"What's New" Medical Pharmaceutical Policy May 2024 Updates

The following policy updates and reviews apply to all GHP members (Commercial, Marketplace, TPA, Medicare and Medicaid):

MBP 177.0 Prevymis IV (letermovir) – Updated Policy

Stem Cell Transplant

- Prescription written by or in consultation with a hematologist/oncologist, infectious disease, or transplant specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the member is a recipient of an allogeneic hematopoietic stem cell transplant **AND**
- Medical record documentation that the member is a confirmed CMV seropositive recipient (R+) **AND**
- Medical record documentation that Prevymis is being used for CMV prophylaxis **AND**
- Medical record documentation that Prevymis is being initiated between Day 0 and Day 28 post-transplantation **AND**
- Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine) **AND**
- Medical record documentation of intolerance to or contraindication to Prevymis tablets

OR

Kidney Transplant

- Medical record documentation that Prevymis is prescribed by or in consultation with a transplant specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that member is a recipient of a kidney transplant **AND**
- Medical record documentation that member is at high risk of CMV [defined as CMV seropositive donor and CMV seronegative recipient (D+/R-)] **AND**
- Medical record documentation that Prevymis is being used for cytomegalovirus (CMV) prophylaxis **AND**
- Medical record documentation that Prevymis is being initiated between Day 0 and Day 7 post-transplantation **AND**
- Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine) **AND**
- Medical record documentation of intolerance to or contraindication to Prevymis tablets.

AUTHORIZATION DURATION:

- **Stem Cell Transplant:** If approved, a one-time authorization for 100 days with a maximum of 100 doses will apply.
- **Kidney Transplant:** If approved, a one-time authorization for 200 days with a maximum of 200 doses will apply.

QUANTITY LIMIT:

- **Stem Cell Transplant:** 100 doses per 100 days
- **Kidney Transplant:** 200 doses per 200 days

MBP 209.0 Padcev (enfortumab vedotin-ejfv) – Updated Policy

- Medical record documentation that prescription is written by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of locally advanced or metastatic urothelial cancer **AND**
- Medical record documentation of one of the following:
    - Medical record documentation that member has received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy **OR**
    - Medical record documentation that member has received at least one prior line of therapy and is ineligible for cisplatin-containing chemotherapy* **OR**
    - ~~Medical record documentation that member is ineligible for cisplatin-containing chemotherapy* AND~~ medical record documentation that Padcev will be prescribed in combination with Keytruda

MBP 314.0 Loqtorzi (toripalimab-tpzi) – New Policy

Loqtorzi (toripalimab-tpzi) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Medical record documentation that Loqtorzi is prescribed by an oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- One of the following:
    - Medical record documentation that Loqtorzi is being given as first-line treatment in combination with cisplatin and gemcitabine **AND**
    - Medical record documentation of a diagnosis of metastatic or recurrent locally advanced nasopharyngeal carcinoma (NPC)

    OR

    - Medical record documentation that Loqtorzi is being used as a single agent **AND**
    - Medical record documentation of a diagnosis of recurrent unresectable or metastatic nasopharyngeal carcinoma (NPC) **AND**
    - Medical record documentation of disease progression on or after a platinum-containing chemotherapy.

AUTHORIZATION DURATION: Initial approval will be for **12 months**. Subsequent approvals will be for an additional **12 months** and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

The following policy updates and reviews apply to Commercial, Marketplace, TPA, and Medicare GHP members only:

MBP 11.0 Botulinum Toxin and Derivatives (Botox, Dysport, Daxxify, Myobloc, Xeomin) – Updated Policy

Botulinum Toxin Type A, **daxibotulinumtoxinA-lanm (Daxxify)**, is considered to be medically necessary for the commercial, exchange, and CHIP lines of business for following indications when the following criteria are met (Note: The Medicare line of business is reviewed according to Centers for Medicare and Medicaid Services [CMS] Local Coverage Determination [LCD]):

1. **Cervical Dystonia (Spasmodic Torticollis)**
   - Medical record documentation of age greater than or equal to 18 years **AND**
   - Medical record documentation of a diagnosis of Cervical Dystonia (Spasmodic torticollis) **AND**
   - Medical record documentation that the proposed injection sites and dosage regimen are consistent with Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature for the requested indication.

   Quantity Limit: 300 units per 12 weeks (3 months)

   AUTHORIZATION DURATION: Initial approval will be for **12 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:
   - Medical record documentation of continued disease improvement or lack of disease progression** **AND**
   - Medical record documentation of one of the following:
     - Repeated administrations are not being given more frequently than once every 12 weeks **OR**
     - Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing more frequently than every 12 weeks.

MBP 13.0 Viscosupplementation using hyaluronan injections (Gel-One, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Visco-3) – Updated Policy

NOTE: For commercial, exchange, and CHIP~~, and Medicare~~ lines of business, Durolane, Euflexxa, Gelsyn-3, Supartz FX, Synvisc, and Synvisc One are preferred agents and DO NOT Require Prior Authorization

Gel-One, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Synojoynt, Triluron, TriVisc, and **Visco-3** require Prior Authorization and will be considered medically necessary for the commercial, exchange and CHIP lines of business when all of the following criteria are met:

NOTE: For the Medicare line of business, Durolane, Euflexxa, Gelsyn-3, GenVisc, Hyalgan, Orthovisc, Supartz, Synvisc, Synvisc-One, and Visco-3 are preferred agents and DO NOT require Prior Authorization.

Gel-One, Hymovis, Monovisc, Synojoynt, Triluron, and TriVisc require Prior Authorization and will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

MBP 106.0 Injectable Antipsychotic Medications

The following Injectable Antipsychotic Medications (Invega Trinza, Invega Sustenna, Invega Hafyera, Aristada, Aristada Initio, Abilify Asimtufii, Abilify Maintena, Zyprexa Relprevv, Risperdal Consta, Rykindo, Perseris, or Uzedy) will be considered medically necessary when the following criteria are met:

- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of a history of poor adherence to oral medications and documentation that education to improve adherence has been attempted **AND**
- Medical record documentation of use for an FDA approved indication.
    - Abilify Asimtufii – Schizophrenia or maintenance monotherapy treatment of Bipolar I Disorder
    - Abilify Maintena – Schizophrenia or maintenance monotherapy treatment of Bipolar I Disorder
    - Aristada – Schizophrenia
    - Aristada Initio – Initiation of Aristada (in combination with oral aripiprazole) to treat schizophrenia
    - Invega Hafyera - Schizophrenia
    - Invega Sustenna – Schizophrenia or Schizoaffective disorders as monotherapy and as an adjunct to mood stabilizers or antidepressants
    - Invega Trinza – Schizophrenia
    - Perseris- Schizophrenia
    - Risperdal Consta – Schizophrenia or Bipolar I Disorder as monotherapy or as adjunctive therapy to lithium or valproate
    - Rykindo– Schizophrenia or Bipolar I Disorder as monotherapy or as adjunctive therapy to lithium or valproate
    - Uzedy - Schizophrenia
    - Zyprexa Relprevv – Schizophrenia
- In addition: The following criteria should apply to Invega Trinza:
    - Medical record documentation that the patient has been adequately treated with Invega Sustenna for at least 4 months.
- In addition: The following criteria should apply to Invega Hafyera:
    - Medical record documentation that the patient has been adequately treated with Invega Sustenna for at least 4 months OR Invega Trinza for at least 3 months.

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

LIMITATIONS:

The following quantity limits should apply (please enter claims payment note, when entering authorization)

- Abilify Asimtufii - One syringe per 56 days (960 mg/3.2 mL, 720 mg/2.4 mL)
- Abilify Maintena – One syringe or vial per 28 days
- Aristada – One syringe per 28 days (441mg/1.6ml, 662mg/2.4ml, 882mg/3.2ml strength), one syringe per 56 days (1064mg/3.9ml strength)
- Aristada Initio – Enter claims payment note as follows:
    - Aristada Initio – Rx Count of 1, quantity limit of 2.4mL (one syringe) per 28 days
    - Aristada – Open-ended authorization with quantity limit: One syringe per 28 days (441mg/1.6ml, 662mg/2.4ml, 882mg/3.2ml strength), one syringe per 56 days (1064mg/3.9ml strength)
- Invega Hafyera – One syringe per 168 days (6 months)

- Invega Sustenna – two syringes per 1 week, then one syringe per 28 days thereafter
  Enter claims payment note as follows to account for loading dose in the first week:
  - Rx Count of 1 approved by GPI-14 for 234 mg, quantity limit 1
  - Rx Count of 1 approved by GPI-14 for 156 mg, quantity limit 1
  - Open-ended authorization for quantity limit 1 syringe per month, request to be approved by GPI-14 for the prescribed strength.
- Invega Trinza – One syringe per 84 days (3 months)
- Perseris - One syringe kit per 28 days
- Risperdal Consta – Two vials per 28 days
- Rykindo – One syringe per 14 days
- Uzedy - One syringe per 28 days (50 mg/0.14 mL, 75 mg/0.21mL, 100 mg/0.28mL, 125 mg/0.35mL), one syringe per 56 days (150 mg/0.42 mL, 200 mg/0.56 mL, 250 mg/0.7 mL)
- Zyprexa Relprevv – Two vials per 28 days

MBP 131.0 Cosentyx (secukinumab) vials – Policy reinstated and edited

Cosentyx (secukinumab) vials will be considered medically necessary when all of the following criteria are met:

1. Psoriatic Arthritis:

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
  - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Prescription must be written by a rheumatologist or dermatologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation that Cosentyx is not being used concurrently with a TNF blocker or other biologic agent **AND**
- **For peripheral disease**: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate **AND** an adequate trial of at least two (2) formulary NSAIDs **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
- **For axial disease**: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary NSAIDs **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that the prescribed dosing is appropriate for member's weight AND does not exceed 300mg per infusion

2. Ankylosing Spondylitis:

- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Prescription must be written by a rheumatologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation that Cosentyx is not being used concurrently with a TNF blocker or other biologic agent **AND**
- A therapeutic failure on, contraindication to, or intolerance to an adequate trial of at least two (2) NSAIDs OR a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that the prescribed dosing is appropriate for member's weight AND does not exceed 300mg per infusion.

3. **Non-radiographic Axial Spondylarthritis:**
   - Medical record documentation of a diagnosis of non-radiographic axial spondylarthritis **AND**
   - Prescription must be written by a rheumatologist **AND**
   - Member must be at least 18 years of age **AND**
   - Medical record documentation that Cosentyx is not being used concurrently with a TNF blocker or other biologic agent **AND**
   - Medical record documentation of at least one of the following:
     - C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) OR
     - Sacroiliitis on magnetic resonance imaging (MRI)

     AND
   - Medical record documentation of a therapeutic failure on, contraindication to, or intolerance to an adequate trial of at least two (2) NSAIDs OR a therapeutic failure on or intolerance to prior biologic therapy **AND**
   - Medical record documentation that the prescribed dosing is appropriate for member's weight AND does not exceed 300mg per infusion

Note: The recommended dosing for PsA, AS, and nr-axSpA is listed below.

- With loading dose:
  - 6 mg/kg given at Week 0 as a loading dose, followed by 1.75 mg/kg every 4 weeks thereafter (max. maintenance dose 300 mg per infusion).
- Without loading dose:
  - 1.75 mg/kg every 4 weeks (max. maintenance dose 300 mg per infusion).

AUTHORIZATION DURATION: Approval will be given for an initial duration of one (1) year. Subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in signs and symptoms of the treated indication while on Cosentyx therapy.

MBP 243.0 Durysta (bimatoprost intraocular implant) – Updated Policy

- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on ~~latanoprost AND travoprost AND bimatoprost ophthalmic solutions~~. three ophthalmic prostaglandin analogs, one of which must be bimatoprost*

MBP 316.0 Izervay (avacincaptad pegol) – New Policy

Izervay (avacincaptad pegol) will be considered medically necessary for the Commercial, Exchange, CHIP, and Medicare lines of business when ALL of the following criteria are met:

- Medical record documentation of the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) **AND**
- Medical record documentation of a confirmed diagnosis of GA using imagining modalities, including but not limited to fundus autofluorescence (FAF), fundus photography, or optical coherence tomography (OCT) **AND**
- For new starts only: Medical record documentation of the absence of active, or history of, choroidal neovascularization* (CNV) in the eye(s) to be treated with Izervay **AND**
- Medical record documentation that Izervay will not be administered concurrently with other complement inhibitors for the treatment of geographic atrophy secondary to age-related macular degeneration (AMD) (e.g. Syfovre)

*Note: Age-related macular degeneration (AMD) with CNV is often referred to as exudative AMD (eAMD), neovascular AMD (nAMD), or wet AMD (wAMD).

AUTHORIZATION DURATION: 12 Months

QUANTITY LIMIT: 0.2 mL (4 mg) per 28 days (2 mg per eye per 28 days)

MBP 317.0 Omvoh (mirikizumab-mrkz) – New Policy

Omvoh (mirikizumab-mrkz) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation that Omvoh is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active ulcerative colitis **AND**
- Medical record documentation that Omvoh is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of three (3) preferred formulary biologics for the treatment of ulcerative colitis **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on Entyvio* **AND** infliximab* **AND**
- Medical record documentation that Omvoh 300 mg vials as intravenous (IV) infusion are being used for induction therapy