this space intentionally left blank
PREMPRO (estrogen, conj. M-progest) TABLET	this space intentionally left blank

Topical Gel/Spray

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DIVIGEL (estradiol) GEL PACKET – *Brand Required*	estradiol gel
ELESTRIN (estradiol) GEL MDP	this space intentionally left blank
EVAMIST (estradiol) SPRAY	this space intentionally left blank

Topical Patch

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CLIMARA PRO (estradiol-levonorgestrel) PATCH - ONCE WEEKLY	DOTTI (estradiol) PATCH TWICE WEEKLY
COMBIPATCH (estradiol- norethindrone) PATCH - TWICE WEEKLY	estradiol patch weekly
CLIMARA (estradiol) PATCH WEEKLY - *Brand Required*	estradiol patch twice weekly
VIVELLE-DOT (estradiol) PATCH TWICE WEEKLY - *Brand Required*	LYLLANA (estradiol) PATCH TWICE WEEKLY
this space intentionally left blank	MENOSTAR (estradiol) PATCH ONCE WEEKLY
this space intentionally left blank	MINIVELLE (estradiol) PATCH TWICE WEEKLY

Vaginal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
estradiol vaginal cream	ESTRACE (estradiol) CREAM
ESTRING (estradiol)	estradiol vaginal tablet
FEMRING (estradiol)	YUVAFEM (estradiol) VAGINAL TABLET

PREMARIN (estrogens, conjugated) CREAM	this space intentionally left blank
VAGIFEM (estradiol) VAGINAL TABLET *– Brand Required*	this space intentionally left blank

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed 30-day trials of at least two preferred products, as evidenced by paid claims or pharmacy printouts.
- See Preferred Dosage Form Criteria

Menopause – Vasomotor Symptoms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
citalopram	LYNKUET (elinzanetant)
clonidine	paroxetine mesylate 7.5mg capsules
desvenlafaxine	VEOZAH (fezolinetant)
escitalopram	this space intentionally left blank
estrogen products	this space intentionally left blank
gabapentin	this space intentionally left blank
oxybutynin	this space intentionally left blank
paroxetine hydrochloride tablets	this space intentionally left blank
venlafaxine	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- BOTH of the following must be met (1 and 2):
  1. One of the following must be met (a or b):
     a. The member must have failed a 90-day trial of estrogen therapy, as evidenced by paid claims or pharmacy printouts
     b. The member has prior history of stroke, myocardial infarction, venous thromboembolism, coronary artery disease, or breast cancer.
  2. The member must have failed a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
     - SNRI: Venlafaxine or desvenlafaxine
     - SSRI: citalopram, escitalopram, or paroxetine
- Paroxetine mesylate: See Preferred Dosage Form criteria

References:

1. Khan SJ, Kapoor E, Faubion SS, Kling JM. Vasomotor Symptoms During Menopause: A Practical Guide on Current Treatments and Future Perspectives. Int J Women's Health. 2023 Feb 14;15:273-287. doi: 10.2147/IJWH.S365808. PMID: 36820056; PMCID: PMC9938702.

Mifepristone

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Form – Mifepristone

Initial Criteria – Approval Duration: 1 month

- Gestational age must be less than or equal to 70 days
- One of the following criteria must be met (A or B):
  - **A. Pregnancy must have resulted from an act of rape or incest, and one of the following (I or II)**
    - I. A written statement signed by the provider must be submitted stating that the rape or act of incest has been reported to the appropriate law enforcement agency, or in the case of a minor who is a victim of incest, to an agency authorized to receive child abuse and neglect reports and it must be indicated to whom the report was made.
    - II. A written statement signed by the member and the provider must be submitted stating that the member's pregnancy resulted from rape or incest and by professional judgement, the provider agrees with the statement.
  - **B. Both of the following must be met (I and II)**
    - I. The member must suffer from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would as certified by a provider, place the member in danger of death unless an abortion is performed
    - II. A written statement signed by the provider must be provided indicating why, in the provider's professional judgement, the life of the member would be endangered if the fetus were carried to term

Nausea/Vomiting – Pregnancy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DICLEGIS (doxylamine/vitamin B6) *– Brand Required*	BONJESTA (doxylamine/vitamin B6)
meclizine	doxylamine/vitamin B6
metoclopramide	this space intentionally left blank
ondansetron	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: until due date

- The member's due date must be provided
- See Preferred Dosage Form criteria

Progesterone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
progesterone capsule	this space intentionally left blank

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Uterine Fibroids

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MYFEMBREE (relugolix, estradiol, and norethindrone acetate)	this space intentionally left blank
ORIAHNN (elagolix, estradiol, and norethindrone acetate)	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts:
  A. A 3-menstrual cycle trial of mefenamic acid or meclofenamate, celecoxib, ibuprofen 1800 mg/day or equivalent high dose NSAID
  B. A 3-menstrual cycle trial of an oral estrogen-progestin or progestin contraceptives

Renewal Criteria – Approval Duration: 18 months

- The member has received therapeutic response as evidenced by improvement in pain score from baseline

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Vaginal Infections

Bacterial Infections

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
metronidazole tablet	metronidazole 125 mg tablet
tinidazole tablet	SOLOSEC (secnidazole)

Vaginal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CLEOCIN (clindamycin) SUPPOSITORY	CLINDESSE (clindamycin) CREAM
CLEOCIN (clindamycin) CREAM – Brand Required	clindamycin cream
metronidazole gel	VANDAZOLE (metronidazole) GEL
NUVESSA (metronidazole) GEL	this space intentionally left blank
XACIATO (clindamycin phosphate) GEL	this space intentionally left blank

Fungal Infections

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluconazole tablet	BREXAFEMME (ibrexafungerp) TABLETS
this space intentionally left blank	VIVJOA (oteseconazole) CAPSULES

Vaginal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
terconazole cream	miconazole 3 suppository
terconazole suppository – labeler 00713	GYNAZOLE 1 (butoconazole) CREAM
this space intentionally left blank	terconazole suppository – labeler 45802

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed trials of all preferred agents of unique ingredients (oral and vaginal), as evidenced by paid claims or pharmacy printouts.
- Vivjoa Only:
  - The member must have failed a six-month trial of oral fluconazole maintenance prophylaxis treatment, as evidenced by paid claims or pharmacy printouts.
  - The member must not be of reproductive potential defined as:
    - The member is postmenopausal
    - The member is known to not be of reproductive potential (e.g., history of tubal ligation, salpingo-oophorectomy, or hysterectomy)

Ophthalmology

Antihistamines

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azelastine	ALOMIDE (lodoxamide)

BEPREVE (bepotastine) – *Brand Required*	bepotastine
cromolyn	epinastine
olopatadine 0.1%	olopatadine 0.2%
this space intentionally left blank	ZERVIATE (cetirizine)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed 30-day trials of olopatadine and bepotastine, as evidenced by paid claims or pharmacy printouts.

Anti-infectives

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BESIVANCE (besifloxacin) DROPS	AZASITE (azithromycin) DROPS
ciprofloxacin drops	gatifloxacin drops
gentamicin sulfate drops	OCUFLOX (ofloxacin) DROPS
moxifloxacin drops (generic Vigamox)	VIGAMOX (moxifloxacin) DROPS
NATACYN (natamycin) DROPS	XDEMVY (lotilaner)
neomycin SU/polymyxin B/gramicidin drops	this space intentionally left blank
ofloxacin drops	this space intentionally left blank
polymyxin B/trimethoprim drops	this space intentionally left blank
sulfacetamide drops	this space intentionally left blank
tobramycin drops	this space intentionally left blank

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bacitracin/polymyxin B ointment	bacitracin ointment
CILOXAN (ciprofloxacin) OINTMENT	NEO-POLYCIN (neomycin SU/bacitracin/polymyxin B) OINTMENT
erythromycin ointment	POLYCIN (bacitracin/polymyxin B) OINTMENT
neomycin SU/bacitracin/polymyxin B ointment	sulfacetamide ointment
TOBREX (tobramycin) OINTMENT	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- *Xdemvy Only:* The member must have failed a 2-dose regimen of oral ivermectin, as evidenced by paid claims or pharmacy printouts.
- *All other agents:* The member must have failed a 5-day trial of a preferred agent in each unique therapeutic class, as evidenced by paid claims or pharmacy printouts.

Anti-infectives/Anti-inflammatories

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
neomycin/polymyxin b/dexamethasone drops	MAXITROL (neomycin/polymyxin b/dexamethasone) DROPS
sulfacetamide/prednisolone drops	neomycin/polymyxin b/hydrocortisone drops
tobramycin/dexamethasone drops	tobramycin-lotepred etab drops
TOBRADEX ST (tobramycin/dexamethasone) DROPS	this space intentionally left blank
ZYLET (tobramycin/lotepred etab) DROPS – *Brand Required*	this space intentionally left blank

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
neomycin/polymyxin b/dexamethasone ointment	BLEPHAMIDE (sulfacetamide/prednisone)
TOBRADEX (tobramycin/dexamethasone) OINTMENT	MAXITROL (neomycin/polymyxin b/dexamethasone) OINTMENT
this space intentionally left blank	neomycin/bacitracin/polymyxin b/hydrocortisone ointment
this space intentionally left blank	NEO-POLYCIN HC (neomycin SU/bacitracin/ polymyxin B/hydrocortisone) OINTMENT
this space intentionally left blank	PRED G S.O.P. (gentamicin/prednisone) OINTMENT

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 5-day trial of a preferred agent in each unique therapeutic class, as evidenced by paid claims or pharmacy printouts.

Anti-inflammatories

Corticosteroids

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALREX (loteprednol) DROPS – *Brand Required*	clobetasol 0.05% drops
DUREZOL (difluprednate) DROPS – *Brand Required*	dexamethasone sodium phosphate drops

FLAREX (fluorometholone) DROPS	difluprednate drops
fluorometholone drops	INVELTYS (loteprednol) DROPS
FML FORTE (fluorometholone) DROPS	fluorometholone drops (labeler 60219)
LOTEMAX (loteprednol) GEL DROPS – *Brand Required*	FML LIQUIFILM (fluorometholone) DROPS
MAXIDEX (dexamethasone) DROPS	LOTEMAX SM (loteprednol) DROPS
PRED MILD 0.12% (prednisolone acetate) DROPS	loteprednol eye drops
prednisolone acetate 1% drops	loteprednol gel eye drops
prednisolone sodium phosphate 1% drops	PRED FORTE 1% (prednisolone acetate) DROPS

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LOTEMAX (loteprednol) OINTMENT	this space intentionally left blank

Non-Steroidal Anti-inflammatory Drugs (NSAIDS)

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diclofenac sodium drops	ACULAR (ketorolac) DROPS
ketorolac 0.5% drops	ACULAR LS (ketorolac) DROPS
NEVANAC (nepafenac) DROPS	ACUVAIL (ketorolac) DROPS
PROLENSA (bromfenac) DROPS – *Brand Required*	bromfenac sodium drops
this space intentionally left blank	BROMSITE (bromfenac sodium) DROPS
this space intentionally left blank	ILEVRO (nepafenac) DROPS
this space intentionally left blank	ketorolac 0.4% drops

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 5-day trial of each preferred agent in the respective therapeutic class, as evidenced by paid claims or pharmacy printouts.

Dry Eye Syndrome

Initial Management - Lubricants

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
See "Wetting Eye Drops" under Covered APIs and OTCs	FRESHKOTE (polyvinyl alcohol/povidone)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 1-month trial of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- See Preferred Dosage Form Criteria

Persistent Symptoms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
EYSUVIS (loteprednol) DROPS	TYRVAYA (varenicline) NASAL SPRAY	CEQUA (cyclosporine)
RESTASIS (cyclosporine) DROPPERETTE – *Brand Required*	this space intentionally left blank	cyclosporine dropperette
XIIDRA (lifitegrast)	this space intentionally left blank	MIEBO (perfluorohexyloctane)
this space intentionally left blank	this space intentionally left blank	RESTASIS MULTIDOSE (cyclosporine)
this space intentionally left blank	this space intentionally left blank	TRYPTYR (acoltremon)
this space intentionally left blank	this space intentionally left blank	VERKAZIA (cyclosporine)
this space intentionally left blank	this space intentionally left blank	VEVYE 0.1% EYE DROP (cyclosporine)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Non-Preferred Step 1 Agents

- The requested medication must be prescribed by, or in consult with, an ophthalmologist.
- The member must have failed a 1-month trial of Eysuvis, a 6-month trial of Restasis and a 2-month trial of Xiidra, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Step 2 Agents:

- The requested medication must be prescribed by, or in consult with, an ophthalmologist.
- The member must have failed a 6-month trial of Restasis and a 2-month trial of Xiidra, and a 1-month trial of Eysuvis and Tyrvaya, as evidenced by paid claims or pharmacy printouts.
- Cyclosporine products: See Preferred Dosage Form criteria
- Tryptyr Only: The member must have failed a 30-day trial of Miebo, as evidenced by paid claims or pharmacy printouts.
- Verkazia Only: The member must have failed a 6-month trial of Vevye, as evidenced by paid claims or pharmacy printouts, and provide clinical justification why Verkazia is expected to have a different outcome (subject to clinical review).

Glaucoma

Alpha Adrenergic

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPHAGAN P 0.1% (brimonidine) DROPS – *Brand Required*	apraclonidine 0.5% drops
ALPHAGAN P 0.15% (brimonidine) DROPS – *Brand Required*	brimonidine 0.1% drops
brimonidine 0.2% drops	brimonidine 0.15% drops
COMBIGAN (brimonidine-timolol) DROPS – *Brand Required*	brimonidine-timolol 0.2%-0.5% drops
SIMBRINZA (brinzolamide/brimonidine) DROPS	IOPIDINE (apraclonidine) 1% DROPS

Beta Blockers

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BETIMOL (timolol) DROPS	betaxolol 0.5% drops
BETOPTIC S (betaxolol) 0.25% DROPS	brimonidine/timolol drops
carteolol drops	COSOPT (dorzolamide/timolol) DROPS
COMBIGAN (brimonidine/timolol) DROPS – *Brand Name Required*	timolol drops once daily
dorzolamide/timolol drops	timolol drops (Betimol generic)
ISTALOL (timolol maleate) DROPS ONCE DAILY – *Brand Required*	timolol gel forming solution
levobunolol drops	TIMOPTIC (timolol maleate) DROPS
timolol maleate drops (Timoptic generic)	TIMOPTIC OCUDOSE (timolol) PF DROPS
timolol maleate/PF drops	TIMOPTIC-XE (timolol gel forming solution)

Prior Authorization Criteria

- See Preferred Dosage Form criteria

Carbonic Anhydrase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AZOPT (brinzolamide) – *Brand Required*	brinzolamide
dorzolamide	COSOPT (dorzolamide/timolol)
dorzolamide/timolol	this space intentionally left blank
SIMBRINZA (brinzolamide/brimonidine)	this space intentionally left blank

Prostaglandins

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
latanoprost	bimatoprost 0.01%
LUMIGAN (bimatoprost) 0.01% - *Brand Required*	bimatoprost 0.03%
ROCKLATAN (netarsudil/latanoprost)	IYUZEH (latanoprost/pf)
this space intentionally left blank	tafluprost/pf
this space intentionally left blank	TRAVATAN Z (travoprost)
this space intentionally left blank	travoprost
this space intentionally left blank	VYZULTA (latanoprostene)
this space intentionally left blank	XALATAN (latanoprost)
this space intentionally left blank	XELPROS (latanoprost)
this space intentionally left blank	ZIOPTAN (tafluprost/pf)
this space intentionally left blank	ZOLYMBUS (bimatoprost/pf)

Prior Authorization Criteria

- The member must have failed a 14-day trial of each of the preferred agents, as evidenced by paid claims or pharmacy printouts.

Rho Kinase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RHOPRESSA (netarsudil)	this space intentionally left blank
ROCKLATAN (netarsudil/latanoprost)	this space intentionally left blank

Presbyopia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pilocarpine 1%, 2%, 4% drops	pilocarpine hydrochloride 1.25% drops
this space intentionally left blank	VUITY (pilocarpine hydrochloride) 1.25% drops

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Preferred Dosage Form criteria
- The requested medication must be prescribed by, or in consult with, an optometrist or ophthalmologist.
- Clinical justification must be provided (subject to clinical review), including contraindication to the use of corrective lenses and how activities of daily living are adversely impacted due to inability to correct vision with corrective lenses.

Renewal Criteria – Approval Duration: 12 months

- Clinical justification must be provided (subject to clinical review), including activities of daily living are positively impacted by drug therapy.

Inherited Retinal Dystrophy

PA REQUIRED
LUXTURNA (alglucosidase alfa) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: Approval Duration: 1 month (once per lifetime per eye)

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, an ophthalmologist or retinal surgeon with experience providing subretinal injections
- The member must have a diagnosis of inherited retinal dystrophy (i.e., Leber's congenital amaurosis [LCA], retinitis pigmentosa [RP]); confirmed by biallelic pathogenic variants in the RPE65 gene by molecular genetic testing
- The member has sufficient viable retinal cells as measured by OCT (optical coherence tomography) defined as one of the following:
  - retinal thickness greater than 100 microns within the posterior pole
  - ≥ 3-disc areas of the retina without atrophy or pigmentary degeneration within the posterior pole
  - remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent
- The member has remaining light perception in the eye(s) that will receive treatment.
- The member has not previously received RPE65 gene therapy in intended eye.

Uveitis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	tocilizumab - See Biosimilar Agents
infliximab - See Biosimilar Agents	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an ophthalmologist or rheumatologist.
- The member has failed a 6-month trial of a preferred agent, as evidenced by paid claims or pharmacy printouts.

Vernal Keratoconjunctivitis

PA REQUIRED
VERKAZIA (cyclosporine) 0.1%

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an allergist or ophthalmologist.
- The member has failed* a 3-month trial of combination of each of the following, as evidenced by paid claims or pharmacy printouts:
  - Topical dual-acting mast cell stabilizers/antihistamines (e.g., olopatadine, azelastine hydrochloride, epinastine, pemirolast potassium, or ketotifen fumarate)
  - Second- and third-generation oral antihistamines (e.g., fexofenadine, loratadine, desloratadine, cetirizine, or levocetirizine)
  - Cyclosporine ophthalmic emulsion 0.05%

  *Failure is defined as requiring frequent or prolonged courses of topical ophthalmic corticosteroids include prednisone acetate 1% and dexamethasone 0.1% for severe cases and prednisolone acetate 0.12%, fluorometholone, medrysone, loteprednol, etabonate 0.2 or 0.5%, and rimexolone 1% or compromised corneal epithelium

Ophthalmology Injection- Complement Inhibitors

PA REQUIRED
IZERVAY (avacincaptad pegol) – *Medical Billing*
SYFOVRE (pegcetacoplan) – *Medical Billing*

Izervay was tested in two key studies (GATHER1 NCT02686658 and GATHER2 NCT04435366) and showed significant reduction in autofluorescence loss at 12 months. However, patients in the treatment groups did not show any improvement in best-corrected visual acuity or low luminance visual acuity compared to placebo.

In two Phase 3 clinical studies of Syfovre (OAKS NCT03525613 and DERBY NCT03525600), at 24 months both studies showed a significant reduction in autofluorescence-detected atrophy compared to placebo. However, there were no functional improvements in visual acuity, reading speed, reading independence, or mean microperimetry sensitivity between the treatment and placebo groups.

Prior Authorization Criteria

For Izervay:

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, an ophthalmologist or retina specialist with experience providing intraocular injections and implants
- The member must be ≥50 years of age
- The member must have a diagnosis of GA not affecting the foveal center point, secondary to AMD
- The member must meet the following requirements:
  - Best-Corrected Visual Acuity (BCVA) between 20/25 and 20/320 in study eye
  - GA lesion size ≥2.5 and ≤17.5 mm2 with at least 1 lesion ≥1.25 mm2
  - Absence of Choroidal neovascularization (CNV) in both eyes

For Syfovre:

Initial Criteria – Approval Duration: 12 months
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, an ophthalmologist or retina specialist with experience providing intraocular injections and implants
- The member must be ≥60 years of age
- The member must meet the following requirements:
  - Best-Corrected Visual Acuity (BCVA) ≥ 24 Early Treatment of Diabetic Retinopathy Study (ETDRS) letters
  - GA lesion size ≥2.5 and ≤17.5 mm2 with at least 1 lesion ≥1.25 mm2
  - Presence of extrafoveal lesions
  - Absence of Choroidal neovascularization (CNV) in both eyes

Renewal Criteria – Approval Duration: 12 months
- The member must have experienced clinical benefit since starting treatment with the requested medication, subject to clinical review

Ophthalmology Injection- VEGF Inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
aflibercept – See Biosimilar Agents	SUSVIMO (ranibizumab) – *Medical Billing*
BEOVU (brolucizumab-dbll) – *Medical Billing*	this space intentionally left blank
EYLEA HD (aflibercept) – *Medical Billing*	this space intentionally left blank
ranibizumab – See Biosimilar Agents	this space intentionally left blank
VABYSMO (faricimab-svoa) – *Medical Billing*	this space intentionally left blank

For the indication: Retinopathy of prematurity

Prior Authorization Criteria

- See Medications that cost over $3000/month criteria

For the indications:
- diabetic macular edema
- macular edema following central retinal vein occlusion
- macular edema following branch retinal vein occlusion
- neovascular (wet) age-related macular degeneration
- diabetic retinopathy (ranibizumab only)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, an ophthalmologist or retina specialist with experience providing intraocular injections and implants
- The member must have a mean visual acuity letter score (VALS) of 70 or Best Corrected Visual Acuity of 20/40 or worse at baseline

- The member must have failed a trial consisting of at least 2 doses of a bevacizumab agent, as evidenced by paid claims or pharmacy printouts.
- For Susvimo only: the member must have previously responded to at least two intravitreal injections of a VEGF inhibitor medication

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced clinical benefit since starting treatment with the requested medication, subject to clinical review, including improvement or stabilization in VALS, defined as a loss of not more than 5 letters compared to baseline.
- The member must have at least a mean VALS of 20 or BCVA of 20/400

Otic

Anti-infectives - Fluoroquinolones

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ofloxacin otic drops	ciprofloxacin otic drops

Anti-infectives/Anti-inflammatories – Fluoroquinolones

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CIPRO HC (ciprofloxacin/hydrocortisone) – *Brand Required*	ciprofloxacin/dexamethasone otic drops++
this space intentionally left blank	ciprofloxacin/hydrocortisone otic suspension
this space intentionally left blank	ciprofloxacin/fluocinolone

++ Please note, for otitis externa with non-intact tympanic membrane, ciprofloxacin (eye drops) and ofloxacin (eye and ear drops) are required preferred agents.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

For ciprofloxacin/dexamethasone only:

- One of the following is met (A or B):
  A. All of the following are met (1, 2 and 3):
     1. The member has tympanostomy tubes
     2. The member has otitis media
     3. There is granulation tissue present
  B. The member must have failed a 7-day trial of each of the preferred agent, as evidenced by paid claims or pharmacy printouts.

All other agents:

- The member must have failed a 7-day trial of each of the preferred agent, as evidenced by paid claims or pharmacy printouts.

Pain

Non-Opioid Pain Medications

Lidocaine Patch

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lidocaine 5% patch	LIDOCAN (lidocaine) 5% PATCH
PREFERRED AGENTS (PA REQUIRED)	LIDODERM (lidocaine) 5% PATCH
ZTLIDO (lidocaine) 1.8% PATCH	TRIDACAINE (lidocaine) 5% PATCH

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of lidocaine 5% patch, as evidenced by paid claims or pharmacy printouts.

Lidocaine Topical

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The request must be for injection pain from a medically necessary procedure

NSAIDS

Oral Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
celecoxib	ARTHROTEC (diclofenac/misoprostol)
diclofenac potassium 50 mg tablet	CELEBREX (celecoxib)
diclofenac sodium DR 50 mg, 75 mg	DAYPRO (oxaprozin)
etodolac	diclofenac potassium 25 mg tablet
flurbiprofen	diclofenac potassium 25 mg capsule
ibuprofen	diclofenac sodium 25 mg DR
indomethacin	diclofenac sodium 100 mg ER tablet
indomethacin ER	diclofenac/misoprostol
ketoprofen IR	etodolac ER
ketorolac	famotidine/ibuprofen
mefenamic acid	FELDENE (piroxicam)
meloxicam	fenoprofen
nabumetone	ketoprofen ER 200 mg
naproxen	LOFENA (diclofenac potassium)

piroxicam	meclofenamate
sulindac	meloxicam, submicronized
this space intentionally left blank	NALFON (fenoprofen)
this space intentionally left blank	NAPRELAN (naproxen)
this space intentionally left blank	naproxen ER 500 mg
this space intentionally left blank	naproxen/esomeprazole
this space intentionally left blank	oxaprozin
this space intentionally left blank	RELAFEN DS (nabumetone)
this space intentionally left blank	tolmetin

Electronic Diagnosis Verification

- Mefenamic acid and Meclofenamate: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- *Non-preferred agents with no same active ingredient preferred:*
  - The member must have failed a 7-day trial of 3 different oral generic NSAIDs, as evidenced by paid claims or pharmacy print outs
    - Trial must include a COX-2 inhibitor if member has experienced GI intolerances
    - Trial must include mefenamic acid if member has dysmenorrhea
- *Non-preferred agents with same active ingredient preferred*:
  - See Preferred Dosage Form Criteria

Therapeutic Duplication

- One strength of one medication is allowed at a time (topical and oral formulations are not allowed together)

If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:

- The member is prescribed ketorolac and will stop regular NSAID therapy during course of ketorolac

Oral Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ibuprofen suspension	indomethacin solution
naproxen suspension	VYSCOXA (celecoxib suspension)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy print outs.

Nasal Dosage Forms

PA REQUIRED
ketorolac nasal spray

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of 3 different oral generic NSAIDs including a COX-2 inhibitor if member has experienced GI intolerances, as evidenced by paid claims or pharmacy print outs
- Clinical justification must be provided explaining why the member is unable to use another dosage form (subject to clinical review).

Topical Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diclofenac gel	diclofenac 1.3% patch
diclofenac topical solution (all other labelers)	diclofenac 2% pump
this space intentionally left blank	diclofenac topical solution (labeler 59088)

Prior Authorization Criteria

- See Preferred Dosage Form criteria
- See Non-Solid Dosage Form criteria

Rectal Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	indomethacin suppository

Prior Authorization Criteria

- See Preferred Dosage Form criteria
- See Non-Solid Dosage Form criteria

Sodium Channel Blockers

PREFERRED AGENTS (NO PA REQUIRED)
JOURNAVX (suzetrigine)

Electronic Age Verification

- The member must be 18 years of age or older.

Electronic Duration Verification

- 14-days allowed per 60 days

First Fill

- Journavx must be filled with a 7-day supply if no previous fill within past 40 days

Therapeutic Duplication

- Concurrent use with opioid medication is not covered

Opioid Pain Medications

The Centers for Disease Control (CDC) have published guidelines for the prescribing of opioids for pain.

Therapeutic Duplication

- One extended-release product/strength is allowed at a time
- One immediate release product is allowed (single ingredient or combination)
- Opioid-acetaminophen combination products are not allowed with acetaminophen
- Carisoprodol: The “Holy Trinity” consists of an opioid, a benzodiazepine, and carisoprodol and is a highly abused dangerous combination that can lead to additive CNS depression, overdose, and death. It is not covered.
- Methadone is not allowed with opioids, benzodiazepines, or opioid use disorder medications
- Morphine is not covered with clopidogrel, prasugrel, ticagrelor, and ticlopidine (does not include other opioid analgesics)
  - Morphine may diminish the antiplatelet effect and serum concentrations of P2Y12 Inhibitor antiplatelet agents (clopidogrel, prasugrel, ticagrelor, and ticlopidine).
- Tramadol immediate release with tramadol extended release

Opioids and Benzodiazepine Concurrent Use

Opioid and Benzodiazepines Concurrent Use Form

- Due to guidance in The SUPPORT for Members and Communities Act (H.R. 6) on CNS depression, this includes long-acting opioids over 90 MME/day or immediate release opioids over 15 MME/dose in combination with benzodiazepines.

Initial Criteria – Approval Duration: 12 months

- The member has access to an opioid reversal medication and has been counseled on overdose risk.

- The member has been counseled on the risks of utilizing opioids and benzodiazepines in combination with each other and other CNS depressing medications, including antipsychotics and sedatives.
- The member must currently be on long-acting opioid therapy or must not have achieved therapeutic goal with non-narcotic medication (NSAIDs, TCAs, SNRIs, corticosteroids, etc.) and non-medication alternatives (weight loss, physical therapy, cognitive behavioral therapy, etc.)
- One of the following criteria must be met:
  - The member resides in a facility with skilled nursing care.
  - The member must have taper plan of one or both agents.
  - The opioid medication must be prescribed by, or in consult with, with a palliative care, oncologist OR pain management specialist with a treatment plan including goals for pain and function, and urine and/or blood screens if the cumulative daily dose of opioids exceeds 90 MME/day (specialist requirement not applicable to skilled nursing facility residents or tapering requests).
- The prescriber(s) of both agents have provided reasons why opioid analgesics and benzodiazepines cannot be avoided, or lower doses be used (subject to clinical review).
- The past 3 months of the member's North Dakota PDMP reports must have been reviewed.

Greater than 90 Morphine Milligram Equivalents (MME) per Day:

Prior Authorization Form – Opioid Analgesics

- A cumulative maximum of 90 MME will be allowed without authorization: MME calculator

Initial Criteria – Approval Duration: 12 months

- One of the following criteria must be met:
  - The member resides in a facility with skilled nursing care.
  - The member must have taper plan of one or both agents.
  - The opioid medication must be prescribed by, or in consult with, with a palliative care, oncologist OR pain management specialist with a pain management contract with a treatment plan including goals for pain and function, and urine and/or blood screens

Opioid Analgesics – Long Acting

Partial Agonist/Antagonist Opioids

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BELBUCA (buprenorphine)	buprenorphine patches
butorphanol	this space intentionally left blank
BUTRANS (buprenorphine) PATCHES - Brand Required	this space intentionally left blank

Abuse Deterrent Formulations/Unique Mechanisms from Full Agonists Opioids

Abuse-Deterrent Opioid Analgesics | FDA

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OXYCONTIN (oxycodone) – Brand Required	CONZIP (tramadol ER) CAPSULES
this space intentionally left blank	hydrocodone ER tablets
this space intentionally left blank	HYSINGLA ER (hydrocodone)
this space intentionally left blank	levorphanol
this space intentionally left blank	methadone
this space intentionally left blank	tramadol ER

Full Agonist Opioids Without Abuse Deterrent Formulations

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fentanyl 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr	fentanyl patch 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr
morphine ER tablets	hydrocodone ER capsules
this space intentionally left blank	hydromorphone ER tablets
this space intentionally left blank	morphine ER capsules
this space intentionally left blank	MS CONTIN (morphine)
this space intentionally left blank	oxycodone ER
this space intentionally left blank	oxymorphone ER tablets
this space intentionally left blank	tapentadol ER

Prior Authorization Criteria

Prior Authorization Form – Opioid Analgesics

Initial Criteria – Approval Duration: 12 months

- The past 3 months of the member's North Dakota PDMP reports must have been reviewed.
- One of the following criteria must be met:
  - The member has access to an opioid reversal medication and has been counseled on overdose risk.
  - The member resides in a facility with skilled nursing care.
- One of the following criteria must be met:
  - The member is currently on a long-acting opioid therapy.
  - The member must have been established on opioid therapy during hospitalization
  - Both of the following are met:
    - The member must have a diagnosis of cancer pain, palliative care, or sickle cell disease.
    - The member must currently be on around-the-clock opioid therapy of at least 30 Morphine Milligram equivalents (MME) for at least a week, as evidenced by paid claims or pharmacy printouts.
      - If member is unable to swallow (e.g., mucositis, head/neck radiation, head/neck cancers, uncontrollable vomiting) and has severe pain (>6/10), fentanyl patch 12 mcg/hr may be considered for approval for opioid naïve members (subject to clinical review).
  - Both of the following are met:
    - The member must currently be on around-the-clock opioid therapy of at least 30 Morphine Milligram equivalents (MME) for at least a week, as evidenced by paid claims or pharmacy printouts.

        - The member has not achieved therapeutic goal with non-narcotic medication (NSAIDs, TCAs, SNRIs, corticosteroids, etc.) and non-medication alternatives (weight loss, physical therapy, cognitive behavioral therapy, etc.).
- One of the following criteria must be met:
  - The member resides in a facility with skilled nursing care.
  - The member must have taper plan
  - The member must have a treatment plan including goals for pain and function, and urine and/or blood screens.

Fentanyl Patch:

- The member must have a BMI ≥17.

Non-Preferred Agents Criteria:

- Clinical justification must be provided explaining why the member is unable to use other opioid and non-opioid analgesic agents (subject to clinical review).

Renewal Criteria – Approval Duration: 12 months

- One of the following must be met:
  - Progress toward therapeutic goal must be included with request (e.g., improvement in pain level, quality in life, or function).
  - The member must be stable on long-acting opioid medication for 2 years or longer.

Underutilization

- Long-acting opioid analgesics must be used adherently and will reject on point of sale for late fill.

Opioid Analgesic – Short Acting

Opioid Combination Solid Oral Products

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
acetaminophen-codeine tablets	ENDOCET (oxycodone-acetaminophen)
hydrocodone-acetaminophen 5-325 MG, 7.5-325 MG, 10-325 MG	hydrocodone-acetaminophen 2.5-325 MG
hydrocodone-ibuprofen 7.5-200 MG	hydrocodone-acetaminophen 5-300 MG, 7.5-300 MG, 10-300 MG
oxycodone-acetaminophen 5-325 MG, 7.5-325 MG, 10-325 MG	hydrocodone-ibuprofen 5-200 MG, 10-200 MG
tramadol-acetaminophen tablets	NALOCET (oxycodone-acetaminophen)
this space intentionally left blank	oxycodone-acetaminophen 2.5-325 MG
this space intentionally left blank	PERCOCET (oxycodone/acetaminophen)
this space intentionally left blank	PROLATE (oxycodone/acetaminophen)

Opioid – Acetaminophen Combination Non-Solid Oral Products

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

acetaminophen-codeine solution	this space intentionally left blank
hydrocodone-acetaminophen 7.5-325/15 ml solution	this space intentionally left blank

Opioid Single Agent Solid Oral Products

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
codeine tablets	DILAUDID (hydromorphone) TABLET
hydromorphone tablet	oxycodone capsule
meperidine tablet	oxycodone 15 mg, 20 mg, 30 mg tablet
morphine tablet	ROXICODONE (oxycodone) TABLET
oxycodone 5 mg, 10 mg tablet	ROXYBOND (oxycodone) TABLET
oxymorphone tablet	tapentadol tablet
tramadol 50 mg tablet	tramadol 25 mg, 75 mg, 100 mg tablet

Opioid Single Agent Non-Solid Oral Products

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydromorphone liquid	tapentadol solution
morphine solution	this space intentionally left blank
oxycodone solution	this space intentionally left blank

First Fill

- Short acting opioid analgesics must be filled with a 7-day supply if no previous fill within past 34 days
  - If member is filling prescription less than every 34 days due to decreased utilization, please get a new prescription for a lower quantity that reflects actual utilization within a 34-day window.

Prior Authorization Criteria

Prior Authorization Form – Opioid Analgesics

Initial Criteria – Approval Duration: 12 months

Oxycodone IR Only

- The past 3 months of the member's North Dakota PDMP reports must have been reviewed.
- The member must currently be on a long-acting opioid analgesic that provides a daily Morphine Milligram Equivalent (MME) which meets requirements below (based on requested strength), as evidenced by paid claims or pharmacy printouts (Please use an Opioid Dose Calculator to find the MME for specific products):
  - Oxycodone 15 mg tablet: long-acting opioid must provide ≥150 mg MME per day
  - Oxycodone 20 mg tablet: long-acting opioid must provide ≥200 mg MME per day
  - Oxycodone 30 mg tablet: long-acting opioid must provide ≥300 mg MME per day

Non-preferred agents with same active ingredient preferred:

o See Preferred Dosage Form Criteria

Member with a History of Opioid Use Disorder

If 1 and 2 are met, please call for an override by calling provider relations at 1-800-755-2604 (chart notes will be required for requests beyond one fill):

1. The request is for one of the following:
   - A one-time fill request where pain cannot be reasonably treated with non-opioid therapy (e.g., surgery)
   - A request exceeding a one-time fill and a treatment plan has been provided with expected duration of use and why non-opioid therapy is not an option (subject to clinical review) or a taper plan is provided
2. One of the following is met:
   - Prescribers of both opioid prescription and MOUD (medication for opioid use disorder) are aware of each other and agree to opioid therapy
   - MOUD has been discontinued, and the prescriber of the opioid is aware of previous MOUD treatment and confirms opioid therapy is required

Renewal Criteria – Approval Duration: 12 months

- Progress toward therapeutic goal must be included with request (e.g., improvement in pain level, quality in life, or function).

Qutenza (capsaicin patch)

PA REQUIRED
QUTENZA (capsaicin patch) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a pain specialist
- The member must have failed a 3-month treatment of topical lidocaine patch

Skeletal Muscle Relaxants

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
baclofen	AMRIX (cyclobenzaprine) TAB 24 HR
chlorzoxazone 500 mg	chlorzoxazone 375 mg and 750 mg
cyclobenzaprine 5 mg and 10 mg	cyclobenzaprine 7.5 mg
dantrolene	cyclobenzaprine ER
methocarbamol	carisoprodol
orphenadrine ER	carisoprodol-aspirin
tizanidine tablets	carisoprodol-aspirin-codeine
this space intentionally left blank	DANTRIUM (dantrolene)

this space intentionally left blank	LORZONE (chlorzoxazone)
this space intentionally left blank	metaxalone
this space intentionally left blank	SOMA (carisoprodol)
this space intentionally left blank	tizanidine capsules
this space intentionally left blank	ZANAFLEX (tizanidine)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months (carisoprodol = 1 week)

- Carisoprodol products only:
  - The member must be undergoing dose tapering
- Metaxalone
  - The member must have failed two 30-day trials of other skeletal muscle relaxants, including methocarbamol, as evidenced by paid claims or pharmacy printouts.
- All other products:
  - See *Preferred Dosage Form* Criteria

Therapeutic Duplication

- One strength of one medication is allowed at a time
  - If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
    - The member has cerebral palsy or another chronic spastic disorder
    - The prescriber is a physiatrist or neurologist
    - The requested combination is baclofen and tizanidine
- Carisoprodol is not allowed with opioids, benzodiazepines, or opioid use disorder medications
  - The “Holy Trinity” consists of an opioid, a benzodiazepine, and carisoprodol and is a highly abused dangerous combination that can lead to additive CNS depression, overdose, and death. It is not covered.
- Tizanidine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
  - tizanidine is also an alpha 2 agonist

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
baclofen solution 5 mg/5 mL	ATMEKSI (methocarbamol) SUSPENSION
this space intentionally left blank	baclofen 25mg/5mL suspension
this space intentionally left blank	FLEQSUVY (baclofen) 25mg/5mL SUSPENSION
this space intentionally left blank	TONMYA (cyclobenzaprine) SL TABLET

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

Psychiatry

ADHD

Non-Stimulants

Alpha 2 Agonists

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
clonidine	clonidine ER 0.1 mg	INTUNIV (guanfacine ER)
guanfacine	this space intentionally left blank	ONYDA XR (clonidine)
guanfacine ER	this space intentionally left blank	this space intentionally left blank

First Fill

- Clonidine ER and guanfacine ER must be filled with a 14-day supply (or less) if no previous fill within past 99 days

Therapeutic Duplication

Please see the **Psychotropic Monitoring Program** document for detailed information regarding clinical criteria for Therapeutic Duplication Requests.

- One strength of one medication is allowed at a time. Guanfacine 4 mg IR or ER can be combined with other strengths to form dosages up to 7 mg per day. Guanfacine IR and ER cannot be combined.
- Clonidine and guanfacine are not allowed with each other or other alpha 2 agonists (clonidine/chlorthalidone, methyldopa, or tizanidine)

Electronic Step Therapy Required

- Clonidine ER:
  - PA Not Required Criteria: A 30-day supply of clonidine IR has been paid within 90 days prior to clonidine ER's date of service.
  - PA Required Criteria: The member must have failed a 30-day trial of clonidine IR, as evidenced by paid claims or pharmacy printouts.

Prior Authorization Criteria

- *Initial Criteria – Approval Duration: 12 months*
  - The member must have failed a 14-day trial of two stimulants and a 30-day trial of clonidine IR, as evidenced by paid claims or pharmacy printouts.
  - Non-Solid Dosage Form criteria must be met

Norepinephrine Reuptake Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atomoxetine	this space intentionally left blank
PREFERRED AGENTS (PA REQUIRED)	this space intentionally left blank
QELBREE (viloxazine)	this space intentionally left blank

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atomoxetine oral solution	this space intentionally left blank
ATONCY (atomoxetine) ORAL SOLUTION	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet one of the following:
  - The member has failed a 14-day trial of two stimulants, as evidenced by paid claims or pharmacy printouts.
  - The member has failed a 60-day trial of atomoxetine, as evidenced by paid claims or pharmacy printouts.

Therapeutic Duplication

- One strength of one medication is allowed at a time. Qelbree is not allowed with stimulants.

Stimulants

Amphetamines

Solid Dosage Forms

Extended Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dextroamphetamine/amphetamine ER (generic Adderall XR)	ADDERALL XR (dextroamphetamine/amphetamine)
dextroamphetamine ER	DEXEDRINE SPANSULE (dextroamphetamine ER)
lisdexamfetamine 10 mg capsules	dextroamphetamine/amphetamine ER (generic Mydayis ER)
VYVANSE (lisdexamfetamine) – Brand Required except for 10 mg	DYANAVEL XR (amphetamine)
this space intentionally left blank	lisdexamfetamine capsules

this space intentionally left blank	MYDAYIS ER (dextroamphetamine/amphetamine)
this space intentionally left blank	VYVANSE (lisdexamfetamine) 10 mg

Immediate Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amphetamine	ADDERALL (dextroamphetamine/amphetamine)
dextroamphetamine 2.5 mg, 5 mg, 10 mg	dextroamphetamine 7.5 mg, 15 mg, 20 mg, 30 mg
dextroamphetamine/amphetamine	EVEKEO (amphetamine)
this space intentionally left blank	methamphetamine
this space intentionally left blank	ZENZEDI (dextroamphetamine)

Non-Solid Dosage Forms

Extended Release

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lisdexamfetamine chew	ADZENYS XR – ODT (amphetamine) – Brand Required
this space intentionally left blank	amphetamine ER ODT
this space intentionally left blank	ARYNTA (lisdexamfetamine) SOLUTION
this space intentionally left blank	DYANAVEL XR (amphetamine) SUSPENSION
this space intentionally left blank	VYVANSE (lisdexamfetamine) CHEW TABLET
this space intentionally left blank	XELSTRYM (dextroamphetamine) PATCH

Immediate Release

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dextroamphetamine 5 mg/5 ml	PROCENTRA (dextroamphetamine) SOLUTION

Methylphenidate

Solid Dosage Forms

Extended Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dexmethylphenidate ER	APTENSIO XR (methylphenidate)
methylphenidate CD 30-70 (generic Metadate CD)	AZSTARYS (serdexmethylphenidate/dexmethylphenidate)
methylphenidate ER tablet (generic Concerta)	CONCERTA (methylphenidate)
methylphenidate ER tablet (generic Metadate CD)	FOCALIN XR (dexmethylphenidate)
methylphenidate LA capsules – 50-50 (generic Ritalin LA) – 10 mg, 20 mg, 30 mg, 40 mg	JORNAY PM (methylphenidate)
this space intentionally left blank	methylphenidate ER 45 mg, 63 mg, 72 mg tablet (generic Relexxii ER)

this space intentionally left blank	methylphenidate ER capsule (generic Aptensio XR)
this space intentionally left blank	methylphenidate LA capsules – 50-50 (generic Ritalin LA) – 60 mg
this space intentionally left blank	RELEXXII ER (methylphenidate)

Immediate Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dexmethylphenidate	FOCALIN (dexmethylphenidate)
methylphenidate	RITALIN (methylphenidate)

Non-Solid Dosage Forms

Extended Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
QUILLICHEW ER (methylphenidate)	COTEMPLA XR – ODT (methylphenidate) – Brand Required
QUILLIVANT XR (methylphenidate)	methylphenidate ER ODT
this space intentionally left blank	methylphenidate patch

Immediate Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methylphenidate solution	METHYLIN (methylphenidate) SOLUTION
this space intentionally left blank	methylphenidate chew tablet

Electronic Age Verification

- The member must be age 6 or older or must meet prior authorization criteria for ages 5 and under listed below.
- Non-solid dosage forms:
  - The member must meet both of the following criteria or meet Non-Solid Dosage Form criteria
    - The member must be age 9 or younger
    - The member must not be on other solid dosage forms (this will be rejected for Therapeutic Duplication)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- For members ages 5 and under:
  - There is a moderate-severe continuing disturbance in the child's function in both home and other settings (e.g., preschool or daycare) despite a 9-month trial of parent-teacher behavior management and/or behavior classroom interventions to help parents learn age-appropriate developmental expectation, specific management skills for problem behaviors, and behaviors that strengthen the parent-child relationship (subject to clinical review).

Non-Preferred Agent Criteria:

- Amphetamine Non-Solid Dosage Forms Only:
  - The member must have had two 7-day trials of a methylphenidate non-solid dosage form, as evidenced by paid claims or pharmacy printouts.
- Aptensio XR and Azstarys Only – Both of the following must be met:
  - The member must have a wearing off effect where late afternoon/evening functioning performance has been impacted despite a 7-day trial with a long-acting methylphenidate medication with an afternoon short acting booster, as evidenced by paid claims or pharmacy printouts.
  - The member must have a wearing off effect where late afternoon/evening functioning performance has been impacted despite a 7-day trial with Concerta or its generic alternative, as evidenced by paid claims or pharmacy printouts.
- Cotempla XR ODT Only:
  - The member must have had a 7-day trial of methylphenidate patch in addition to preferred agents, as evidenced by paid claims or pharmacy printouts.
- Jornay PM Only - Both of the following must be met:
  - The member must have had two 7-day trials of a fast onset to peak methylphenidate medication (i.e., Concerta, Focalin XR, Metadate CD, Methylin, Ritalin and their generic alternatives), as evidenced by paid claims or pharmacy printouts.
  - The member must have the inability to time the administration of medication where the peak is occurring at the start of work or school and early morning performance has been impacted at school or work due to the approximate 1-hour delay to peak after administration (subject to clinical review).
- Mydayis Only:
  - The member must have a wearing off effect where late afternoon/evening functioning performance has been impacted despite a 7-day trial with Vyanse or its generic alternative, as evidenced by paid claims or pharmacy printouts.
- All Other Agents: See Preferred Dosage Form Criteria

References:

1. Wolraich, Mark L., et al. "Clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents." *Pediatrics* 144.4 (2019).
2. Hulkower RL, Kelley M, Cloud LK, Visser SN. Medicaid Prior Authorization Policies for Medication Treatment of Attention-Deficit/Hyperactivity Disorder in Young Children, United States, 2015. Public Health Rep. 2017 Nov/Dec;132(6):654-659. doi: 10.1177/0033354917735548. Epub 2017 Oct 26. PMID: 29072963; PMCID: PMC5692165.

Therapeutic Duplication

Please see the **Psychotropic Monitoring Program** document for detailed information regarding clinical criteria for Therapeutic Duplication requests.

For all stimulants, the following are not payable:
- multiple strengths of a single medication
- amphetamine agent + methylphenidate agent
- multiple long-acting agents
- multiple short acting agents
- non-solid dosage + solid dosage forms

These long-acting stimulants are not allowed with short-acting stimulants:

- Aptensio XR (methylphenidate)
- Adhansia XR (methylphenidate)
- Arynta (lisdexamfetamine oral solution)
- Azstarys (serdexmethylphenidate/dexmethylphenidate)
- Cotempla XR-ODT (methylphenidate)
- Daytrana (methylphenidate)
- Jornay PM (methylphenidate)
- Adderall XR (mixed salts of a single-entity amphetamine product)
- Adzenys XR ODT (amphetamine suspension, extended release)
- Adzenys ER (amphetamine suspension, extended release)
- Dyanavel XR (amphetamine)
- Mydayis (mixed salts of a single-entity amphetamine product)
- Quillivant XR (methylphenidate)
- Vyvanse (lisexamfetamine)
- Vyvanse Chewable (lisexamfetamine)

Amphetamines: One product will be allowed at a time. The following are not payable regimens:

- Dextroamphetamine/Amphetamine ER with Proton Pump Inhibitors
  - Proton pump inhibitors increase blood levels and potentiate the action of amphetamine. Co-administration of Adderall XR and gastrointestinal or urinary alkalizing agents should be avoided.
- Concurrent use of Mydayis and Dyanavel XR with sedatives
  - Members reporting insomnia can use a shorter acting product that does not reach steady state.

Methylphenidates: The following are not payable regimens:

- Concurrent use of dexmethylphenidate and methylphenidate
- Concurrent use of Adhansia XR and Azstarys with sedatives
  - Members reporting insomnia can use a shorter acting product that does not reach steady state.

Electronic Diagnosis Verification

- Adderall, Azstarys, Jornay PM, Mydayis: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

First Fill

- Long-acting stimulants must be filled with a 14-day supply (or less) if no previous fill within past 70 days

Antidepressants

Oral

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amitriptyline	ANAFRANIL (clomipramine)
amoxapine	CELEXA (citalopram)
bupropion	CYMBALTA (duloxetine)
bupropion ER	EFFEXOR XR (venlafaxine)
bupropion SR	LEXAPRO (escitalopram)
citalopram tablet	PAMLEOR (nortriptyline)
clomipramine	PAXIL (paroxetine)
desipramine	PAXIL CR (paroxetine)
desvenlafaxine ER	PRISTIQ ER (desvenlafaxine)
doxepin	PROZAC (fluoxetine)
duloxetine	REMERON (mirtazapine)
escitalopram	VIIBRYD (vilazodone)
fluoxetine	WELLBUTRIN (bupropion)
fluvoxamine	WELLBUTRIN SR (bupropion)
mirtazapine	WELLBUTRIN XL (bupropion)
nefazodone	ZOLOFT (sertraline)
nortriptyline	this space intentionally left blank
paroxetine	this space intentionally left blank
sertraline tablet	this space intentionally left blank
trazodone	this space intentionally left blank
venlafaxine	this space intentionally left blank
venlafaxine ER	this space intentionally left blank
vilazodone	this space intentionally left blank
High-Cost Preferred Options (No PA Required)	**High Cost Non—Preferred Options (Requires PA)**
AUVELITY (dextromethorphan/bupropion)	citalopram capsule 30 mg
EXXUA (gepirone)	desvenlafaxine ER
FETZIMA (levomilnacipran)	duloxetine 40 mg
fluvoxamine ER	escitalopram 15 mg
imipramine	fluoxetine weekly
protriptyline	paroxetine ER
trimipramine	paroxetine mesylate
TRINTELLIX (vortioxetine)	sertraline capsule
this space intentionally left blank	venlafaxine besylate

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
citalopram oral solution	LEXAPRO (escitalopram) ORAL SOLUTION
doxepin oral solution	PAXIL (paroxetine) ORAL SUSPENSION
escitalopram oral solution	REMERON (mirtazapine) SOLTAB
fluoxetine oral solution	ZOLOFT (sertraline) ORAL CONCENTRATE
mirtazapine ODT	this space intentionally left blank
nortriptyline oral solution	this space intentionally left blank
sertraline oral concentrate	this space intentionally left blank
RALDESY (trazodone) ORAL SOLUTION	this space intentionally left blank
High-Cost Preferred Options (No PA Required)	**High Cost Non—Preferred Options (Requires PA)**
DRIZALMA (duloxetine) SPRINKLE CAPSULE	this space intentionally left blank
paroxetine oral suspension	this space intentionally left blank

Electronic Age Verification

- Auvelity, Exxua, Fetzima, vilazodone: The member must be 18 years of age or older.

Electronic Step Therapy Required

- Trintellix Only: Initiation with 10 mg must be used for 10 days prior to continuing therapy with 20 mg.
  - Trintellix recommended starting dose is 10 mg once daily.
- Exxua Only: Titration required, at least 3 days of 18.2 mg before increasing to 36.3 mg; at least 4 days of 36.3 mg before increasing to 54.5 mg; after an additional 7 days the dose can be increased to the maximum dosage of 72.6 mg.
- Desvenlafaxine ER Only: 30 days of 50 mg must be paid within 40 days of 25 mg date of service.
  - 25 mg is intended only for gradual titration before discontinuation. It is not a therapeutic dose.

First Fill

- Exxua, Viibryd, and Trintellix must be filled with a 10-day supply if no previous fill within past 99 days

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Preferred Dosage Form Criteria

Therapeutic Duplication

Please see **Appendix B** for antidepressant cross tapering coverage guidance.

- One strength of one medication per therapeutic class is allowed at a time

- Therapeutic classes:
  - SSRIs
  - SNRIs
  - Tricyclic Antidepressants
  - bupropion
  - mirtazapine
  - selegiline
- Exxua, Fetzima, Viibryd, or Trintellix are not allowed with other SSRIs or SNRIs (exceptions: trazodone)
- Fluvoxamine, a strong 1A2 inhibitor, is not covered with Ramelteon, a 1A2 Substrate.

Antipsychotics

Oral

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
aripiprazole	ABILIFY (aripiprazole)
clozapine	CLOZARIL (clozapine)
lurasidone	GEODON (ziprasidone)
olanzapine	INVEGA ER (paliperidone)
quetiapine	LATUDA (lurasidone)
quetiapine ER	RISPERDAL (risperidone)
paliperidone ER	SEROQUEL (quetiapine)
risperidone	SEROQUEL XR (quetiapine)
ziprasidone	ZYPREXA (olanzapine)
High-Cost Preferred Options (No PA Required)	**High Cost Non—Preferred Options (Requires PA)**
BYSANTI (milsaperidone)	olanzapine/fluoxetine
CAPLYTA (lumateperone)	this space intentionally left blank
COBENFY (xanomeline/trospium)	this space intentionally left blank
FANAPT (iloperidone)	this space intentionally left blank
LYBALVI (olanzapine/samidorphan)	this space intentionally left blank
REXULTI (brexpiprazole)	this space intentionally left blank
VRAYLAR (cariprazine)	this space intentionally left blank

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
aripiprazole ODT	RISPERDAL (risperidone) ORAL SOLUTION
aripiprazole solution	SAPHRIS (asenapine)
asenapine	ZYPREXA ZYDIS (olanzapine)
clozapine ODT	this space intentionally left blank
olanzapine ODT	this space intentionally left blank

risperidone ODT	this space intentionally left blank
risperidone oral solution	this space intentionally left blank
High-Cost Preferred Options (No PA Required)	**High Cost Non—Preferred Options (Requires PA)**
this space intentionally left blank	OPIPZA FILM (aripiprazole)
this space intentionally left blank	SECUADO (asenapine) PATCH

Electronic Step Therapy Required

Vraylar requires initiation titration:
- For 3 mg dose: Initiation pack or 1 day of the 1.5 mg tablet is required
- For 4.5 mg dose: Initiation pack or 1 day of the 1.5 mg tablet plus 6 days of 3 mg tablets is required

Cobenfy requires initiation titration:
- For 100 mg/20 mg dose: Initiation pack or 2 days of the 50 mg/20 mg capsules is required
- For 125 mg/30 mg dose: Initiation pack or 5 days of the 100 mg/20 mg capsules is required

Therapeutic Duplication

Prior Authorization Form - Concurrent Antipsychotics

Please see **Appendix A** for clinical criteria for multiple oral antipsychotics and oral and injectable antipsychotic requests
- One strength of one medication is allowed at a time with the following exceptions:
    - risperidone 0.25 mg, 0.5 mg and 1 mg are allowed with other strengths of risperidone
    - quetiapine 25 mg and 50 mg are allowed with other strengths of quetiapine IR
    - quetiapine 50 mg ER is allowed with other strengths of quetiapine ER
    - olanzapine 2.5 mg is allowed with 10 mg, 15 mg, and 20 mg
    - olanzapine 5 mg is allowed with 7.5 mg and 20 mg

Underutilization

- Bysanti, Caplyta, Cobenfy, Fanapt, Latuda, Paliperidone ER, Rexulti, Saphris, Sacuado, and Vraylar must be used adherently and will reject on point of sale for late fill

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

First Fill

- Caplyta, Cobenfy, Fanapt, Paliperidone ER, Rexulti, Saphris, Sacuado, and Vraylar must be filled with a 10-day supply if no previous fill within past 99 days

Long Acting Injectable (LAI)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

ABILIFY ASIMTUFII (aripiprazole)	PERSERIS (risperidone)
ABILIFY MAINTENA (aripiprazole)	risperidone ER (risperidone microspheres)
ARISTADA (aripiprazole lauroxil)	this space intentionally left blank
ARISTADA INITIO (aripiprazole lauroxil)	this space intentionally left blank
ERZOFRI (paliperidone)	this space intentionally left blank
INVEGA HAFYERA (paliperidone)	this space intentionally left blank
INVEGA SUSTENNA (paliperidone)	this space intentionally left blank
INVEGA TRINZA (paliperidone)	this space intentionally left blank
RISPERDAL CONSTA (risperidone microspheres) – *Brand Required*	this space intentionally left blank
UZEDY (risperidone)	this space intentionally left blank
ZYPREXA RELPREVV (olanzapine)	this space intentionally left blank

Electronic Step Therapy Required

- Oral formulations must be used prior to injectable formulations to establish tolerability and achieve steady state.

  If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
  - There is a history of tolerability to active ingredient and no requirement for oral overlap for missed dose / initiation of long-acting injectable antipsychotic.
  - Invega Sustenna is being initiated (234 mg x 7 days requires an override for correct billing)

- Aristada Initio: Requires Aristada claim to be billed first.

Therapeutic Duplication

Prior Authorization Form - Concurrent Antipsychotics

Please see **Appendix A** for clinical criteria for multiple oral antipsychotics and oral and injectable antipsychotic requests

- One strength of one medication is allowed at a time.

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

Benzodiazepines

Therapeutic Duplication

- One short acting medication is allowed at a time: alprazolam, lorazepam, oxazepam.
- One long-acting medication is allowed at a time: chlordiazepoxide, clonazepam, diazepam, alprazolam ER
- Benzodiazepines are not covered with:
  - Opioids: Override Criteria Available – See Opioid or Benzodiazepine criteria

- Xyrem, Xywav
- Mydayis
  - Insomnia has been reported in 25-56% of members receiving Mydayis. Members reporting insomnia should use a shorter acting product that does not reach steady state.

- For benzodiazepines only indicated for insomnia: see Insomnia criteria

Insomnia

Non-addictive (Non-DEA scheduled) medications

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydroxyzine	doxepin
mirtazapine	ROZEREM (ramelteon)
ramelteon	SILENOR (doxepin)
trazodone	this space intentionally left blank

Addictive (DEA scheduled) Medications

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
BELSOMRA (suvorexant)	zolpidem 10 mg	AMBIEN (zolpidem)
eszopiclone	this space intentionally left blank	AMBIEN CR (zolpidem)
zaleplon	this space intentionally left blank	DAYVIGO (lemborexant)
zolpidem 5 mg	this space intentionally left blank	EDLUAR (zolpidem)
zolpidem ER	this space intentionally left blank	estazolam
this space intentionally left blank	this space intentionally left blank	flurazepam
this space intentionally left blank	this space intentionally left blank	LUNESTA (eszopiclone)
this space intentionally left blank	this space intentionally left blank	QUVIVIQ (daridorexant)
this space intentionally left blank	this space intentionally left blank	temazepam
this space intentionally left blank	this space intentionally left blank	triazolam
this space intentionally left blank	this space intentionally left blank	zolpidem 7.5 mg
this space intentionally left blank	this space intentionally left blank	zolpidem SL tab

Electronic Step Therapy Required

- Zolpidem 10 mg:
  - PA Not Required Criteria: A 7-day supply of zolpidem 5mg or zolpidem ER has been paid within 90 days prior to zolpidem 10mg's date of service.
  - PA Required Criteria: The member must have failed 7-day trial of zolpidem 5mg or zolpidem ER, as evidenced by paid claims or pharmacy printouts.

Prior Authorization Criteria

Prior Authorization Form – Sedative/Hypnotic

Initial Criteria – Approval Duration: 3 months

- Doxepin only
  - The member must have failed a 25-day trial with ramelteon with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts.
  - Clinical justification must be provided explaining why the member is unable to use mirtazapine, hydroxyzine, or trazodone (subject to clinical review)
- Edluar (zolpidem) only
  - The member's insomnia must be characterized by difficulty with sleep onset.
  - The member must have failed a 25-day trial of each of the following with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts.
    - eszopiclone
    - zolpidem IR
    - zaleplon
- temazepam and Dayvigo only
  - The member's insomnia must be characterized by difficulty with sleep onset and maintenance.
  - The member must have failed a 25-day trial of each of the following with the most recent failure within the last 45 days, as evidenced by paid claims or pharmacy printouts.
    - eszopiclone
    - zolpidem ER
    - Belsomra
- zolpidem SL and Quviviq only
  - The member's insomnia must be characterized by difficulty with sleep onset and maintenance.
  - The member must have failed a 25-day trial of each of the following with the most recent failure within the last 45 days, as evidenced by paid claims or pharmacy printouts.
    - eszopiclone
    - zolpidem ER
    - Belsomra
    - Dayvigo
- triazolam, fluazepam, estazolam, zolpidem 7.5mg only
  - Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

Renewal Criteria – Approval Duration: 6 months (2 weeks for benzodiazepines)

- Other conditions causing sleep issues have been ruled out
- benzodiazepines (temazepam, triazolam, flurazepam, estazolam) only:
  - The member must be undergoing dose tapering

Therapeutic Duplication

- One strength of one medication is allowed at a time
  - Benzodiazepines indicated only for insomnia are not covered with other non-barbiturate insomnia medications or other benzodiazepines
- Sedative/hypnotics are not covered with:
  - Xyrem
  - Mydayis

        - Insomnia has been reported in 25-56% of members receiving Mydayis. Members reporting insomnia should use a shorter acting product that does not reach steady state.
    - Long-acting benzodiazepines. Belsomra and Dayvigo are not covered with short or long-acting benzodiazepines.
        - Concomitant use can lead to CNS depression.
- Ramelteon, a 1A2 Substrate, is not covered with fluvoxamine, a strong 1A2 inhibitor
- Mirtazapine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
    - Mirtazapine is also an alpha 2 agonist
- Sedating benzodiazepines are not covered with opioids

Non-24-hour Sleep-Wake Disorder

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ramelteon	HETLIOZ (tasimelteon)
this space intentionally left blank	ROZEREM (ramelteon)
this space intentionally left blank	tasimelteon

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in sleep disorders.
- The member must have had a 30-day trial of ramelteon, as evidenced by paid claims or pharmacy printouts.
- One of the following must be met:
    - The member must be unable to perceive light in either eye.
    - Sighted members must confirm diagnosis by documentation submitted of self-reported sleep diaries or actigraphy for at least 14 days demonstrating a gradual daily drift (typically later) in rest-activity patterns not better explained by sleep hygiene, substance, or medication use, or other neurological or mental disorders.

Underutilization

- Hetlioz/tasimelteon must be used compliantly and will reject on point of sale for late fill.

Smith-Magenis Syndrome

PA REQUIRED
HETLIOZ (tasimelteon) – *Brand Required*
tasimelteon

Prior Authorization Criteria

Initial Criteria – Approval Duration: *6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in sleep disorders.
- Genetic testing confirms deletion 17p11.2 (cytogenetic analysis or microarray) or RAI1 gene mutation.
- Documentation of self-reported sleep diaries or actigraphy must be submitted for at least 14 days must be submitted.

Underutilization

- Hetlioz/tasimelteon must be used compliantly and will reject on point of sale for late fill.

Pulmonology

Asthma/COPD

Therapeutic Duplication

o One medication from each class is allowed at time.
  - One inhaled steroid
  - Long-acting anticholinergic
  - Leukotriene pathway inhibitor
  - One short-acting beta agonist
  - One long-acting beta agonist

Electronic Concurrent Medication Required

- Roflumilast: A total of 90 days of an inhaled short or long-acting anticholinergic must be paid within 115 days prior to roflumilast's date of service.
  - According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, roflumilast is a recommended add-on therapy to members experiencing exacerbations while on antimuscarinic therapy.

Anticholinergics/Beta Agonists Combinations – Short Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
albuterol/ipratropium	this space intentionally left blank
COMBIVENT RESPIMAT (albuterol/ipratropium)	this space intentionally left blank

Anticholinergics/Beta Agonists Combinations – Long Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)

ANORO ELLIPTA (umeclidinium/vilanterol) – *Brand Required*	BEVESPI AEROSPHERE (glycopyrrolate/formoterol)	DUAKLIR PRESSAIR (aclidinium/formoterol)
STIOLTO RESPIMAT (tiotropium/olodaterol)	this space intentionally left blank	umeclidinium/vilanterol

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Non-Preferred Step 1 Agents

- The member must have failed a 30-day trial of each preferred agents, as evidenced by paid claims or pharmacy printouts

Non-Preferred Step 2 Agents

- The member must have failed a 30-day trial of Bevespi Aerosphere and each preferred agent, as evidenced by paid claims or pharmacy printouts

Anticholinergics – Long-Acting

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
INCRUSE ELLIPTA (umeclidinium) – *Brand Required*	SPIRIVA RESPIMAT 1.25 MCG (tiotropium)	tiotropium handihaler
SPIRIVA HANDIHALER (tiotropium) – *Brand Required*	this space intentionally left blank	TUDORZA PRESSAIR (aclidinium)
SPIRIVA RESPIMAT 2.5 MCG (tiotropium)	this space intentionally left blank	umeclidinium ellipta
this space intentionally left blank	this space intentionally left blank	YUPELRI (revefenacin)

Electronic Concurrent Medications Required

- Spiriva Respimat 1.25 mg: A total of 30 days of a long-acting beta agonist (ICS should be used with LABA as combination or single ingredient inhalers) must be paid within 40 days prior to the Spiriva Respimat 1.25 mg date of service.

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.
  - Spiriva Respimat 1.25 mg is indicated for asthma.
  - Spiriva Respimat 2.5 mg is indicated for COPD.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of at least 2 preferred long-acting anticholinergic agents of unique ingredients (in combination or alone), as evidenced by paid claims or pharmacy printouts.
- If the member is a current smoker, the member must have received smoking cessation counseling in the past year

Beta Agonists – Long-Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
arformoterol	formoterol
SEREVENT DISKUS (salmeterol)	PERFOROMIST (formoterol)
this space intentionally left blank	STRIVERDI RESPIMAT (olodaterol)

Biologics

Anti-IL-5 biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FASENRA (benralizumab)	CINQAIR (reslizumab) – *Medical Billing*
NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR	EXDENSUR (depemokimab-ulaa) – *Medical Billing*
NUCALA (mepolizumab) VIAL – *Medical Billing*	this space intentionally left blank

Anti-IL-4/13 biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab)	this space intentionally left blank

Allergic Asthma-directed biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR	this space intentionally left blank
XOLAIR (omalizumab) VIAL – *Medical Billing*	this space intentionally left blank

Thymic Stromal Lymphopoietin (TSLP) blocker

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TEZSPIRE (tezepelumab-ekko) PENS	this space intentionally left blank
TEZSPIRE (tezepelumab-ekko) VIAL and SYRINGES – *Medical Billing*	this space intentionally left blank

Prior Authorization Criteria

Prior Authorization Form – Asthma

Initial Criteria – Approval Duration: 6 months

For Asthma Only

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist
- If the member is a current smoker, the member must have received smoking cessation counseling in the past year
- The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a high dose inhaled steroid in combination with a long-acting beta agonist (LABA) for at least 3 months prior to the exacerbation, as evidenced by paid claims or pharmacy printouts

Dupixent Only:

- The member must have an eosinophil count of ≥ 150 cells/mcL or FeNO ≥ 25 ppb within the past year

Xolair Only:

- The member has a serum total IgE level, measured before the start of treatment within the past year, of ≥ 30 IU/mL and ≤ 700 IU/mL in members age ≥ 12 years or ≥ 30 IU/mL and ≤ 1300 IU/mL in members ages 6 to < 12 years.
- The member has had a positive skin test or in vitro reactivity to a perennial aeroallergen

Anti-IL-5 biologics:

- The member has an eosinophil count ≥ 150 cells/mcL within the past year
- *Cinqair Only*:
  - The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a triple therapy regimen (high dose inhaled steroid + long-acting beta agonist (LABA) + long-acting muscarinic antagonist (LAMA)) in combination with each of the following for at least 4 months, as evidenced by paid claims or pharmacy printouts: Dupixent, Fasenra, Nucala, and Tezspire.

Exdensur Only:

  - The member must have had at least two exacerbations requiring use of oral corticosteroids in the past year despite continued compliant use of a triple therapy regimen (medium-to-high dose inhaled steroid + long-acting beta agonist (LABA) + long-acting muscarinic antagonist (LAMA)) in combination with each of the following for at least 4 months, as evidenced by paid claims or pharmacy printouts: Dupixent, Fasenra, Nucala, and Tezspire.

For COPD Only

Dupixent Only:

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist

- If the member is a current smoker, the member must have received smoking cessation counseling in the past year
- The member must have had at least one exacerbation requiring use of oral corticosteroids in the previous year despite continued compliant use of an inhaled steroid AND long-acting beta agonist (LABA) AND long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy printouts
- The member has an eosinophil count of ≥ 300 cells/mcL within the past year

Nucala Only:

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist
- If the member is a current smoker, the member must have received smoking cessation counseling in the past year
- The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year months despite continued compliant use of an inhaled steroid AND long-acting beta agonist (LABA) AND long-acting muscarinic antagonist (LAMA) for at least 4 months, as evidenced by paid claims or pharmacy printouts
- The member has an eosinophil count of ≥ 300 cells/mcL within the past year

Renewal Criteria – Approval Duration: 12 months

- The member must have achieved a significant reduction in exacerbations and utilization of systemic steroids and rescue medications since treatment initiation since starting treatment with the requested medication (subject to clinical review).

Corticosteroids – Inhaled (Steroid Inhalers)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ARNUITY ELLIPTA (fluticasone) – *Brand Required*	ALVESCO (ciclesonide)
ASMANEX HFA (mometasone)	beclomethasone HFA
ASMANEX (mometasone) TWISTHALER	fluticasone ellipta
budesonide suspension	fluticasone HFA
this space intentionally left blank	fluticasone diskus
this space intentionally left blank	PULMICORT RESPULES (budesonide)
this space intentionally left blank	QVAR REDIHALER (beclomethasone)

GINA and EPR-3 Guidelines – SMART:

- For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment
- Please consider SMART therapy instead of single agent inhaled corticosteroid.
  - Both Symbicort and Dulera are available as HFA products

Quantity Limits to accommodate SMART therapy:

- 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 182 days without prior approval.

References:

1. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Updated July 2023. Available from: www.ginasthma.org
2. Cloutier, Michelle M., et al. "2020 focused updates to the asthma management guidelines: a report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group." *Journal of Allergy and Clinical Immunology* 146.6 (2020): 1217-1270. Available at: https://www.epa.gov/sites/default/files/2021-05/documents/_sites_default_files_publications_asthmamanagementguidelinesreport-2-4-21.pdf

Electronic Age Verification:

- Fluticasone HFA does not require PA for ages 4 and under
- Arnuity Twisthaler 110 mcg – The member must be 4 years old or greater and less than 12 years old
- Asmanex Twisthaler/Arnuity Ellipta 50 mcg – The member must be 5 years old or greater and less than 12 years old.
- Arnuity Ellipta 100 mcg and 200 mcg, Asmanex HFA 100 mg and 200 mg – The member must be 12 years of age or older

Electronic Duration Verification:

- Budesonide Suspension 1 mg/2 mL is payable for 30 days every 75 days. For diluted nasal rinses or oral use, please use 0.5 mg/2 mL instead of 1 mg/2 mL for doses 1 mg per day or higher.
  - Guidelines recommend that once control is achieved, dose should be titrated down to minimum dose required to maintain control. For doses 1.5 mg per day or lower, please use 0.5 mg/2 mL strength.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred inhaler of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.

QVAR Redihaler Only:

- Arnuity Ellipta trial may be bypassed if member meets one of the following criteria:
  - The member is unable to achieve inspiratory flow rate of 40 L/min.
  - The member is unable to achieve inspiratory flow rate of 60 L/min and has previously had adrenal insufficiency with fluticasone.
  - The member has a permanent disability preventing use of a dry powder inhaler

fluticasone HFA only:

- Arnuity Ellipta trial trials may be bypassed if member meets one of the following criteria:
  - The member is unable to achieve inspiratory flow rate of 40 L/min.
  - The member has a permanent disability preventing use of a dry powder inhaler

References:

1. Sannarangappa V, Jalleh R. Inhaled corticosteroids and secondary adrenal insufficiency. Open Respir Med J. 2014 Jan 31;8:93-100. doi: 10.2174/1874306401408010093. PMID: 25674179; PMCID: PMC4319207.
2. Saag KG, Furst DE, Barnes PJ . Major side effects of inhaled glucocorticoids In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023

Corticosteroid/Long-Acting Beta Agonist (LABA) Combination Inhalers

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
DULERA (mometasone/formoterol)	ADVAIR DISKUS (fluticasone/salmeterol) – Brand Required	*BREYNA (budesonide/formoterol)
this space intentionally left blank	ADVAIR HFA (fluticasone/salmeterol) – Brand Required	BREO ELLIPTA (fluticasone/vilanterol) – Brand Required
this space intentionally left blank	this space intentionally left blank	*budesonide/formoterol
this space intentionally left blank	this space intentionally left blank	*fluticasone/salmeterol
this space intentionally left blank	this space intentionally left blank	*fluticasone/vilanterol
this space intentionally left blank	this space intentionally left blank	SYMBICORT (budesonide/formoterol) *– Brand Required*
this space intentionally left blank	this space intentionally left blank	*WIXELA INHUB (fluticasone/salmeterol)

GINA Guidelines – SMART:

- For mild asthma, ICS-formoterol is the preferred reliever medication for as needed symptom relief
- For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment

Quantity Limits to accommodate SMART therapy:

- 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 182 days without prior approval.

Electronic Age Verification

- Dulera 50 mcg–5 mcg: The member must be between 5 years and 11 years old
- Dulera 100 mcg–5 mcg: The member must 5 years old or older
- Dulera 200 mcg–5 mcg: The member must be 12 years old or older

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: *12 months*

Non-Preferred Step 1 Agents:

- The member must have failed a 30-day trial of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- For COPD diagnosis only: The member must currently be taking a long acting antimuscarinic agent.

Non-Preferred Step 2 Agents:

- The member must have failed a 30-day trial of each preferred and non-preferred step 1 agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- If the member is a current smoker, the member must have received smoking cessation counseling in the past year
- For COPD diagnosis only: The member must currently be taking a long acting antimuscarinic agent.
- *Generic Non-Preferred Agents: See Generic Non-Preferred Agents Criteria

Corticosteroid/Anticholinergics/Long-Acting Beta Agonists Combinations

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BREZTRI AEROSPHERE (budesonide/glycopyrrolate/formoterol)	this space intentionally left blank
TRELEGY ELLIPTA (fluticasone/umeclidinium/vilanterol)	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: *12 months*

- The member must have blood eosinophil of ≥ 100 cells/mcL within the past 90 days
- If the member is a current smoker, the member must have received smoking cessation counseling in the past year
- The member must have experienced an exacerbation while adherent to a 90-day trial of triple therapy (Steroid/Long-Acting Beta Agonist/Long-Acting Anticholinergic), as evidenced by paid claims or pharmacy printouts.

Phosphodiesterase-3 (PDE3) and Phosphodiesterase-4 (PDE4) Inhibitor

PREFERRED AGENTS (PA REQUIRED)
OHTUVAYRE (ensifentrine)

Prior Authorization Criteria

Initial Criteria – Approval Duration: *12 months*

- The requested medication must be prescribed by, or in consult with, a pulmonologist

- If the member is a current smoker, the member must have received smoking cessation counseling in the past year
- The member must meet one of the following criteria:
    - The member has a blood eosinophil of ≥ 100 cells/mcL and has experienced an exacerbation while adherent to a 60-day trial of a triple combination regimen consisting of an inhaled steroid, long-acting beta agonist, and long-acting anticholinergic, as evidenced by paid claims or pharmacy printouts.
    - The member has a blood eosinophil of < 100 cells/mcL and has experienced an exacerbation while adherent to a 60-day trial of a dual combination regimen consisting of a long-acting beta agonist and long-acting anticholinergic, as evidenced by paid claims or pharmacy printouts.

Rescue Inhalers

Albuterol / Levalbuterol

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
VENTOLIN (albuterol) HFA – Brand Required	PROAIR RESPICLICK (albuterol)	albuterol HFA - 18 gram (generic Ventolin)
albuterol HFA 6.7 gram	XOPENEX (levalbuterol) HFA - Brand Required	levalbuterol HFA
albuterol HFA 8.5 gram	this space intentionally left blank	this space intentionally left blank

Rescue Inhaler - Corticosteroid/Short-Acting Beta Agonist (SABA) Combination

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	AIRSUPRA (albuterol/budesonide)

According to the GINA guidelines:

- A low dose ICS should be taken whenever SABA taken for step 1 control of asthma.
- Dispensing ≥ 3 SABA canisters/year is associated with higher risk of emergency department presentations.
- Dispensing ≥ 12 SABA canisters/year is associated with higher risk of death.

GINA Guidelines – SMART:

- For mild asthma, ICS-formoterol is the preferred reliever medication for as needed symptom relief.
- For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment.

Quantity Limits to accommodate SMART therapy:

- 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 365 days without prior approval.

Electronic Step Therapy Required

- Levalbuterol HFA:
  - PA Not Required Criteria: A 30-day supply of albuterol HFA has been paid within 180 days prior to levalbuterol HFA's date of service.
  - PA Required Criteria: The member must have failed a 30-day trial of albuterol HFA, as evidenced by paid claims or pharmacy printouts.

Electronic Concurrent Medications Required

- ProAir Respiclick: A total of 30 days of steroid inhaler must be paid within 40 days prior to ProAir Respiclick's date of service.
  - The quantity limit for Ventolin HFA is set to 2 canisters per 6 months (2 puffs per day). If more is needed, member must switch to ProAir Respiclick HFA and be on a steroid inhaler to control asthma.

If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:

- If primary insurance will only pay for ProAir Respiclick and member is well-controlled without steroid inhaler (i.e., uses less than 2 canisters per 6 months).

Therapeutic Duplication

- Short acting beta agonist nebulizers and inhalers are not payable together.
  - Inhalers and Nebulizers work equally well whether used at home, in school, or otherwise outside of the home. If member receives multiple forms of rescue medication, the risk of unidentified uncontrolled asthma and rescue inhaler dependence is increased.

If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:

- Maximally treated members with end-stage COPD will be allowed an ongoing override (compliance with inhaled steroid, long-acting beta agonist, long-acting muscarinic antagonist, and Daliresp)
- Members with cystic fibrosis will be allowed an ongoing override.
- Acutely ill children will be allowed a one-time override.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Airsupra only:

- One of the following must be met (1 or 2):
  1. The member must have failed a 30-day trial of each albuterol and an ICS/formoterol, as evidenced by paid claims or pharmacy printouts.
  2. The member is not on any other asthma medications and ages ≥ 6 or ≤ 11

Non-preferred albuterol only:

- See *Preferred Dosage Form* Criteria

References:

1. Albuterol Overuse: A Marker of Psychological Distress? Joe K. Gerald, Tara F. Carr, Christine Y. Wei, Janet T. Holbrook, Lynn B. Gerald. J Allergy Clin Immunol Pract. 2015 Nov-Dec; 3(6): 957–962. Published online 2015 Sep 1. Doi: 10.1016/j.jaip.2015.06.021. PMCID: PMC4641773
2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2025. Updated May 2025. Available from: www.ginasthma.org Cloutier, Michelle M., et al. "2020 focused updates to the asthma management guidelines: a report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group." Journal of Allergy and Clinical Immunology 146.6 (2020): 1217-1270
3. Ploin, D., Chapuis, F. R., Stamm, D., Robert, J., David, L., Chatelain, P. G., Dutau, G., & Floret, D. (2000). High-dose albuterol by metered-dose inhaler plus a spacer device versus nebulization in preschool children with recurrent wheezing: A double-blind, randomized equivalence trial. Pediatrics, 106(2), 311–317. https://doi.org/10.1542/peds.106.2.311

Fibrosis

Cystic Fibrosis – Inhaled Antibiotics

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tobramycin (generic Tobi)	BETHKIS (tobramycin)
PREFERRED AGENTS (PA REQUIRED)	CAYSTON (aztreonam)
ARIKAYCE (amikacin/nebulizer)	KITABIS PAK (tobramycin/nebulizer)
this space intentionally left blank	TOBI (tobramycin)
this space intentionally left blank	TOBI PODHALER (tobramycin)
this space intentionally left blank	tobramycin/nebulizer (generic Kitabis)
this space intentionally left blank	tobramycin (generic Bethkis)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Arikayce only:
  - The member must be colonized with *Mycobacterium avium* complex (MAC).
  - The member must have not achieved negative sputum cultures after a minimum duration of 6 consecutive months of background treatment with a macrolide, a rifamycin, and ethambutol.
- Cayston only:
  - The member must be colonized with *Pseudomonas aeruginosa.*
  - The member must have had a 28-day trial of tobramycin as evidenced by paid claims or pharmacy printouts.
- Tobi Podhaler only:
  - The member must have failed one 28-day trial of each: Kitabis Pak and a generic tobramycin nebulized agent, as evidenced by paid claims or pharmacy printouts.
- All other agents: See Preferred Dosage Form Criteria

Cystic Fibrosis – CFTR Modulators

PA REQUIRED
ALYFTREK (vanzacaftor/tezacaf/deutivacaf)
KALYDECO (ivacaftor)
ORKAMBI (lumacaftor/ivacaftor)
SYMDEKO (tezacaftor/ivacaftor)
TRIKAFTA (elexacaftor/tezacaftor/ivacaftor)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months (Renewal Approval – 5 years)

- The member must have a CFTR mutation that the requested medication is FDA-approved to treat

Idiopathic Pulmonary Fibrosis

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pirfenidone	JASCAYD (nerandomilast)
this space intentionally left blank	nintedanib
this space intentionally left blank	OFEV (nintedanib)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist or rheumatologist.
- The member must have forced vital capacity (FVC) ≥ 40% of predicted within prior 60 days.
- The member must have carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) of 30% to 79% of predicted.

Non-Preferred Agent Criteria:

- The member must have failed a 6-month trial with the preferred agent, as evidenced by paid claims or pharmacy printouts.
- Jascayd Only: The member must have failed a 6-month trial with nintedanib, as evidenced by paid claims or pharmacy printouts.

Interstitial Lung Disease

First Line Therapy - Orals

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine	this space intentionally left blank
cyclophosphamide	this space intentionally left blank
mycophenolate mofetil (MMF)	this space intentionally left blank

First Line Therapy - Biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tocilizumab – See Biosimilar Agents	this space intentionally left blank

Progressive Disease

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rituximab - See Biosimilar Agents	JASCAYD (nerandomilast)
this space intentionally left blank	nintedanib
this space intentionally left blank	OFEV (nintedanib)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist or rheumatologist.
- The member must have forced vital capacity (FVC) ≥ 45% of predicted within prior 60 days
- The member must have carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) of 30% to 79% of predicted.
- If the member is a current smoker, the member must have received smoking cessation counseling in the past year
- The member must have one of the following within the past 24 months:
  - a FVC decline of ≥10%
  - a FVC decline of ≥ 5% and worsening respiratory symptoms or fibrotic changes
  - worsening respiratory symptoms and fibrotic changes
  - absolute decline in DLCO ≥10 percent predicted
- Jascayd Only: The member must have failed a 6-month trial with nintedanib, as evidenced by paid claims or pharmacy printouts.

Non-Cystic Fibrosis Bronchiectasis

DPP-1 Inhibitor

PA REQUIRED
BRINSUPRI (brensocatib)

Underutilization

- Brinsupri must be used adherently and will reject on point of sale for late fill.

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist

- The member must have a clinical history consistent with non-cystic fibrosis bronchiectasis (NCFB) (cough, chronic sputum production and/or recurrent respiratory infections) that is confirmed by chest computerized tomography (CT) scan.
- The member must have documented at least 2 pulmonary exacerbations despite antibiotic therapy in the past 12 months, or be unable to tolerate ongoing antibiotic therapies
  - Pediatric members over the age of 12 are required to have at least 1 pulmonary exacerbation in the prior 12 months.
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- For ages 18 and older: Documentation must be submitted of a baseline quality of life score, as assessed by the QoL bronchiectasis questionnaire, respiratory domain if this will be the chosen method for showing future clinical benefit
- The member's baseline current Forced Vital capacity (FVC and FEV1) via Pulmonary Function Test must be provided

Renewal Criteria – Approval Duration: 12 months
- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by one of the following (subject to clinical review):
  - The member has experienced a decrease in the number or frequency of pulmonary exacerbations
  - The member shows improvement in pulmonary function (FEV1)
  - The member reports an increased quality of life, as assessed by the QoL bronchiectasis questionnaire, respiratory domain, with an increase from baseline of at least 8 points

Obstructive Sleep Apnea (OSA)

PA REQUIRED
ZEPBOUND (tirzepatide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- The requested medication must be prescribed by, or in consult with, a neurologist, pulmonologist, otolaryngologist, or other sleep medicine specialist
- The member must have a diagnosis of moderate to severe OSA defined as apnea-hypopnea index (AHI) > 15 determined by in-lab attended sleep study or polysomnography (PSG)
- The member does not have diabetes type II
- The member must have a diagnosis of obesity (defined as BMI ≥ 30 kg/m2)
- The member must have failed a 6-month trial of continuous positive airway pressure (CPAP) along with the weight management program within the past year, as evidenced by apnea-hypopnea index (AHI) > 15.
- *Tirzepatide Only*:
  - The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
  - The member must have documentation of participation in a comprehensive weight management program that includes behavioral modification, a reduced-calorie diet, increased physical activity, and pharmacotherapy for at least 6 months with semaglutide.

        - If semaglutide is not tolerated, the pharmacotherapy requirement must be met with phentermine (if phentermine is unable to be used, bupropion, naltrexone, or topiramate may also be used to meet this requirement)
    - If the member qualifies for tirzepatide, the most cost-effective tirzepatide product will be authorized

Renewal Criteria – Approval Duration: 12 months

- The member has demonstrated clinical response evidenced by any of the following:
    - Decrease in AHI determined by PSG ≥ 20%, or change in OSA severity status to Remission or Mild Non-Symptomatic OSA (defined as AHI < 5 or AHI 5-14 AND Epworth Sleepiness Scale (ESS) ≤ 10)
    - Weight loss from base line ≥ 10% and the member has submitted chart notes from a visit focused on sleep apnea in the past 12 months documenting current weight.

Rheumatology

Axial Spondyloarthritis/Ankylosing Spondylitis

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	CIMZIA (certolizumab) SYRINGE
infliximab - See Biosimilar Agents	CIMZIA (certolizumab) VIAL – *Medical Billing*
ENBREL (etanercept)	SIMPONI ARIA (golimumab)– *Medical Billing*
SIMPONI (golimumab)	this space intentionally left blank

Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)	COSENTYX (secukinumab)
this space intentionally left blank	COSENTYX (secukinumab) – *Medical Billing*

Interleukin (IL)-17A and IL-17F inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	BIMZELX (bimekizumab-bkzx)

Janus Kinase (JAK) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ IR (tofacitinib) 5 mg – *Brand Necessary*	RINVOQ ER (upadacitinib)
XELJANZ (tofacitinib) SOLUTION – *Brand Necessary*	tofacitinib

this space intentionally left blank	XELJANZ IR (tofacitinib) 10 mg
this space intentionally left blank	XELJANZ XR (tofacitinib)

Electronic Step Therapy Required

- Taltz:
  - PA Not Required Criteria: A total of 84-day supply of adalimumab or certolizumab has been paid within 120 days prior to Taltz's date of service.
  - PA Required Criteria: The member must have failed a 3-month trial of a TNF inhibitor (adalimumab, certolzumab, infliximab, or goliumamab), as evidenced by paid claims or pharmacy printouts.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed all preferred agents in the same class as requested product
- Cimzia Only: The member must have failed a 90-day trial of TNF inhibitor (adalimumab, certolzumab, infliximab, or goliumamab), as evidenced by paid claims or pharmacy printouts.
- Rinvoq ER Only: The member must have failed a 30-day trial of Xeljanz and a 90-day trial of a TNF inhibitor (adalimumab, certolzumab, infliximab, or goliumamab), as evidenced by paid claims or pharmacy printouts.
- Bimzlex, Cosentyx and Simponi Aria Only: The member must have failed a 30-day trial of Xeljanz and Rinvoq ER, and a 90-day trial of a TNF inhibitor (adalimumab, certolzumab, infliximab, or goliumamab) and Taltz, as evidenced by paid claims or pharmacy printouts.
- Xeljanz IR 10 mg, Xeljanz XR Only: See Preferred Dosage Form Criteria
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review).

Behçet syndrome

Phosphodiesterase 4 (PDE4) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OTEZLA (apremilast)	OTEZLA XR (apremilast)

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	this space intentionally left blank
infliximab - See Biosimilar Agents	this space intentionally left blank

Prior Authorization Criteria

- See Medications that cost over $3000/month criteria

Cryopyrin Associated Periodic Syndrome (CAPS)

Includes: Familiar Cold Autoinflammatory Syndrome, Muckle-Wells Syndrome, and Neonatal Onset Multisystem Inflammatory Disease (NOMID) or Chronic Infantile Neurological Cutaneous and Articular (CINCA) Syndrome

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ARCALYST (rilonacept)
this space intentionally left blank	ILARIS (canakinumab) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member has failed a 3-month trial of Kineret, as evidenced by paid claims or pharmacy print outs.
- The member has elevated pretreatment serum inflammatory markers (e.g., C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) serum amyloid A(SAA))
- The member has at least two of the following symptoms:
  - Urticaria-like rash
  - Cold/stress triggered episodes
  - Sensorineural hearing loss
  - Musculoskeletal symptoms of arthralgia/arthritis/myalgia
  - Chronic aseptic meningitis
  - Skeletal abnormalities of epiphyseal overgrowth/frontal bossing

Familial Mediterranean Fever (FMF)

Colchicine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
colchicine tablets	colchicine capsules
this space intentionally left blank	GLOPERBA (colchicine) ORAL SOLUTION
this space intentionally left blank	MITIGARE (colchicine) CAPSULE

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ARCALYST (rilonacept)
this space intentionally left blank	ILARIS (canakinumab) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member experiences one or more attacks each month despite receiving maximally tolerated dose of colchicine for at least 6 months, as evidenced by paid claims or pharmacy print outs and clinical documentation.
- The member has failed a 3-month trial of Kineret, as evidenced by paid claims or pharmacy print outs.

Giant Cell Arteritis (Temporal Arteritis)

Janus Kinase (JAK) inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RINVOQ ER (upadacitinib) TABLET	this space intentionally left blank

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tocilizumab – See Biosimilar Agents	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member must meet one of the following conditions:
  - A minimum 7-day trial of high dose glucocorticoids
  - At high risk of glucocorticoid side effects or complications, including osteoporosis, diabetes, hypertension, or glaucoma

Hyperimmunoglobulin D Syndrome/Mevalonate Kinase (MVK) Deficiency

Symptomatic Treatment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NSAIDs	this space intentionally left blank
glucocorticoids	this space intentionally left blank
KINERET (anakinra)	this space intentionally left blank

Preventative Treatment

PA REQUIRED
ILARIS (canakinumab)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member has failed a 3-month trial of Kineret, as evidenced by paid claims or pharmacy print outs.
- The member is experiencing frequent and/or severe attacks that have significantly diminished quality of life

Juvenile Idiopathic Arthritis

Juvenile Idiopathic Arthritis – Enthesitis-Related Arthritis (ERA)

Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	COSENTYX (secukinumab)
this space intentionally left blank	COSENTYX (secukinumab) – *Medical Billing*

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	this space intentionally left blank
ENBREL (etanercept)	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member has failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy print outs.

Juvenile Idiopathic Arthritis – Polyarticular Course

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tocilizumab – See Biosimilar Agents	KEVZARA (sarilumab)

Janus Kinase (JAK) Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ IR (tofacitinib) 5 MG TABLET – *Brand Required*	RINVOQ ER TABLET, SOLUTION
XELJANZ (tofacitinib) SOLUTION – *Brand Required*	tofacitinib
this space intentionally left blank	XELJANZ IR (tofacitinib) 10 MG TABLET
this space intentionally left blank	XELJANZ XR (tofacitinib)

T-cell Costimulation Blocker

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENCIA (abatacept) – 125 mg/mL syringe	ORENCIA (abatacept) - 50 mg/0.4 mL and 87.5 mg/0.7 ml syringes
this space intentionally left blank	ORENCIA (abatacept) – *Medical Billing*

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	CIMZIA (certolizumab) SYRINGE
ENBREL (etanercept)	CIMZIA (certolizumab) VIAL – *Medical Billing*
this space intentionally left blank	SIMPONI ARIA (golimumab) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member has failed all preferred agents in the same class as requested product
- The member has failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy print outs.
- Cimzia, Orencia, and Toclizumab Only: The member has failed a 3-month trial of a TNF inhibitor and a 30-day trial of Xeljanz, as evidenced by paid claims or pharmacy print outs.

- Kevzara, Rinvoq, and Simponi Aria Only: The member has failed a 3-month trial of a TNF inhibitor, toclizumab, and Orencia, and a 30-day trial of Xeljanz, as evidenced by paid claims or pharmacy print outs.
- Xeljanz IR 10mg, Xeljanz XR Only: See Preferred Dosage Form criteria
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review)

Juvenile Chronic Arthritis – Systemic Onset

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	ILARIS (canakinumab) – *Medical Billing*

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tocilizumab – See Biosimilar Agents	this space intentionally left blank

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	this space intentionally left blank
ENBREL (etanercept)	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Ilaris Only: The member has failed a 3-month trial of tocilizumab, as evidenced by paid claims or pharmacy print outs.

References:

1. Dewitt, E.M., Kimura, Y., Beukelman, T., Nigrovic, P.A., Onel, K., Prahalad, S., Schneider, R., Stoll, M.L., Angeles-Han, S., Milojevic, D., Schikler, K.N., Vehe, R.K., Weiss, J.E., Weiss, P., Ilowite, N.T., Wallace, C.A. and (2012), Consensus treatment plans for new-onset systemic juvenile idiopathic arthritis. Arthritis Care Res, 64: 1001-1010. https://doi.org/10.1002/acr.21625

Osteoporosis

Antiresorptive Agents

Bisphosphonates

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

alendronate	ACTONEL (risedronate)
alendronate oral solution	ATELVIA (risedronate DR)
BONIVA (ibandronate) – *Medical Billing*	FOSAMAX (alendronate)
ibandronate – *Medical Billing*	FOSAMAX D (alendronate/vitamin D)
RECLAST (zoledronic acid) – *Medical Billing*	risedronate DR
risedronate IR	this space intentionally left blank
zoledronic acid – *Medical Billing*	this space intentionally left blank

Prior Authorization Criteria

- Risedronate DR Only: See Preferred Dosage Form criteria

Calcitonins

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcitonin, salmon nasal spray++	calcitonin, salmon vial
MIACALCIN (calcitonin, salmon) VIAL++ – *Medical Billing*	this space intentionally left blank

++ Clinically Non-Preferred: An FDA advisory panel concluded that the benefits of calcitonin do not outweigh its potential risks as an osteoporosis drug due to increased risk of malignancy. Bisphosphonates are more effective agents.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must be experiencing pain from an acute osteoporotic fracture

Estrogen Agonist/Antagonist

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
raloxifene	EVISTA (raloxifene)

Monoclonal Antibodies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
denosumab- See Biosimilar Agents	this space intentionally left blank

Anabolic Agents

Parathyroid Hormone (PTH)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FORTEO (teriparatide) – *Brand Required*	teriparatide

PTH-related protein

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	TYMLOS (abaloparatide)

Monoclonal Anti-sclerostin Antibody

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EVENITY (romosozumab-aqqg) *– Medical Billing*	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 2 years

- The member must have a current BMD T-score ≤ -2.5 OR new fracture after a 6-month trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - teriparatide
- The member must be at high risk of fracture, confirmed by at least one of the following:
  - The member with a history of hip or vertebral fracture
  - The member with a T-score of −2.5 or lower at the femoral neck or spine
  - The member has a T-score of between −1.0 and −2.5 at the femoral neck or spine and a ten-year hip fracture risk of ≥3% as assessed with the FRAX
  - 10-year risk of a major osteoporosis-related fracture of ≥20% as assessed with the FRAX

Polymyalgia Rheumatica

Interleukin (IL) -6 Receptor Inhibitors

PA REQUIRED
KEVZARA (sarilumab)

Prior Authorization Criteria

- See Medications that cost over $3000/month criteria

Psoriatic Arthritis

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	CIMZIA (certolizumab) SYRINGE
infliximab - See Biosimilar Agents	CIMZIA (certolizumab) VIAL – *Medical Billing*
ENBREL (etanercept)	SIMPONI ARIA (golimumab)– *Medical Billing*
SIMPONI (golimumab)	this space intentionally left blank

Phosphodiesterase 4 (PDE4) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OTEZLA (apremilast)	OTEZLA XR (apremilast)

Janus Kinase (JAK) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ IR (tofacitinib) 5 mg – *Brand Required*	RINVOQ ER (upadacitinib)
XELJANZ (tofacitinib) SOLUTION – *Brand Required*	tofacitinib
this space intentionally left blank	XELJANZ IR (tofacitinib) 10 mg
this space intentionally left blank	XELJANZ XR (tofacitinib)

Tyrosine Kinase 2 (TYK2) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	SOTYKTU (deucravacitinib)

T-cell Costimulation Blocker

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENCIA (abatacept) – 125 mg/mL syringe	ORENCIA (abatacept) – *Medical Billing*
this space intentionally left blank	ORENCIA (abatacept) – 50 mg/0.4mL, 87.5 mg/0.7 mL syringe

Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)	COSENTYX (secukinumab)
this space intentionally left blank	COSENTYX (secukinumab) – *Medical Billing*

Interleukin (IL)-17A and IL-17F inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	BIMZELX (bimekizumab-bkzx)

Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TREMFYA (guselkumab)	SKYRIZI (risankizumab-rzaa)

Interleukin (IL)-12/IL-23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ustekinumab - See Biosimilar Agents	this space intentionally left blank

Electronic Step Therapy Required

- Taltz:
  - PA Not Required Criteria: A total of 84-day supply of adalimumab or certolizumab has been paid within 120 days prior to Taltz's date of service.
  - PA Required Criteria: The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Pediatric Members:

- The member must have failed a 90-day trial of etanercept, as evidenced by paid claims or pharmacy printouts:

Adult Members:

- The member must have failed all preferred agents in the same class as requested product
- Bimzelx, Cimzia, Cosentyx, Rinvoq ER, Simponi Aria, and Sotyktu Only:
  - The member must have failed a 30-day trial of a JAK inhibitor and a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
    - Interleukin (IL) – 17 inhibitor
    - TNF inhibitor
    - Ustekinumab
- Tremfya Only:
  - The member must have failed a 30-day trial of a JAK inhibitor and a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
    - Bimzelx
    - Interleukin (IL) – 17 inhibitor
    - TNF inhibitor
    - Ustekinumab
- Skyrizi Only:
  - The member must have failed a 30-day trial of a JAK inhibitor and a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
    - Bimzelx
    - Interleukin (IL) – 17 inhibitor
    - TNF inhibitor
    - Ustekinumab
    - Tremfya
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why self-administered agents cannot be used (subject to clinical review).
- All other Agents: See Preferred Dosage Form Criteria

Rheumatoid Arthritis

Anti-CD20 Monoclonal Antibodies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rituximab - See Biosimilar Agents	this space intentionally left blank

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	this space intentionally left blank

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tocilizumab – See Biosimilar Agents	KEVZARA (sarilumab)

Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	COSENTYX (secukinumab)
this space intentionally left blank	COSENTYX (secukinumab) – *Medical Billing*

Janus Kinase (JAK) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ IR (tofacitinib) 5 mg – *Brand Required*	OLUMIANT (baricitinib)
XELJANZ (tofacitinib) SOLUTION – *Brand Required*	RINVOQ ER (upadacitinib)
this space intentionally left blank	tofacitinib
this space intentionally left blank	XELJANZ IR (tofacitinib) 10 mg
this space intentionally left blank	XELJANZ XR (tofacitinib)

T-cell Co-stimulation Blocker

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENCIA (abatacept) – 125 mg/mL syringe	ORENCIA (abatacept) – *Medical Billing*

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	CIMZIA (certolizumab) SYRINGE
infliximab - See Biosimilar Agents	CIMZIA (certolizumab) VIAL – *Medical Billing*

ENBREL (etanercept)	SIMPONI ARIA (golimumab)– *Medical Billing*
SIMPONI (golimumab)	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed all preferred agents in the same class as requested product
- The member must have had a 3-month trial of each of the following, as evidenced by paid claims and pharmacy printouts:
  - TNF Inhibitor
  - Orencia
  - JAK inhibitor
- Cosentyx, Kevzara, Rinvoq ER and Simponi Aria only: The member must have had a 3-month trial of each of the following, as evidenced by paid claims and pharmacy printouts:
  - TNF Inhibitor
  - Orencia
  - JAK inhibitor
  - Tocilizumab
- Xeljanz IR 10mg, Xeljanz XR only: See Preferred Dosage Form criteria
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review).

Adult-Onset Still's Disease

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ILARIS (canakinumab) – *Medical Billing*

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
infliximab – See Biosimilar Agents	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member must have had a 3-month trial of each of Kineret, as evidenced by paid claims and pharmacy printouts:

Tumor Necrosis Factor Receptor Associated Periodic Syndrome

PA REQUIRED
ILARIS (canakinumab)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- One of the following must be met (A or B):
  A. Genetic testing confirming pathogenic variants in the tumor necrosis factor receptor 1 (TNFR1) gene (TNF receptor superfamily member 1A, TNFRSF1A).
  B. Both of the following:
    - Elevated serum inflammatory markers (e.g., C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) serum amyloid A(SAA))
    - History of recurrent fever, prominent myalgias, migratory rash, and periorbital edema

Substance Use

Nicotine / Tobacco Dependence Treatment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bupropion SR	CHANTIX (varenicline)
nicotine lozenge	NICODERM CQ (nicotine) PATCH
nicotine patch	NICORETTE (nicotine polacrilex) GUM
nicotine polarcrilex gum	ZYBAN (bupropion SR)
NICOTROL (nicotine polacrilex) SPRAY	this space intentionally left blank
varenicline	this space intentionally left blank

Concurrent Medication Required

- Short-acting nicotine agents (nasal spray, lozenge, and gum) require concurrent nicotine patch, bupropion SR (generic Zyban), or varenicline since better outcomes are associated with concurrent use of short-acting and long-acting tobacco cessation products.
  - o A total of 14 days of nicotine patch, bupropion SR (generic Zyban), or varenicline must be paid within 40 days prior to nicotine nasal spray, lozenge, or gum's date of service.

Clinically Important Information: Bupropion SR (generic Zyban) takes 5 to 7 days to reach steady state. It is recommended to start one week before target quit date. NRT products are allowed in addition to bupropion SR to bridge therapy until bupropion SR becomes effective and for concurrent use.

Electronic Duration Verification

- A total of 12 consecutive weeks will be covered for all other products, every 6 months.

  Varenicline or bupropion SR (generic Zyban): If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
  - o Patient is abstinent from tobacco.
  - o Treatment duration is requested to be extended to 24 consecutive weeks.

Therapeutic Duplication

- Nicotine gum, lozenge, and spray will not be paid concurrently.
- Bupropion SR (generic Zyban) will not be paid with other forms of bupropion.

Underutilization

- Nicotine Patch, varenicline, and bupropion SR (generic Zyban) must be used adherently and will reject on point of sale for late fill.

Opioid Use Disorder

Alpha-2 Adrenergic Agonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clonidine	lofexidine
guanfacine	LUCEMYRA (lofexidine) – *Brand Required*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have had a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Outpatient status must be verified (not for inpatient use).
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

Opioid Antagonist

PREFERRED AGENTS (NO PA REQUIRED)
naltrexone tablets
VIVITROL (naltrexone microspheres) INJECTION

Opioid Reversal Medications

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KLOXXADO (naloxone) NASAL SPRAY	NARCAN (naloxone) NASAL SPRAY - *Prescription Brand (please use Brand OTC)*

nalmefene injection	REXTOVY (naloxone) NASAL SPRAY
naloxone nasal spray	ZURNAI (nalmefene) INJECTOR
naloxone injection	this space intentionally left blank
NARCAN (naloxone) NASAL SPRAY *– OTC Brand Co-Preferred*	this space intentionally left blank
OPVEE (nalmefene) NASAL SPRAY	this space intentionally left blank

Electronic Duration Verification

- 4 doses are covered every 60 days without an override.

If one of the following criteria are met (A or B), please request an override by calling provider relations at 1-800-755-2604 or emailing medicaidpharmacy@nd.gov:

A. The previous dose has expired.
B. The dose was used by member for an opioid overdose. (In this case, it is recommended to follow up with prescriber to discuss frequency of use and potential regimen review/adjustments)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have had a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Please see Preferred Dosage Form criteria

Opioid Partial Agonist

Electronic Step Therapy Required

- A total of 28 days of Sublocade 300 mg must be paid within 60 days prior to Sublocade 100 mg date of service.

Per Sublocade package insert:

Established Transmucosal Buprenorphine Doses	Initial Dose of TM Buprenorphine	Injection #1	Injection #2[a]	Maintenance Dose[b]
N/A, none	4 mg[c]	300 mg	100 mg	100 mg
8 – 24 mg/day	N/A	300 mg	300 mg[d]	100 mg

[a]The second injection may be administered as early as 1 week and up to 1 month after the initial injection based on patient need.
[b]A monthly maintenance dosage of 300 mg may be considered in patients who tolerate SUBLOCADE, but do not demonstrate a satisfactory clinical response
[c]On induction day, additional transmucosal buprenorphine may be administered as needed to manage withdrawal symptoms. Monitor patients for 1 hour to confirm tolerability before administering the first injection of Sublocade

[d]Patients established on long-term treatment and whose symptoms are controlled with 8 mg to 18 mg daily of transmucosal buprenorphine may receive 100 mg of SUBLOCADE as their second dose if symptoms remain controlled following the initial dose of 300 mg

Therapeutic Duplication

- One strength of one medication is allowed at a time.
- Opioid partial agonists are not allowed with:
  - methadone
  - carisoprodol
  - opioids
- Opioid full agonist requested with member with history of opioid use disorder.
  - If 1 and 2 are met, please call for an override by calling provider relations at 1-800-755-2604 (chart notes will be required for requests beyond one fill)
    1. The request is for one of the following:
       - A one-time fill request where pain cannot be reasonably treated with non-opioid therapy (e.g., surgery)
       - A request exceeding a one-time fill and a treatment plan has been provided with expected duration of use and why non-opioid therapy is not an option (subject to clinical review) or a taper plan is provided.
    2. One of the following is met:
       - Prescribers of both opioid prescription and MOUD (medications for opioid use disorder) are aware of each other and agree to opioid therapy.
       - MOUD has been discontinued, and the prescriber of the opioid is aware of previous MOUD treatment and confirms opioid therapy is required.
- Opioid partial agonist injection + oral overlap

  Please call for an override by calling provider relations at 1-800-755-2604 to request a 4 month overlap period with oral buprenorphine/naloxone while initiating long-acting injectable buprenorphine (until the therapeutic levels are achieved).

Mono Product

Oral Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	buprenorphine tablets++

++ Clinically Non-Preferred: Naloxone is added to buprenorphine to prevent misuse. When taken correctly, a baby will have little to no absorption of naloxone which a growing body of evidence show is safe. Taking combination product during pregnancy or breastfeeding means that products don't need to be switched to a different medication after the baby is born during this high anxiety time. Risk of withdrawal to a neonate is a labeled warning on each product. Pregnancy and breastfeeding are not listed as contraindications on either product.

References:

1. Opioid use and opioid use disorder in pregnancy. Committee Opinion No. 711. American College of Obstetricians and Gynecologists. Obstet Gynecol 2017;130:e81–94.

2. Perry, Briana N. MD; Vais, Simone BA; Miller, Melissa BA; Saia, Kelley A. MD. Buprenorphine-Naloxone Versus Buprenorphine for Treatment of Opioid Use Disorder in Pregnancy [07E]. Obstetrics & Gynecology 135():p 51S, May 2020. | DOI: 10.1097/01.AOG.0000663444.50960.74
3. Substance Abuse and Mental Health Services Administration. Clinical Guidance for Treating Pregnant and Parenting Women With Opioid Use Disorder and Their Infants. HHS Publication No. (SMA) 18-5054. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 1 year

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)
  - Allergy to oral naloxone is extremely rare and must be well documented.
  - Any request for transmucosal buprenorphine should include justification why long-acting injectable buprenorphine can't be used
    - Pregnancy or breastfeeding will not be approved as clinical justification based on the clinically non-preferred information provided above.
    - Stability will not be approved as clinical justification, although limited approval may be granted to allow for recommended pre-treatment and titration prior to initiation of long-acting buprenorphine product – maximum of 7 days for Sublocade, and 1 dose for Brixadi

Non-Oral Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BRIXADI (buprenorphine)	this space intentionally left blank
BRIXADI (buprenorphine – *Medical Billing*	this space intentionally left blank
SUBLOCADE (buprenorphine)	this space intentionally left blank
SUBLOCADE (buprenorphine) – *Medical Billing*	this space intentionally left blank

Combination Product

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
buprenorphine-naloxone tablets	buprenorphine/naloxone film
this space intentionally left blank	SUBOXONE FILM (buprenorphine/naloxone)
this space intentionally left blank	ZUBSOLV (buprenorphine/naloxone)

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

Preferred Diabetic Supply List (PDSL)

Electronic Concurrent Medications Required

- One of the following must apply:
  - A total of a 25-day supply of one of the following must be paid within 150 days prior to diabetic supplies' date of service:
    - agents that cause hypoglycemia (insulin or sulfonylureas)
    - agents that indicate pregnancy (folic acid or prenatal vitamins)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- For coverage of blood glucose monitoring devices for those not meeting electronic concurrent medication required criteria above, the member has one of the following (A or B):
  - A. Recurrent hypoglycemia and the test strips are prescribed by or in consult with, a medical geneticist or an endocrinology specialist (subject to clinical review)
  - B. A diagnosis of diabetes and meet **one of the following** criteria:
    1. Newly diagnosed within the last 6 months
    2. Acutely ill
    3. Significant change in health status causing blood sugar variability
    4. Currently pregnant

The ADA guidelines point out the lack of clinical utility and cost-effectiveness of routine Self-Monitoring of Blood Glucose (SMBG) in non-insulin treated members. Both the Society of General Internal Medicine and the Endocrine Society recommend against routine SMBG for type 2 diabetes members not on insulin or agents that cause hypoglycemia.

Test Strips

Manufacturer Name	NDC	Product Description
Roche Diabetes Care, Inc.	65702-0711-10	Accu-Chek Guide Test Strip
Roche Diabetes Care, Inc.	65702-0712-10	Accu-Chek Guide Test Strip

Electronic Quantity Per Duration Verification

- Override not required: 200 test strips are covered every 365 days without an override.

If BOTH of the following criteria are met (A and B), please request an override for up to 6 test strips per day by calling provider relations at 1-800-755-2604 or emailing medicaidpharmacy@nd.gov:

- A. The member is not currently using a continuous glucose monitor
- B. The member meets prior authorization criteria or electronic concurrent medications required criteria for diabetic supplies above (under Preferred Diabetic Supply List header).

Test Strip Electronic Duration Verification Override Requests after CGM approval

For replacement inquiries, sensor overpatches, and troubleshooting please contact Dexcom Global Technical Support at 1-844-607-8398 or visit Dexcom Support

- ND Medicaid will cover 200 test strips per year to facilitate instances where CGM is not displaying blood sugar readings that correspond with the symptoms member is experiencing or that are consistently outside of the 20 rule: Is my Dexcom sensor accurate?

Prior Authorization Criteria

- The following criteria will apply if CGM has previously been paid, but will no longer be used and over 400 test strips per year are requested:
  - The member must be seen for education by a diabetic specialist or educator
  - Documentation must be submitted noting what caused the CGM failure and education / mitigation efforts that have been taken to prevent the failure, including the following as applicable:
    - Stickiness: Skin adhesive and / or overpatches have been trialed without success
    - Sensor not working: at least 2 sensor replacements have been trialed
    - Sensitive Skin: How can I avoid irritated or sensitive skin caused by the sensor adhesive?

Meters

Quantity Limits

- 1 meter is covered every 365 days

Manufacturer Name	NDC	Product Description
Roche Diabetes Care, Inc.	65702-0731-10	Accu-Chek Guide Me Glucose Meter
Roche Diabetes Care, Inc.	65702-0729-10	Accu-Chek Guide Monitor System

InPen

Quantity Limits

- 1 InPen is covered every 365 days

Manufacturer Name	NDC	Product Description
Minimed Distribution Corporation	62088-0000-31	InPen Smart Insulin Pen (Humalog - Blue)
Minimed Distribution Corporation	62088-0000-32	InPen Smart Insulin Pen (Humalog - Grey)
Minimed Distribution Corporation	62088-0000-33	InPen Smart Insulin Pen (Humalog - Pink)
Minimed Distribution Corporation	62088-0000-34	InPen Smart Insulin Pen (Novolog or Fiasp – Blue)
Minimed Distribution Corporation	62088-0000-35	InPen Smart Insulin Pen (Novolog or Fiasp – Gray)
Minimed Distribution Corporation	62088-0000-36	InPen Smart Insulin Pen (Novolog or Fiasp – Pink)
Minimed Distribution Corporation	63000-0827-15	InPen Smart Insulin Pen (Humalog - Blue)
Minimed Distribution Corporation	63000-0827-16	InPen Smart Insulin Pen (Humalog - Grey)

Minimed Distribution Corporation	63000-0827-17	InPen Smart Insulin Pen (Humalog - Pink)
Minimed Distribution Corporation	63000-0827-18	InPen Smart Insulin Pen (Novolog or Fiasp – Blue)
Minimed Distribution Corporation	63000-0827-19	InPen Smart Insulin Pen (Novolog or Fiasp – Gray)
Minimed Distribution Corporation	63000-0827-20	InPen Smart Insulin Pen (Novolog or Fiasp – Pink)

Pen Needles

Manufacturer Name	NDC	Product Description	Gauge/Size
Becton Dickinson & Company	08290-3207-49	Ultra-Fine Micro Pen Needle	32 G X 1/4"
Becton Dickinson & Company	08290-3201-19	Ultra-Fine Mini Pen Needle	31 G X 3/16"
Becton Dickinson & Company	08290-3201-22	Ultra-Fine Nano Pen Needle	32 G X 5/32"
Becton Dickinson & Company	08290-3282-03	Ultra-Fine Original Pen Needle	29 G X 1/2"
Becton Dickinson & Company	08290-3201-09	Ultra-Fine Short Pen Needle	31 G X 5/16"
Becton Dickinson & Company	08290-3205-50	Nano 2 Gen Pen Needle	32 G X 5/32"
Embecta	83017-0109-03	Ultra-Fine Pen Needle	31 G x 5/16”
Embecta	83017-0119-03	Ultra-Fine Pen Needle	31 G X 3/16"
Embecta	83017-0122-03	Nano Pen Needle	32 G X 5/32"
Embecta	83017-0550-03	Nano 2 Pen Needle	32 G X 5/32"
Embecta	83017-0749-03	Ultra-Fine Pen Needle	32 G X 1/4"
Embecta	83017-8203-03	Ultra-Fine Pen Needle	29 G X 1/2"
Owen Mumford USA, Inc.	08470-0540-01	Unifine Pentips	32GX 5/32"
Owen Mumford USA, Inc.	08470-0540-41	Unifine Pentips	32GX 5/32"
Owen Mumford USA, Inc.	08470-3429-01	Pentips	29 G X 1/2"
Owen Mumford USA, Inc.	08470-3430-01	Pentips	31 G X 5/16"
Owen Mumford USA, Inc.	08470-3440-01	Pentips	32 G X 5/32"
Owen Mumford USA, Inc.	08470-3450-01	Pentips	31 G X 3/16"
Owen Mumford USA, Inc.	08470-3490-01	Pentips	31 G X 1/4"
Owen Mumford USA, Inc.	08470-3495-01	Pentips	32 G X 1/4"
Owen Mumford USA, Inc.	08470-3529-01	Unifine Pentips	29 G X 1/2"
Owen Mumford USA, Inc.	08470-3530-01	Unifine Pentips	31 G X 5/16"
Owen Mumford USA, Inc.	08470-3540-01	Unifine Pentips	32 G X 5/32"
Owen Mumford USA, Inc.	08470-3550-01	Unifine Pentips	31 G X 3/16"
Owen Mumford USA, Inc.	08470-3560-01	Unifine Pentips	33 G X 5/32"
Owen Mumford USA, Inc.	08470-3590-01	Unifine Pentips	31 G X 1/4"
Owen Mumford USA, Inc.	08470-3595-01	Unifine Pentips	32 G X 1/4"
Owen Mumford USA, Inc.	08470-3829-01	Unifine Pentips Plus	29 G X 1/2"
Owen Mumford USA, Inc.	08470-3830-01	Unifine Pentips Plus	31 G X 5/16"
Owen Mumford USA, Inc.	08470-3840-01	Unifine Pentips Plus	32 G X 5/32"
Owen Mumford USA, Inc.	08470-3850-01	Unifine Pentips Plus	31 G X 3/16"
Owen Mumford USA, Inc.	08470-3860-01	Unifine Pentips Plus	33 G X 5/32"
Owen Mumford USA, Inc.	08470-3890-01	Unifine Pentips Plus	31 G X 1/4"

Owen Mumford USA, Inc.	08470-7935-01	Unifine Safecontrol	30 G X 5/16"
Owen Mumford USA, Inc.	08470-7930-01	Unifine Safecontrol	31 G X 5/16"
Owen Mumford USA, Inc.	08470-7940-01	Unifine Safecontrol	32 G X 5/32"
Owen Mumford USA, Inc.	08470-7950-01	Unifine Safecontrol	31 G X 3/16"
Owen Mumford USA, Inc.	08470-7955-01	Unifine Safecontrol	30 G X 3/16"
Owen Mumford USA, Inc.	08470-7990-01	Unifine Safecontrol	31 G X 1/4"

Insulin Syringes

Manufacturer Name	NDC	Product Description	Gauge/Size
Embecta	83017-4909-03	syring-needl,disp,insul,0.3 mL	31 G X 15/64"
Embecta	83017-4910-03	syrge-ndl,ins 0.3 mL half mark	31 G X 15/64"
Embecta	83017-4911-03	syringe-needle,insulin,0.5 mL	31 G X 15/64"
Embecta	83017-4912-03	syringe and needle,insulin,1mL	31 G X 15/64"
Embecta	83017-6730-03	syringe,insul U-500,ndl,0.5mL	31 G X 15/64"
Embecta	83017-8411-03	syringe and needle,insulin,1mL	30 G X 1/2"
Embecta	83017-8418-03	syringe and needle,insulin,1mL	31 G X 5/16"
Embecta	83017-8431-03	syring-needl,disp,insul,0.3 mL	30 G X 1/2"
Embecta	83017-8438-03	syring-needl,disp,insul,0.3 mL	31 G X 5/16"
Embecta	83017-8440-03	syrge-ndl,ins 0.3 mL half mark	31 G X 5/16"
Embecta	83017-8466-03	syringe-needle,insulin,0.5 mL	30 G X 1/2"
Embecta	83017-8468-03	syringe-needle,insulin,0.5 mL	31 GX5/16"
Ultimed Inc.	08222-0933-56	Ulticare Ins 0.3 Ml	30 G X 1/2"
Ultimed Inc.	08222-9100-66	Ulticare Ins 0.3 Ml	31 G X 1/4"
Ultimed Inc.	08222-9100-80	Ulticare Ins 0.5 Ml	31 G X 1/4"
Ultimed Inc.	08222-9100-97	Ulticare Ins 1 Ml	31 G X 1/4"
Ultimed Inc.	08222-0933-94	Ulticare Syr 0.3 Ml	30 G X 5/16"
Ultimed Inc.	08222-0935-92	Ulticare Syr 0.5 Ml	30 G X 5/16"
Ultimed Inc.	08222-0931-96	Ulticare Syr 1 Ml	30 G X 5/16"
Ultimed Inc.	08222-0943-91	Ulticare Syr 0.3 Ml	31 G X 5/16"
Ultimed Inc.	08222-0945-99	Ulticare Syr 0.5 Ml	31 G X 5/16"
Ultimed Inc.	08222-0941-93	Ultcare Ins Syr 1 Ml	31 G X 5/16"
Ultimed Inc.	08222-0931-58	Ulticare Ins Syr 1 Ml	30 G X 1/2"
Ultimed Inc.	08222-0935-54	Ulticare Ins 0.5 Ml	30 G X 1/2"
Ultimed Inc.	08222-0933-56	Ulticare Ins 0.3 Ml	30 G X 1/2"
Ultimed Inc.	08222-0821-83	Ulticare Ins Syr 1 Ml	28 G X 1/2"
Ultimed Inc.	08222-0923-97	Ulticare Syrin 0.3 Ml	29 G X 1/2"
Ultimed Inc.	08222-0925-95	Ulticare Syr 0.5 Ml	29 G X 1/2"
Ultimed Inc.	08222-0921-99	Ulticare Ins Syr 1 Ml	29 G X 1/2"

Ketone Strips

Quantity Limits

- 120 strips per 30 days

Manufacturer Name	NDC	Product Description
Trividia Health, Inc.	56151-0601-50	Ketone Test Strip

Continuous Glucose Monitors (CGM)

Preferred CGM

Quantity Limits

- NDC 08627005303- Dexcom G6 Sensor: up to 9 sensors/90-day supply
- NDC 08627001601- Dexcom G6 Transmitter: 1= 90-day supply (4 transmitters/365 days allowed)
- NDC 08627009011- Dexcom G6 Receiver: 1= 250-day supply (1 receiver/365 days allowed)
- NDC 08627007701- Dexcom G7 Sensor: up to 9 sensors/90-day supply
- NDC 08627007801- Dexcom G7 Receiver: 1= 250-day supply (1 receiver/365 days allowed)
- NDC 08627007901- Dexcom G7 Sensor: up to 6 sensors/90-day supply

Manufacturer Name	NDC	Product Description
Dexcom, Inc.	08627-0016-01	Dexcom G6 Transmitter
Dexcom, Inc.	08627-0053-03	Dexcom G6 10-day Sensor
Dexcom, Inc.	08627-0091-11	Dexcom G6 Receiver
Dexcom, Inc.	08627-0077-01	Dexcom G7 10-day Sensor
Dexcom, Inc.	08627-0078-01	Dexcom G7 Receiver
Dexcom, Inc.	08627-0079-01	Dexcom G7 15-day Sensor

Concurrent Medication Required

- Dexcom Sensors:
  - PA Not Required Criteria: A total of 50-day supply of insulin has been paid within 150 days prior to Dexcom sensor's date of service.
  - PA Required Criteria: The member must meet the prior authorization requirements below.
- Dexcom Transmitters and Receivers: **Please bill sensors first** followed by the transmitter or receiver.
  - If the transmitter or receiver is billed first, a "prior authorization required" rejection will occur even if a sensor PA does not require PA or has already been approved.

Prior Authorization Criteria

Continuous Glucose Monitor (CGM) Prior Authorization Form

Initial Criteria – Approval Duration: 1 year (Until due date or 6 months, if unknown, for gestational diabetes)

- The member must meet **one of the following** criteria (1 or 2):

1. The member has diabetes (e.g., type 1, type 2, gestational diabetes)
2. The member has recurrent hypoglycemia and CGM is prescribed by or in consult with, a medical geneticist, an endocrinology specialist, or a diabetic educator.

- The member must not have a life expectancy of less than 12 months.
- The member must not reside in a skilled nursing facility, intermediate care facility, or swing bed.
- Members with type 2 diabetes must be on insulin
- Members with gestational diabetes using insulin, type 1 diabetes, or type 2 diabetes, must meet one of the following (1, 2, 3 or 4):
  1. The member is newly diagnosed with diabetes using insulin and only has had one fill of insulin
  2. The member was at least 80% adherent to insulin, excluding any claim gaps due to hospitalization or eligibility.
  3. Clinical justification must be provided for non-adherence to insulin (subject to clinical review).
  4. A method to improve adherence to insulin must be provided such as addressing adherence barriers, implementing a treatment plan, medication therapy management (MTM), etc.

Non-Preferred CGM

A coverage exception will be considered for members that has had a Medtronic insulin pump for over a year or have had a Medtronic insulin pump purchased by another payer prior to eligibility for ND Medicaid to allow for CGM integration with their insulin pumps. Please submit supporting information for the coverage of a compatible CGM along with prior authorization information to meet the requirements as outlined in criteria below.

If the Medtronic insulin pump is older than 4 years, the authorization period will be shortened to verify that the pump is still functioning for re-authorization. If the Medtronic Insulin pump fails, the expectation is to switch to an insulin pump that is compatible with a preferred CGM.

- Guardian Sensor 3: max of 5 sensors (1 box) per 35-day supply
- Guardian Link Transmitter 3: max of 1 per 365-day supply
- Guardian Sensor 4: max of 5 sensors (1 box) per 35-day supply
- Guardian Link Transmitter 4: max of 1 per 365-day supply
- Instinct Sensor: max of 2 sensors per 30-day supply
- Simplera Sensor: max of 5 sensors per 35-day supply
- Simplera Sync Sensor: max of 5 sensors per 30-day supply

Guardian Sensor 3 will only be approved for Medtronic pump versions older than Minimed 780G because the other compatible CGM do not require calibration. Clinical justification for use of Guardian Sensor 3 must be submitted (subject to clinical review).

Calibrating your Sensor - MiniMed™ 780G System Support | Medtronic (medtronicdiabetes.com)

Please contact Medtronic for replacement sensor and transmitters:
Sensor and Transmitter Support - Product Support | Medtronic (medtronicdiabetes.com)

CGM Supplies Coverage FAQ

Does ND Medicaid cover Dexcom daily calibration?

- No, the unique Dexcom sensor code must be entered that is printed on each sensor's adhesive label during the startup period, so finger sticks and calibration are not required.
- Does the Dexcom G6 Continuous Glucose Monitoring (CGM) System require calibrations?
- Can I calibrate Dexcom G7? | Dexcom

Will test strips be covered in addition to Dexcom?

- Yes, ND Medicaid will cover 200 test strips per year to facilitate instances where Dexcom is not displaying blood sugar readings that correspond with the symptoms member is experiencing or that are consistently outside of the 20 rule.
- Is my Dexcom sensor accurate?

Does ND Medicaid cover additional sensors, transmitters, or receivers if mine is faulty or broken?

- For replacement inquiries, sensor overpatches, and troubleshooting please contact Dexcom Global Technical Support at 1-844-607-8398 or visit Dexcom Support

If my patient is currently on a CGM that is not Dexcom, is there a grandfathering period?

- No, the member should be converted to Dexcom billed on the pharmacy side to obtain ND Medicaid coverage. Exceptions will be considered for members that already have a Medtronic insulin pump for over a year or has had a Medtronic Insulin pump purchased by another payer prior to eligibility for ND Medicaid to allow for CGM integration.

Does ND Medicaid cover Dexcom for members with Medicare?

- If a member has Medicare Part B, Medicare Part B will need to be billed primary and ND Medicaid may cover the remainder as a crossover claim with medical billing.
- If a member does not have Medicare Part B but has Medicare part A, an override will need to be obtained for coverage and Dexcom must be billed on the pharmacy benefit.
- If the member has a Medicare Advantage plan, any remaining amount will need to be billed to ND Medicaid through the MMIS portal as a medical claim.
- In all cases, the member must meet prior authorization criteria for coverage.

How is CGM billed for Medicaid Expansion members?

- CGM will need to be billed to ND Medicaid for Medicaid Expansion members.

How is CGM billed for Special Health Services (SHS) members eligible for ND Medicaid?

- Members receiving CGM other than Dexcom will need to work with SHS for CGM coverage. Exceptions will be considered for members that already have a Medtronic insulin pump to allow for CGM integration.

Billing FAQ

If I bill Medtronics Guardian sensors under the code A9276 on the medical benefit, will this be covered?

- No, the code will only be covered for members with primary insurance plans that require CGM to be billed on the medical side. Members will need to be converted to Dexcom billed on the pharmacy side to obtain ND Medicaid coverage. Exceptions will be considered for members that have had a Medtronic insulin pump for over a year or has had a Medtronic Insulin pump purchased by another payer prior to eligibility for ND Medicaid or to allow for CGM integration. Medtronic CGM must be billed on the pharmacy side.

Will ND Medicaid cover Dexcom through medical billing?

- ND Medicaid requires Dexcom to be billed through pharmacy NCPDP D.0 billing.
- Exceptions may be made for cases where primary insurance or Medicare requires Dexcom to be billed with medical billing.

Other Insurance FAQ

If primary insurance only covers CGM other than Dexcom, will ND Medicaid pay the copay?

- If primary insurance excludes coverage of a Dexcom, ND Medicaid may make an exception to cover a different CGM if the copay is nominal. Documentation of the exclusion must be submitted with the prior authorization request.
- If primary insurance does cover Dexcom, the member will need to switch to Dexcom for ND Medicaid to pay the copay.

Does ND Medicaid cover Dexcom if member has primary insurance, but it does not cover CGM?

- ND Medicaid may cover Dexcom as a primary payer if CGM is wholly excluded from the primary insurance benefit. Documentation stating the exclusion from the primary insurance must be submitted with the prior authorization request.
- ND Medicaid will not cover CGM as a primary payer if a prior authorization is denied for medical necessity by the primary insurance.

Will ND Medicaid cover Dexcom if member meets primary insurance prior authorization criteria, but does not meet ND Medicaid prior authorization criteria?

- ND Medicaid will not cover Dexcom if ND Medicaid prior authorization criteria is not met, regardless of approval status with primary insurance. Under rare circumstances, exceptions may be made if the copay is nominal as long as the member maintains primary insurance coverage with a Dexcom benefit.

Tubeless Insulin Pumps

Quantity Limits:

- NDC 08508200005 - Omnipod DASH Refill Pods – 10 pods per 30-day supply
- NDC 08508300001 - Omnipod 5 Intro Kit – 1 per 30-day supply (payable 1 per 365 days)
- NDC 08508300021 - Omnipod 5 Refill Pods – 10 pods per 30-day supply
- NDC 08508300088 - Omnipod 5 Intro G6 for Libre 2 – 1 per 30-day supply (payable 1 per 365 days)
- NDC 08508300042 - Omnipod 5 G6 Refill Pods for Libre 2 – 10 pods per 30-day supply

Requests for greater than 10 pods per 30 days must include clinical justification vs using a tubed pump. If requested quantity exceeds 15 pods per 30 days, request will be denied for Omnipod. Member may still be eligible for tubed pump (requires separate medical prior authorization).

Manufacturer Name	NDC	Product Description
Insulet, Inc.	08508-2000-05	Omnipod DASH Refill Pods
Insulet, Inc.	08508-3000-01	Omnipod 5 Intro Kit
Insulet, Inc.	08508-3000-21	Omnipod 5 Refill Pods
Insulet, Inc.	08508-3000-42	Omnipod 5 FSL2 Plus G6 Pods
Insulet, Inc.	08508-3000-88	Omnipod 5 FSL2 Plus G6 Intro Kits

Prior Authorization Criteria

Tubeless Insulin Pump (Omnipod) Prior Authorization Form

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist, diabetic educator, or prescriber specializing in the treatment of diabetes or prescriber must attest to all of the following:
  A. The member will maintain regular provider visits to review glycemic control data every 3-6 months.
  B. The member will receive Omnipod training from Omnipod System Trainer or a healthcare provider.
- The member has not received a tubed insulin pump within the past 4 years or must be experiencing elevated glucose levels from disconnecting due to contact or swimming sports.
- The member must be using a compatible rapid-acting insulin.
- The member must have one of the following (A, B, or C):
  A. Diabetes type 1 or type 2
  B. Diabetes due to pancreatectomy
  C. Diabetes due to an auto-immune beta cell destruction requiring insulin therapy with a long-acting and short-acting insulin for the past 6 months, as evidenced by paid claims or pharmacy print outs.
- Members with Type 2 Diabetes must meet **one of the following** criteria (1 or 2):
  A. The member has been on short-acting and long-acting insulin for at least 6 months, as evidenced by refill history with paid claims or pharmacy printouts.
  B. The member is currently Humulin R U-500 or an insulin pump.
- Requests for greater than 10 pods per 30 days must include clinical justification vs using a tubed pump. If requested quantity exceeds 15 pods per 30 days, request will be denied for Omnipod. Member may still be eligible for tubed pump (requires separate medical prior authorization).

Omnipod Coverage FAQ

For replacement inquiries or troubleshooting please contact Insulet Customer Care team at 1-800-591-3455 or visit https://na.myomnipod.com/contact.

Does ND Medicaid cover insulin pens, syringes, or vials if Omnipod is discontinued?

- Transition should be coordinated with diabetic specialist or educator.
- Current vials of rapid acting insulin should be exhausted before switching to pens. See Insulin category for a list of preferred products.
- Current supply of pods should be exhausted prior to switching to injections.

Does ND Medicaid cover additional pods or Personal Diabetes Manager (PDM) if mine is faulty or broken?

- For replacement inquiries or troubleshooting please contact Insulet Customer Care team at 1-800-591-3455 or visit https://na.myomnipod.com/contact.

Does ND Medicaid cover additional pods, Personal Diabetes Manager (PDM), replacement USB cords or rechargeable batteries if mine is lost or stolen?

- For replacement inquiries or troubleshooting please contact Insulet Customer Care team at 1-800-591-3455 or visit https://na.myomnipod.com/contact.
- PDMs, USB cords, and rechargeable batteries may be replaced once every 365 days.
- Pods are not replaceable.

Will ND Medicaid cover Omnipod through medical billing?

- ND Medicaid requires Omnipod to be billed through pharmacy NCPDP D.0 billing.

How is Omnipod billed for Medicaid Expansion and Special Health Services (SHS) ND Medicaid eligible members?

- Omnipod will need to be billed to ND Medicaid for Medicaid Expansion members.
- Omnipod will need to be billed to ND Medicaid for SHS members who are eligible for ND Medicaid

Does ND Medicaid cover Omnipod for members?

- If a member is eligible for Medicare, Medicare Part D will need to be billed primary.
- If member is not eligible for Medicare, the member must meet prior authorization criteria for coverage.

Does ND Medicaid cover Omnipod if member has primary insurance, but it does not cover tubeless pumps?

- ND Medicaid may cover Omnipod as a primary payer if insulin pumps are wholly excluded from the primary insurance benefit. Documentation stating the exclusion from the primary insurance must be submitted with the prior authorization request.
- ND Medicaid will not cover Omnipod as a primary payer if a prior authorization is denied for medical necessity by the primary insurance or primary insurance only covers tubed pumps.

Will ND Medicaid cover Omnipod if member meets primary insurance prior authorization criteria, but does not meet ND Medicaid prior authorization criteria?

- ND Medicaid will not cover Omnipod if ND Medicaid prior authorization criteria is not met, regardless of approval status with primary insurance. Under rare circumstances, exceptions may be made if the copay is nominal as long as the member maintains primary insurance coverage with a Omnipod benefit.

Appendix A: Concurrent Antipsychotics

Concurrent Oral Antipsychotic

Please use the Concurrent Antipsychotics PA form and attach appropriate documentation as necessary.

Cross-Tapering Plans ARE covered

Antipsychotic cross-taper plans are covered upon request. An expected plan and timeline must be included with the request.

Use of Multiple Antipsychotics MAY be covered

The use of two or more antipsychotics should be limited to cases where three trials of adequate dose and duration monotherapy have failed including a trial of clozapine. Previous adequate trials with response should be well documented.

The use of one antipsychotic to target one symptom and another antipsychotic to target an additional symptom is not covered. A single antipsychotic can target multiple symptoms.

Oral Combination Therapy Criteria

Please use the Concurrent Antipsychotics PA form and attach appropriate documentation as necessary.

Approval: An authorization of oral combination therapy for 3 months

- One of the following must be met (1-3):
  1. The member is stabilized on regimen and is establishing care with the prescriber.
  2. The member has been discharged from a psychiatric hospital within the past month.
  3. Cross tapering from one oral antipsychotic to another.
  4. The prescriber must provide clinical justification (subject to clinical review)

Approval: An authorization of oral combination therapy for 12 months

- For the treatment of schizophrenia, member must meet one of the following:
  - The member has tolerated 2 monotherapy antipsychotic trials at a therapeutic dose and duration.
- For other indications:
  - The prescriber must provide clinical justification that all alternative antipsychotic active ingredient options have been trialed or ruled out as monotherapy for member (subject to clinical review).

Approval: An authorization of oral combination therapy for 2 years

- The member is using aripiprazole for hyperprolactinemia.
- The member has been stabilized on oral combination for over a year and has not had any psychiatric hospitalizations or breakthrough symptoms.
- The prescriber must provide clinical justification (subject to clinical review)

Special considerations

Aripiprazole

- Aripiprazole is supported in the compendia for use for treatment of drug-induced hyperprolactinemia, caused by antipsychotics. Therefore, upon request, aripiprazole is allowed in combination with other antipsychotics for the treatment of hyperprolactemia.

Clozapine

- Clozapine should be reserved for treatment resistant cases where two or more monotherapy trials have already failed. In cases of clozapine treatment resistance and augmentation is considered, note that aripiprazole has been shown to be the most effective antipsychotic in combination with clozapine. Combination therapy is allowed without approval.

Haloperidol

- Haloperidol may be covered for PRN use for acute agitation / violence prevention. Requests should include clinical rationale of use to prevent harm to self or others. PRN use means 10 doses or less per 30 days. More frequent use will only be considered to allow for maintenance medication adjustments to decrease agitation.

Olanzapine

- Olanzapine may be covered for PRN use for acute agitation / violence prevention. Requests should include clinical rationale of use to prevent harm to self or others. PRN use means 10 doses or less per 30 days. More frequent use will only be considered to allow for maintenance medication adjustments to decrease agitation.

Quetiapine

- Nighttime akathisia (e.g., nighttime dosing with risperidone) or daytime sedation (e.g., quetiapine ER dosed at nighttime) must prevent ability to titrate to effective dose with monotherapy.
- Other sleeping medications must be trialed. Primary use for insomnia will not be approved.

Long-Acting Injectable and Oral Combination

Please use the Concurrent Antipsychotics PA form and attach appropriate documentation as necessary.

Shortened interval requests are ***not covered*** as they are not supported in the FDA dosing recommendations or compendia.

Experiencing wearing off symptoms during the titration period (first 3 months of treatment) or first-time experiencing breakthrough symptoms:

Approval: A 3-month authorization of oral supplemental of the same active ingredient

- The medication requires oral overlap at initiation.
- The member has received a proper loading dose at initiation or recommended oral supplementation and is experiencing breakthrough symptoms.

Ongoing request (> 1 incident of breakthrough symptoms after titration):

Approval: An authorization of oral supplemental for 12 months

- A MedWatch form for the long-acting antipsychotic must be filled out and attached to request
- The dose must be optimized to maximum FDA approved dose for the LAI antipsychotic
    - A 3-month override of the same active ingredient may be considered for breakthrough symptoms while optimizing dose
- The member must have breakthrough symptoms for 2 or more injection cycles
- One of the following (1, 2, or 3) must be met if breakthrough symptoms are occurring earlier than 75% of recommended interval:
    1. The member must have had greater than a 20% reduction in symptoms with continued improvement
    2. The member must have had greater than a 50% reduction in symptoms
    3. One of the following must be met:
        - The member has had 2 monotherapy antipsychotic trials for an adequate duration
        - The prescriber must provide justification that all alternative active ingredient options have been trialed or ruled out as monotherapy for member (subject to clinical review)

Appendix B: Antidepressant Cross Tapering:

Selective Serotonin Reuptake Inhibitors (SSRIs) switched to:

Selective Serotonin Reuptake Inhibitors (SSRIs)

Cross Taper is NOT covered

Direct switch between SSRIs is typically well-tolerated as SSRIs overlap in their mechanism of action.

Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)

Cross Taper is generally NOT covered, case by case coverage may be provided

Direct switch between SNRI and SSRI is typically well-tolerated because both SNRIs and SSRIs have strong serotonergic properties, with the following exceptions:

- Patient switching from high dose SSRIs, cross tapering may be of benefit
- Patient switching from fluoxetine or paroxetine to duloxetine or venlafaxine should start SNRI at a low dose. Fluoxetine and paroxetine inhibit the metabolization of duloxetine and venlafaxine.

Tricyclic Antidepressants

Cross Taper is covered

Cross tapering is recommended. Tricyclic antidepressants should be started at a low dose especially when discontinuing fluoxetine, fluvoxamine, and paroxetine. These SSRIs can inhibit the metabolism of tricyclic antidepressants resulting in higher levels of tricyclic antidepressants. Tricyclic antidepressants can be fatal in overdose. Most SSRIs will clear the system within 5 days, but fluoxetine will persist for up to 5 weeks.

Monoamine oxidase inhibitor (MAOIs)

Cross Taper is NOT covered

Cross tapering is not recommended and can result in serotonin syndrome or severe hypertensive crisis. A washout period of two weeks is recommended between last dose of SSRI and MAOI except in the case of fluoxetine, where a 5-week washout period is recommended.

Other Antidepressants

Cross Taper is covered

Appendix C: Prior Authorization Review Dates

Date	Category
06/03/2026	Acromegaly
06/03/2026	Calcium Channel Blockers
06/03/2026	Graft vs Host Disease
06/03/2026	Malaria
03/04/2026	Alzheimer's Disease
03/04/2026	Phenylketonuria (PKU)
03/04/2026	Non-Cystic Fibrosis Bronchiectasis
03/04/2026	IgA Nephropathy
03/04/2026	C3 Glomerulopathy
03/04/2026	Diabetic Kidney Disease
12/03/2025	Niemann-Pick disease type C (NPC)
12/03/2025	ANCA-Associated Vasculitis
09/03/2025	Non-Opioid Analgesics
06/04/2025	Diabetes Mellitus
03/05/2025	Migraine Prophylaxis and Treatment
03/05/2025	Nonsteroidal Anti-Inflammatory Drugs (NSAIDS)
03/05/2025	Primary Biliary Cholangitis
12/04/2024	Stimulants for ADHD
09/04/2024	Molluscum Contagiosum
09/04/2024	Epidermolysis Bullosa
09/04/2024	Metabolic Dysfunction–Associated Steatohepatitis
06/05/2024	Acid Blockers
06/05/2024	Seborrheic Dermatitis
06/05/2024	Primary Hyperoxaluria Type 1
06/05/2024	Myasthenia Gravis
06/05/2024	Duchenne Muscular Dystrophy
06/05/2024	Paroxysmal Nocturnal Hemoglobinuria
12/06/2023	Diuretics
12/06/2023	Menopause
06/07/2023	Hyperparathyroidism
06/07/2023	Influenza
06/07/2023	Neuromyelitis Optica Spectrum Disorder
06/07/2023	Urea Cycle Agents
12/07/2022	Prurigo Nodularis
12/07/2022	Endometriosis Pain
12/07/2022	Hematopoietic Syndrome of Acute Radiation Syndrome (Nplate)
12/07/2022	Amyloidosis
12/07/2022	Amyotrophic Lateral Sclerosis (ALS)
12/07/2022	Chelating Agents
09/07/2022	Presbyopia
09/07/2022	Hypertrophic Cardiomyopathy

09/07/2022	Cushing’s Syndrome
09/07/2022	Vernal Keratoconjunctivitis
09/07/2022	Wilson’s Disease
06/01/2022	Familial Cholestasis Pruritis
03/02/2022	Anti-infectives Resistance Prevention
03/02/2022	Chronic Kidney Disease
03/02/2022	Lupus/Lupus Nephritis
12/01/2021	Atopic Dermatitis/Eczema
12/01/2021	Non-Stimulants for ADHD
09/01/2021	Heart Failure
09/01/2021	Nasal Polyps
09/01/2021	Chronic Spontaneous Urticaria (Chronic Idiopathic Urticaria)
09/01/2021	Uterine Fibroids
09/01/2021	Sedative/Hypnotics – Hetlioz
06/02/2021	Sickle Cell Disease
06/02/2021	Fabry Disease
06/02/2021	Imcivree
06/02/2021	Bowel preparation agents
03/03/2021	Evrysdi
03/03/2021	Hereditary angioedema
03/03/2021	Irritable bowel syndrome
12/02/2020	Agents for the treatment of diabetic gastroparesis
12/02/2020	Oriahnn
12/02/2020	Dojolvi
09/02/2020	Palforzia
09/02/2020	Mytesi
09/02/2020	Antifibrinolytic agents
09/02/2020	ACL inhibitors (Nexletol, Nexlizet)
09/02/2020	Cystic fibrosis agents
06/03/2020	Conjupri
03/04/2020	Glucagon agents
03/04/2020	Ofev for treatment of scleroderma with interstitial lung disease
12/04/2019	antifungal agents for aspergillus and candidiasis infections
12/04/2019	eosinophilic asthma agents
09/04/2019	short-acting opioid analgesic agents
09/04/2019	agents for the treatment of thrombocytopenia
09/04/2019	agents for the treatment of interstitial cystitis
09/04/2019	agents for the treatment of narcolepsy
06/05/2019	Sivextro
06/05/2019	Nuzyra
06/05/2019	agents for treatment of osteoporosis
06/05/2019	agents for treatment of hyperkalemia
06/05/2019	agents for treatment of Parkinson’s disease

04/09/2019	Orilissa
04/09/2019	agents for treatment of vaginal anti-infectives
04/09/2019	agents for treatment of glaucoma
04/09/2019	agents for treatment of dry eye syndrome
12/05/2018	glyburide and Avandia
12/05/2018	Lucemyra
12/05/2018	Palynziq
12/05/2018	Roxybond
12/05/2018	Siklos
09/05/2018	Daxbia
09/05/2018	Dermatophytosis (Tinea infections) agents
09/05/2018	Migraine prophylaxis
09/05/2018	Millipred DP
09/05/2018	Rytary
06/06/2018	Anzemet and Zuplenz
06/06/2018	biosimilar agents
06/06/2018	topical corticosteroid agents
06/06/2018	Dupixent
06/06/2018	Gocovri
06/06/2018	Tussicaps
03/07/2018	Skelaxin
03/07/2018	Eucrisa
09/06/2017	Proglycem
09/06/2017	Biltricide
03/01/2017	prednisolone ODT, Millepred, Veripred
03/01/2017	metformin OSM
03/01/2017	testosterone oral
12/07/2016	Namenda XR
12/07/2016	Dihydroergotamine
12/07/2016	Tetracycline
12/07/2016	Spiriva Respimat 2.5 mcg
12/07/2016	ophthalmic corticosteroids
12/07/2016	erythropoiesis-stimulating agents
09/07/2016	Kits
09/07/2016	dipeptidyl peptidase-4 (DPP-4) inhibitors
09/07/2016	Immunoglobulins
09/07/2016	topical agents used to treat plaque psoriasis
09/07/2016	platelet aggregation inhibitors
09/07/2016	Antihyperuricemics
06/01/2016	Glumetza
06/01/2016	naloxone rescue medications
06/01/2016	Naltrexone
06/01/2016	Edecrin

06/01/2016	interleukin-5 antagonist monoclonal antibodies
06/01/2016	Acitretin
06/01/2016	lice medications
06/01/2016	NK1 receptor antagonists
06/01/2016	Tirosint
03/02/2016	insulins
03/02/2016	steroid inhalers
03/02/2016	digestive enzymes
03/02/2016	nasal steroids
03/02/2016	otic anti-infectives
03/02/2016	ulcer anti-infectives
12/02/2015	Marinol
12/02/2015	skin pigment products
12/02/2015	inhaled corticosteroid/LABA combination products
12/02/2015	Movantik
12/02/2015	medications used to treat irritable bowel syndrome/OIC
12/02/2015	medications used to treat ulcerative colitis
12/02/2015	SGLT2 products
12/02/2015	immediate release oxycodone
12/02/2015	inhaled anti-infectives for cystic fibrosis
12/02/2015	leukotriene modifiers
09/02/2015	cholesterol lowering drugs
09/02/2015	injectable anticoagulants
09/02/2015	Akynzeo
09/02/2015	Nuvessa
09/02/2015	Cholbam
06/03/2015	Otezla
06/03/2015	Xtoro
06/03/2015	Hemangeol
06/03/2015	Lemtrada
06/03/2015	agents used to treat idiopathic pulmonary fibrosis
06/03/2015	GLP-1 receptor agonists
06/03/2015	topical therapies for onychomycosis
12/03/2014	testosterone products
12/03/2014	phosphate binders
12/03/2014	Zontivity
12/03/2014	Evzio
09/03/2014	Northera
09/03/2014	Oral Allergen Extracts
06/02/2014	Cathflo
06/02/2014	Intranasal Cyanocobalamin Products
06/02/2014	Luzu
06/02/2014	Noxafil

06/02/2014	Bethkis
03/03/2014	Statins
03/03/2014	Vecamyl
12/03/2013	Brisdelle
12/03/2013	Nitroglycerin Lingual Spray/Sublingual Tablets
12/03/2013	Agents Used to Treat COPD
12/03/2013	Epinephrine Auto-Injection Devices
12/03/2013	Pulmozyme
09/09/2013	Rayos
09/09/2013	Diclegis
09/09/2013	Sitavig
09/09/2013	Onmel
09/09/2013	Giazo
06/03/2013	Fulyzaq
06/03/2013	Xeljanz
03/11/2013	Genitourinary Smooth Muscle Relaxants
03/11/2013	Agents Used to Treat Multiple Sclerosis
12/03/2012	Actinic Keratosis
12/03/2012	Moxeza
09/17/2012	Kalydeco
09/17/2012	Kuvan
09/17/2012	Elaprase
06/04/2012	Lorzone
06/04/2012	Provigil
06/04/2012	Kapvay
06/04/2012	Dexpak/Zemapak
06/04/2012	Xifaxan
06/04/2012	Vanos
03/05/2012	Pulmonary Arterial Hypertension Agents
03/05/2012	Topical Acne Agents
03/05/2012	Benign Prostatic Hyperplasia Agents
03/05/2012	Juvisync/Combination Products
03/05/2012	Gralise
12/05/2011	Dificid
12/05/2011	Direct Acting Oral Anticoagulants (DOACs)
12/05/2011	agents used to treat Hereditary Angioedema
09/12/2011	Asacol HD
09/12/2011	Ophthalmic Antihistamines
09/12/2011	Horizant
09/12/2011	Daliresp
09/12/2011	narcotics with high dose APAP
06/06/2011	Nuedexta
06/06/2011	Nexiclon

06/06/2011	Topical ketoconazole products
03/07/2011	Statins
03/07/2011	Gilenya
03/07/2011	Xyrem
12/06/2010	agents used to treat Hepatitis C
12/06/2010	ODT preparations
12/06/2010	Oravig
12/06/2010	Zyclara
12/06/2010	Clorpres
12/06/2010	Livalo
12/07/2009	Hemophilia
12/07/2009	Sancuso
12/07/2009	Relistor
12/07/2009	Nuvigil
12/07/2009	Nucynta
09/14/2009	Uloric
09/14/2009	Moxatag
09/14/2009	Targeted Immune Modulators
06/01/2009	Aczone
12/01/2008	Triptans
12/01/2008	Vusion
09/08/2008	Chantix
09/08/2008	Carisoprodol
02/04/2008	Ophthalmic Anti-infectives
08/20/2007	High-Cost Medications
08/20/2007	Ketek
08/20/2007	Xopenex
08/20/2007	Tekturna
08/20/2007	Synagis
08/20/2007	Amrix
06/04/2007	Qualaquin
12/11/2006	Exubera
12/11/2006	Solodyn and Oracea
12/11/2006	Oxycontin
11/13/2006	Generic medications
11/13/2006	Vigamox and Zymar
11/13/2006	Boniva
05/01/2006	Growth Hormone
05/01/2006	Sedative/Hypnotics Agents
02/13/2006	Actoplus met
11/07/2005	Revatio
08/08/2005	Zanaflex capsule
12/13/2004	ACE inhibitors

12/13/2004	ARBs
12/13/2004	Proton Pump Inhibitors
01/26/2004	COX-II and brand name NSAIDS
11/03/2003	Antihistamines
04/29/2002	Out of State Drugs
09/01/1999	Xenical

Appendix D: Disease Prevention Pathway

Disease Prevention Pathway Criteria:

The following criteria may be provided by a pharmacist (billed through the MTM program), a Syringe Service Program, or clinic-based E&M billed service (provided by a nurse or independent practitioner)

- Two visits are required prior to drug approval, a third visit during treatment is strongly recommended.

Persons who Inject Drugs (PWID):

ALL of the following must be provided/evaluated at the first, second, and third appointments:

- Referral to Syringe Service Program
- Access to and use of sterile syringes, needles, and injection equipment (may not be purchased using state funds including billing Medicaid per NDCC 23-01)
- Counseling on storage and disposal of injection equipment safe and legal manner
- Education and training on drug overdose response and treatment, including access and administration of overdose reversal medication.
- Education, referral, and linkage to human immunodeficiency virus, viral hepatitis, and sexually transmitted disease prevention, treatment, and care services
- Substance Use Disorder treatment information, and referrals to treatment programs as appropriate

Follow-up phone call (following first appointment) evaluating the implementation of the following:

- Use of sterile syringe, needle, and injection is implemented.
- Storage and disposal of injection equipment safe and legal manner

People with Alcohol Use Disorder:

ALL of the following must be provided/evaluated at the first, second, and third appointments:

- Education on the impact of alcohol to liver health (i.e., continued use can result in development of cirrhosis even in the absence of Hepatitis C)
- Counseling on how to reduce risk and severity of harmful consequences arising from severe alcohol intoxication (e.g., transportation services, condom use, avoiding fighting, drinking low alcohol beverages, padding furniture and stairs)
- Counseling on Safer-use Strategies: Alcohol
- Provide alcohol addiction treatment information and linkage to alcohol treatment programs as appropriate

Follow-up phone call (following first appointment) evaluating the implementation of the following:

- Safer-use and risk reduction strategies implemented.

References:

- Pharmacy Provider Manual

Appendix E: Preferred Dosage Form Criteria List

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a 30-day trial of each preferred medication, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

Azathioprine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine 50 mg	azathioprine 75 mg
this space intentionally left blank	azathioprine 100 mg

Bendamustine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bendamustine 25 mg and 100 mg vials – *Medical Billing*	BELRAPZO (bendamustine) 100 MG/4 ML VIALS – *Medical Billing*
BENDEKA (bendamustine) 100 MG/4 ML VIALS – *Medical Billing*	bendamustine 100 mg/4 mL vials – *Medical Billing*
this space intentionally left blank	VIVIMUSTA (bendamustine) 100 MG/4 ML VIALS – *Medical Billing*

butalbital-acetaminophen-caffeine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
butalbital-acetaminophen-caffeine tablets	butalbital-acetaminophen-caffeine capsules
this space intentionally left blank	FIORICET (butalbital-acetaminophen-caffeine) CAPSULES

citalopram

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
citalopram tablets	citalopram capsules
citalopram solution	this space intentionally left blank

colchicine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
colchicine tablet	colchicine capsule
this space intentionally left blank	GLOPERBA (colchicine) ORAL SOLUTION

this space intentionally left blank	LODOCO (colchicine) TABLET
this space intentionally left blank	MITIGARE (colchicine) CAPSULE

cyanocobalamin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
cyanocobalamin injection	NASCOBAL (cyanocobalamin) NASAL SPRAY

desmopressin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
desmopressin nasal spray	DESMODA (desmopressin) ORAL SOLUTION
desmopressin tablets	this space intentionally left blank

epinephrine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
epinephrine – labeler 49502	AUVI-Q (epinephrine)
EPIPEN (epinephrine) – *Brand Co-Preferred*	epinephrine – labeler 00093, 00115
EPIPEN (epinephrine) JUNIOR– *Brand Co-Preferred*	NEFFY (epinephrine)

Electronic Duration Verification

- 4 doses are covered every 60 days without an override

If one of the following criteria are met (A or B), please request an override by calling provider relations at 1-800-755-2604 or emailing medicaidpharmacy@nd.gov:

A. The previous dose has expired
B. The dose was used by member for an anaphylactic episode

gabapentin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
gabapentin	gabapentin ER
this space intentionally left blank	GABARONE (gabapentin)
this space intentionally left blank	GRALISE (gabapentin)
this space intentionally left blank	HORIZANT (gabapentin)
this space intentionally left blank	RELGAABI (gabapentin)

Jadenu (deferasirox)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
deferasirox tablet for suspension	EXJADE (deferasirox tablet for suspension)
deferasirox tablets	deferasirox sprinkle
this space intentionally left blank	JADENU (deferasirox) SPRINKLE
this space intentionally left blank	JADENU (deferasirox) TABLETS

Kits

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FDA approved products prescribed separately	CAMPHOTREX 4%-10% ROLL-ON G (menthol/camphor)
this space intentionally left blank	CENTANY AT (mupirocin)
this space intentionally left blank	CICLOPIROX (ciclopirox/urea/camphor/methol)
this space intentionally left blank	CICLODAN (ciclopirox/urea/camphor/methol)
this space intentionally left blank	CICLODAN (ciclopirox/skin cleanser 28)
this space intentionally left blank	CLINDACIN ETZ (clindamycin phos/skin clnsr 19)
this space intentionally left blank	CLINDACIN PAC (clindamycin phos/skin clnsr 19)
this space intentionally left blank	CLINDAVIX (clindamycin/dimethacone/zinc oxide)
this space intentionally left blank	CLOBETEX (clobetasol/desloratadine)
this space intentionally left blank	CYCLOPAK (cyclobenzaprine/lidocaine/prilocaine/glycerine)
this space intentionally left blank	DERMACINRX ARM PAK (lidocaine/dimethacone)
this space intentionally left blank	DERMACINRX LEXITRAL PHARMAP (diclofenac/capsicum oleoresin)
this space intentionally left blank	DERMACINRX PHN PAK (lidocaine/emollient cmb No. 102)
this space intentionally left blank	DERMACINRX SILAPAK (triamcinolone/dimeth/silicone)
this space intentionally left blank	DERMACINRX SILAZONE (triamcinolone/silicones)
this space intentionally left blank	DERMACINRX SURGICAL PHARMAP (mupirocin/chlorhexidine/dimeth)
this space intentionally left blank	DERMACINRX THERAZOLE PAK (clotrimazole/betameth dip/zinc)
this space intentionally left blank	DERMACINRX ZRM PAK (lidocaine/dimethicone)
this space intentionally left blank	DERMALID 5% PATCH (lidocaine/elastic bandage)
this space intentionally left blank	ELLZIA PAK (triamcinolone/dimethicone)
this space intentionally left blank	ESOMEP-EZS KIT (esomeprazole mag/glycerin)
this space intentionally left blank	ECONASIL (econazole/gauze/silicone)
this space intentionally left blank	FLUOPAR (fluocinonide/dimethacone)
this space intentionally left blank	FLUOVIX PLUS (fluocinonide/silicone,adhesive)
this space intentionally left blank	GABACAINE KIT (gabapentin/lidocaine)
this space intentionally left blank	INAVIX (diclofenac/capsaicin)
this space intentionally left blank	INFAMMACIN (diclofenac/capsicum)
this space intentionally left blank	KETODAN (ketoconazole/skin cleanser 28)
this space intentionally left blank	lidocaine-prilocaine cream 2.5%-2.5% kit

this space intentionally left blank	LIDOPURE PATCH 5% COMBO PAC (lidocaine/kinesiology tape)
this space intentionally left blank	LIDOTIN (gabapentin/lidocaine/silicone)
this space intentionally left blank	LIPRITIN (gabapentin/lidocaine/prilocaine/dressing)
this space intentionally left blank	LOPROX (ciclopirox/skin cleanser No. 40)
this space intentionally left blank	MIGRANOW KIT (sumatriptan/menthol/camphor)
this space intentionally left blank	MORGIDOX (Doxycycline/skin cleanser No. 19)
this space intentionally left blank	NAPROTIN (naproxen/capsicum)
this space intentionally left blank	NOPIOID-TC KIT (cyclobenzaprine/lidocaine/menthaine)
this space intentionally left blank	NUVAKAAN KIT (lidocaine/prilocaine/silicone)
this space intentionally left blank	NUSURGEPAK (mupirocin/chlorhexidine/dimethacone)
this space intentionally left blank	NUTRIARX (Triamcinolone/dimethacone/silicone)
this space intentionally left blank	PRILO PATCH KIT (lidocaine/prilocaine)
this space intentionally left blank	PRIZOTRAL II (lidocaine/prilocaine/lidocaine)
this space intentionally left blank	PRO DNA MEDICATED COLLECTION (lidocaine/glycerin)
this space intentionally left blank	REVIVASIL (gel pad/dmc/dime/dec/oct/vit E) KIT
this space intentionally left blank	SALEX (salicylic acid/ceramide comb 1) CREAM KIT
this space intentionally left blank	SALEX (salicylic acid/ceramide comb 1) LOTION KIT
this space intentionally left blank	SILAZONE-II KIT (triamcinolone aceton/silicones)
this space intentionally left blank	SOLARAVIX (Diclofenac/silicone, adhesive)
this space intentionally left blank	SUMADAN KIT (sulfacetamide/sulfur/cleansr23)
this space intentionally left blank	SUMAXIN CP KIT (sulfacetamide/sulfur/cleansr23)
this space intentionally left blank	TICANASE KIT (fluticasone/sodium chloride/sodium bicarbonate)
this space intentionally left blank	TRIVIX (Triamcinolone/dimethacone/silicone)
this space intentionally left blank	TRIXYLITRAL (diclofenac/lidocaine/tape)
this space intentionally left blank	XRYLIX 1.5% KIT (diclofenac/kinesiology tape)
this space intentionally left blank	ZILACAINE PATCH 5% COMBO PA (lidocaine/silicone, adhesive)

lactulose

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CONSTULOSE (lactulose) solution	KRISTALOSE (lactulose) PACKET
ENULOSE (lactulose) solution	lactulose packet
lactulose solution	this space intentionally left blank

metformin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
metformin ER	metformin ER gastric retention 24 hr
this space intentionally left blank	metformin ER osmotic

methotrexate

Required trial duration: 6 weeks

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methotrexate	OTREXUP (methotrexate) AUTO-INJECTOR
JYLAMVO (methotrexate) SOLUTION	RASUVO (methotrexate) AUTO-INJECTOR
XATMEP (methotrexate) SOLUTION	REDITREX (methotrexate) SYRINGE
this space intentionally left blank	TREXALL (methotrexate) TABLET

mycophenolate mofetil

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
mycophenolate mofetil	CELLCEPT (mycophenolate mofetil)
this space intentionally left blank	MYHIBBIN (mycophenolate mofetil)

montelukast

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
montelukast chewable tablets	montelukast granules
montelukast tablets	this space intentionally left blank

Electronic Age Verification

- Montelukast granules are preferred for ages 1 and under

mupirocin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
mupirocin ointment	mupirocin calcium cream

nitisinone

Prior Authorization Criteria

- See Medications that cost over $3000/month criteria

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
nitisinone 2 mg, 5 mg, 10 mg capsule	HARLIKU (nitisinone) TABLET
ORFADIN (nitisinone) SUSPENSION	nitisinone 20 mg capsule
this space intentionally left blank	NITYR (nitisinone) TABLET
this space intentionally left blank	ORFADIN (nitisinone) CAPSULES

nitroglycerin

Required trial duration: 1 dose while on preventative medication

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
nitroglycerin sublingual tablets	GONITRO (nitroglycerin) SUBLINGUAL PACKET
this space intentionally left blank	nitroglycerin spray
this space intentionally left blank	NITROLINGUAL (nitroglycerin) SPRAY

paroxetine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
paroxetine tablets	paroxetine mesylate 7.5 mg capsules

pregabalin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pregabalin	LYRICA (pregabalin)
this space intentionally left blank	LYRICA CR (pregabalin)
this space intentionally left blank	pregabalin ER

Procysbi (cysteamine)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CYSTAGON (cysteamine)	PROCYSBI (cysteamine)
this space intentionally left blank	PROCYSBI GRANULES (cysteamine)

pyridostigmine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pyridostigmine 60 mg	pyridostigmine 30 mg
	pyridostigmine ER

sitagliptan

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
JANUVIA (sitagliptin) – Brand Required	BRYNOVIN (sitagliptin) ORAL SOLUTION
JANUMET (sitagliptin/metformin) – Brand Required	JANUMET XR (sitagliptin/metformin)
ZITUVIMET XR (sitagliptin/metformin) – Brand Required	sitagliptin (generic Januvia and Zituvio)
this space intentionally left blank	sitagliptin/metformin (generic Januvia and Zituvimet)
this space intentionally left blank	sitagliptin/metformin ER (generic Zituvimet XR)
this space intentionally left blank	ZITUVIO (sitagliptin)
this space intentionally left blank	ZITUVIMET (sitagliptin/metformin) – Brand Required

Steroids – Oral

Agamree and Emflaza (deflazacort): See Duchenne Muscular Dystrophy Criteria on this document

Eohilia: See Eosinophilic Esophagitis on this document

Tarpeyo: See Tarpeyo Criteria on this document

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
budesonide 3 mg EC capsules	ALKINDI (hydrocortisone) SPRINKLE CAPSULE
cortisone	budesonide 9 mg ER tablet
dexamethasone	HEMADY (dexamethasone)
hydrocortisone	KHINDIVI (hydrocortisone) ORAL SOLUTION
methylprednisone	*prednisone DR
prednisolone sodium phosphate 5 mg/5 ml, 15 mg/5 ml, 25 mg/5 ml	prednisone intensol
prednisone solution	prednisolone sodium phosphate ODT
prednisone tablets	prednisolone sodium phosphate 10 mg/5 ml, 20 mg/5 ml solution
this space intentionally left blank	TAPERDEX (dexamethasone)

* prednisone DR required trial duration: 12 weeks with 2 AM dosing of prednisone

Tiopronin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
THIOLA (tiopronin) – Brand Required	THIOLA EC (tiopronin)
this space intentionally left blank	tiopronin

ursodiol

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ursodiol capsule	RELTONE (ursodiol) CAPSULE
ursodiol tablet	URSO FORTE (ursodiol) TABLET