"What's New" Medical Pharmaceutical Policy May 2021 Updates

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

MBP 53.0 Eraxis (anidulafungin)-Updated policy

Eraxis (anidulafungin) will be considered medically necessary when all of the following criteria are met:

- The insured individual is at least ~~17 years~~ 1 month of age and non-neutropenic: **AND**
- There is physician provided documentation of a diagnosis of candidemia or other *Candida* infection as determined by an infectious disease specialist; **OR**
- There is physician provided documentation of a diagnosis of esophageal candidiasis with failure on, intolerance to, or contraindication to fluconazole therapy as determined by an infectious disease specialist.

MBP 62.0 Remodulin IV (treprostinil sodium)- Updated policy

Remodulin IV (treprostinil sodium) will be considered medically necessary when all of the following criteria are met:

- Must be prescribed by a pulmonologist or cardiologist; **AND**

- Physician provided documentation of a diagnosis of class 4 pulmonary arterial hypertension; or

- Physician provided documentation of a diagnosis of class 2 or 3 pulmonary arterial hypertension with therapeutic failure on, intolerance to or contraindication to ~~Revatio~~; one (1) formulary preferred agent which is approved or medically accepted for the beneficiary's diagnosis or indication, from any of the following classes of medications
  - Endothelin Receptor Antagonist
  - Phosphodiesterase-5 Enzyme Inhibitor
  - Prostacyclin

  or

- Individuals who require transition from Flolan, to reduce the rate of clinical deterioration. The risks and benefits of each drug should be carefully considered prior to transition

MBP 119.0 Keytruda (pembrolizumab)- Updated policy

5. Microsatellite Instability-High Cancer

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors OR colorectal cancer **AND**
- For solid tumors:
  - Medical record documentation of progression following prior treatment(s) **AND**
  - Medical record documentation of no satisfactory alternative treatment options
- For colorectal cancer:
  - Medical record documentation Keytruda will be used as first-line treatment **OR**
  - Medical record documentation of progression following treatment with fluoropyrimidine, oxaliplatin, and irinotecan

MBP 126.0 Opdivo (nivolumab)- Updated policy

3. *Renal Cell Carcinoma*

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
  - Medical record documentation of use as a single agent for relapse or for surgically unresectable advanced or metastatic renal cell carcinoma **AND**
  - Medical record documentation of a therapeutic failure on or intolerance to prior anti-angiogenic therapy, including, but not limited to, Sutent (sunitinib), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib), Avastin (bevacizumab), Afinitor (everolimus), or Torisel (temsirolimus).

OR

- Medical record documentation of previously untreated advanced renal cell carcinoma **AND** one of the following:
  o Medical record documentation that Opdivo will be given in combination with cabozantinib (Cabometyx)
  OR
- Medical record documentation that the patient is at intermediate to poor risk (defined as having 1 or more 6 prognostic risk factors as per the IMDC criteria*) **AND** Medical record documentation that Opdivo will be given in combination with ipilimumab (Yervoy)

~~*9. Small Cell Lung Cancer (SCLC)*~~

- ~~Prescription written by a hematologist/oncologist **AND**~~
- ~~Medical record documentation that patient is ≥ 18 years of age **AND**~~
- ~~Medical record documentation of a diagnosis of metastatic small cell lung cancer (SCLC) **AND**~~
- ~~Medical record documentation of disease progression after two different lines of therapy, one of which must be a platinum-based chemotherapy.~~

MBP 186.0 Libtayo (cemiplimab-rwlc)- Updated policy

Libtayo (cemiplimab-rwlc) will be considered medically necessary when ALL of the following criteria are met:

Cutaneous Squamous Cell Carcinoma (cSCC)

- Prescription written by a hematologist or oncologist **AND**
- Documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC **AND**
- Medical record documentation that the patient is not a candidate for curative surgery or curative radiation

Basal Cell Carcinoma

- Prescription written by a hematologist or oncologist **AND**
- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of one of the following:
  - Documentation of a diagnosis of locally advanced BCC (laBCC) **OR**
  - Documentation of a diagnosis of metastatic BCC (mBCC)

  AND
- Medical record documentation of previous treatment with a hedgehog pathway inhibitor or documentation that a hedgehog pathway inhibitor is not appropriate

Non-Small Cell Lung Cancer (NSCLC)

- Prescription written by a hematologist or oncologist **AND**
- Medical record documentation that the patient is 18 years of age or older **AND**

- Medical record docuemntation of non-small cell lung cancer (NSCLC) **AND** medical record documentation of one of the following:
    - Documentation of locally advanced disease AND the patient is not a candidate for surgical resection or definitive chemoradiation **OR**
    - Documentation of metastatic disease

  AND
- Medical record documentation of high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] as determined by an FDA-approved test **AND**
- Medical record documentation of no EGFR, ALK, or ROS1 genomic tumor aberrations **AND**
- Medical record documentation that Libtayo is being used as first-line treatment

MBP 208.0 Enhertu (fam-trastuzumab deruxtecan-nxki)- Updated policy

Breast Cancer

- Prescription written by a hematologist or oncologist **AND**
- Medical record documentation of patient age greater than or equal to 18 years **AND**
- Medical record documentation of unresectable or metastatic HER2-positive breast cancer **AND**
- Medical record documentation of two or more prior anti-HER2 based therapies in the metastatic setting

Gastric Cancer

- Medical record documentation that Enhertu is written by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma **AND**

Medical record documentation of one or more prior trastuzumab-based therapies

MBP 219.0 Fetroja (cefiderocol)- Updated policy

Fetroja (cefiderocol) will be considered medically necessary when ALL of the following criteria are met:

- Prescription is written by or in consultation with Infectious Disease **AND**
- Medical record documentation that the member is greater than or equal to 18 years of age **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of a diagnosis of complicated urinary tract infections (cUTI), including pyelonephritis caused by susceptible Gram-negative microorganisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, or Enterobacter cloacae complex* ***OR***
    - Medical record documentation of a diagnosis of hospital-acquired bacterial pneumonia (HABP) OR Ventilator-associated bacterial pneumonia (VABP), caused by susceptible Gram-negative microorganisms*: Acinetobacter baumannii complex, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Serratia marcescens, or Enterobacter cloacae complex*

  AND
- Medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments OR a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity.

MBP 226.0 Viltepso (viltolarsen)- New policy

DESCRIPTION:
Viltepso (viltolarsen) is an antisense oligonucleotide that binds to exon 53 of dystrophin premessenger RNA (mRNA), resulting in exclusion of this exon during mRNA processing. Exon 53 skipping allows for production of an internally truncated dystrophin protein in patients with genetic mutations that are amenable to exon 53 skipping.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Viltepso (viltolarsen) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of interdisciplinary team involvement including, at a minimum, neurology, cardiology, pulmonology, and a genetic specialist (e.g. geneticist, genetic counselor, etc.) **AND**
- Medical record documentation of Duchenne's Muscular Dystrophy (DMD) confirmed by genetic testing **AND**
- Medical record documentation that the member has a confirmed mutation of the DMD gene that is amenable to exon 53 skipping confirmed by a genetic counselor **AND**
- Medical record documentation of a baseline evaluation, including a standardized assessment of motor function by a neurologist with experience treating Duchenne muscular dystrophy **AND**
- Medical record documentation that Viltepso is being given concurrently with oral corticosteroids unless intolerant or contraindicated **AND**
- Medical record documentation that patient will receive a dose consistent with the Food and Drug Administration (FDA) approved labeling (maximum dose of 80 mg/kg infused once weekly) **AND**
- **For Commercial Lines of Business only:**
    - Medical record documentation that the patient is ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility) as proven by documentation of a 6-Minute Walk Test Distance (6MWT) within the past 3 months of initiation of Viltepso **AND**
    - Medical record documentation that patient does not have a symptomatic cardiac abnormality

AUTHORIZATION DURATION Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:

- Medical record documentation that the member continues to benefit from treatment with viltolarsen **AND**
- Medical record documentation of an annual evaluation, including an assessment of motor function ability, by a neurologist with experience treating Duchenne muscular dystrophy **AND**
- Medical record documentation that Viltepso continues to be given concurrently with oral corticosteroids unless intolerant or contraindicated **AND**
- Medical record documentation that the patient will continue to receive a dose consistent with the Food and Drug Administration (FDA) approved labeling (maximum dose of 80 mg/kg infused once weekly) **AND**
- **For Commercial Lines of Business only:**
    - Medical record documentation that the patient remains ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility) as proven by documentation of a follow-up 6-Minute Walk Test Distance (6MWT) within the past 6 months **AND**
    - Medical record documentation that patient does not have a symptomatic cardiac abnormality

MBP 227.0 Danyelza (naxitamab-gqgk)- New policy

DESCRIPTION:
Danyelza (naxitamab-gqgk) is an anti-GD2 monoclonal antibody that binds to the glycolipid disialoganglioside (GD2), which is highly expressed in neuroblastoma, and other cells of neuroectodermal origin, including the central nervous system and peripheral nerves. By binding to cell surface GD2, naxitamab induces cell lysis (of GD2-expressing cells) through antibody-dependent cell-mediated cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC).

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Danyelza (naxitamab-gqgk) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of age greater than or equal to 1 year **AND**
- Medical record documentation of relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy **AND**
- Medical record documentation that Danyelza will be used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF)

AUTHORIZATION DURATION Initial approval will be for 6 months. Subsequent approvals will be for an additional 6 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

MBP 228.0 Breyanzi (lisocabtagene maraleucel)- New policy

DESCRIPTION:
Breyanzi (lisocabtagene maraleucel) is a CD19-directed genetically modified autologous T-cell immunotherapy in which a patient's T-cells are reprogrammed with a transgene encoding a chimeric antigen receptor (CAR) to identify and eliminate CD19-expressing cells (malignant and normal). Lisocabtagene maraleucel has a defined composition of CD8-and CD4-positive CAR T-cells. CAR is comprised of an FMC63 monoclonal antibody-derived single chain variable fragment (scFv), IgG4 hinge region, CD28 transmembrane domain, 4-1BB (CD137) costimulatory domain, and CD3 zeta activation domain. CD3 zeta signaling initiates activation and antitumor activity, while 4-1BB (CD137) signaling enhances T-cell expansion. CAR binding to CD19 (expressed on cell surfaces) induces activation and proliferation of CAR T-cells, release of pro-inflammatory cytokines, and results in cytotoxic destruction of target cells. Lisocabtagene maraleucel is prepared from the patient's T-cells, which are obtained via leukapheresis.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Breyanzi (lisocabtagene maraleucel) will be considered medically necessary when ALL of the following criteria are met:

Medical record documentation that Breyanzi is prescribed by a hematologist/oncologist **AND**

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following diagnoses: o High-grade B-cell lymphoma **OR**
    - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma) **OR**
    - Primary mediastinal large B-cell lymphoma **OR**

- Follicular lymphoma grade 3B

AND

- Medical record documentation of two or more lines of prior systemic therapy **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

MBP 229.0 Olinvyk (oliceridine)- **New policy**

DESCRIPTION:
Olinvyk (oliceridine) is an opioid agonist that selectively binds to the G-protein section of the opioid mu receptor to induce analgesia. Reduced activation of the beta-arrestin pathway associated with opioid-related adverse events (eg, respiratory depression, GI effects)

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Olinvyk (oliceridine) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of age greater than or equal to 18 **AND**
- Medical record documentation of moderate to severe acute pain **AND**
- Medical record documentation that patient requires an intravenous opioid analgesic **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three generic intravenous opioid analgesics.

AUTHORIZATION DURATION: 2 days

MBP 230.0 Darzalex Faspro (daratumumab/hyaluronidase)- New policy

DESCRIPTION:
Darzalex Faspro (daratumumab/hyaluronidase) is an Anti-CD38 monoclonal antibody combination therapy. Daratumumab is an IgG1κ human monoclonal antibody directed against CD38. CD38 is a cell surface glycoprotein which is highly expressed on myeloma cells. By binding to CD38, daratumumab inhibits the growth of CD38-expressing tumor cells by inducing apoptosis directly through Fc mediated cross linking as well as by immune-mediated tumor cell lysis through complement dependent cytotoxicity, antibody dependent cell mediated cytotoxicity, and antibody dependent cellular phagocytosis. Hyaluronidase increases permeability of the subcutaneous tissue by depolymerizing hyaluronan. At the recommended dose, hyaluronidase acts locally and the effects are reversible; permeability of subcutaneous tissue is restored within 24 to 48 hours.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Darzalex Faspro (daratumumab/hyaluronidase) will be considered medically necessary when ALL of the following criteria are met:

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation a diagnosis of multiple myeloma **AND**

If newly diagnosed multiple myeloma (transplant **ineligible**):

- Medical record documentation that the member is not eligible for stem-cell transplantation (e.g. coexisting conditions, age greater than 65, etc.) **AND**
- Medical record documentation that Darzalex will be given in combination with one of the following options:
  - Bortezomib (Velcade), melphalan, AND prednisone [VMP] **OR**

- Lenalidomide (Revlimid) AND dexamethasone

OR

<u>If newly diagnosed multiple myeloma (transplant **eligible**):</u>

- Medical record documentation that the member is eligible for stem-cell transplantation AND
- Medical record documentation that Darzalex will be given in combination with bortezomib (Velcade), thalidomide, and dexamethasone (DVTd)

OR

<u>If relapsed/refractory multiple myeloma:</u>

- One of the following:
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three prior lines of therapy including a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) **OR**
  - Medical record documentation that the patient is double-refractory to a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) **OR**
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 1 prior therapy including a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) or an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) AND one of the following:
    - Medical record documentation that Darzalex will be prescribed in combination with lenalidomide and dexamethasone **OR**
    - Medical record documentation that Darzalex will be prescribed in combination with bortezomib and dexamethasone **OR**
    - Medical record documentation that Darzalex will be prescribed in combination with carfilzomib (Kyprolis) and dexamethasone

OR

<u>If light-chain (AL) amyloidosis:</u>

- Prescription written by or in consultation with and hematologist/oncologist AND
- Medical record documentation of a diagnosis of light-chain (AL) amyloidosis AND
- Medical Record documentation that the patient does NOT have New York Heart Association (NYHA) Class IIIB (as defined by slight limitation during daily living activity and comfortable at rest) or Class IV heart failure, or mayo cardiac stage IIIB* AND
- Medical record documentation that Darzalex Faspro will be used in combination with bortezomib, cyclophosphamide and dexamethasone

*Mayo Cardiac Stage IIIB defined as NT-proBNP > 8500 ng/L

QUANTITIY LIMIT: 2.15 mL/day (15 mL per week)
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 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 policies were reviewed with no changes:

- MBP 196.0 Ultomiris (Ravulizumab-cwvz)
- MBP 211.0 Givlaari (givosiran)
- MBP 212.0 Adakveo (crizanlizumab-tmca)
- MBP 118.0 Entyvio (vedolizumab)

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

Note: For Medicaid GHP Family members please refer to the Pennsylvania Medical Assistance Statewide Preferred Drug List (PDL) https://papdl.com/preferred-drug-list for specific coverage information and policy criteria for any drug listed below.

MBP 112.0 Simponi Aria (golimumab)- Updated policy

Simponi Aria (golimumab) will be considered medically necessary when all of the following criteria are met per indication:

Rheumatoid Arthritis

- Requesting provider must be a rheumatologist **AND**
- Medical record documentation of age ≥18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis according the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis **AND**
- Medical record documentation that Simponi Aria will be given in combination with methotrexate **AND**
- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of Humira*, Rinvoq*, OR Xeljanz*therapy.

Psoriatic Arthritis

- Requesting provider must be a rheumatologist or dermatologist **AND**
- Medical record documentation of age ≥~~18~~ 2 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis, which must include the following:
    - Documentation of active psoriatic lesions OR documentation of a history of psoriasis **AND**
- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent **AND**
- For patients 18 years of age and older, medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of secukinumab (Cosentyx*) AND adalimumab (Humira*) therapy.

Ankylosing Spondylitis

- Requesting provider must be a rheumatologist **AND**
- Medical record documentation of age ≥18 years **AND**
- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of secukinumab (Cosentyx*) AND adalimumab (Humira*) therapy.

Polyarticular juvenile idiopathic arthritis

- Requesting provider must be a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of active polyarticular juvenile idiopathic arthritis **AND**

- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of a therapeutic failure on, contraindication to or intolerance to a minimum 4 month trial of Humira*

(*requires prior authorization)

MBP 141.0 Nucala vial (mepolizumab)- Updated policy

Hypereosinophilic syndrome (HES)

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of hypereosinophilic syndrome (HES) for greater than or equal to 6 months **AND**
- Medical record documentation that member has been evaluated for and does NOT have an identifiable non-hematologic secondary cause* or FIP1 like 1-platelet derived growth factor receptor (FIP1L1-PDGFRα) kinase-positive hypereosinophilic syndrome (HES) **AND**
- Medical record documentation of a blood eosinophil count of 1,000 cells/mcL or higher **AND**
- Medical record documentation of at least two hypereosinophilic syndrome (HES) flares within the previous 12 months with a worsening of clinical symptoms of HES or increasing blood eosinophil level requiring an escalation in therapy **AND**
- Medical record documentation that member is on stable hypereosinophilic syndrome (HES) therapy including, but not limited to oral corticosteroids, immunosuppressives, or cytotoxic therapy.

*Note: Non-hematologic secondary causes can include but are not limited to drug hypersensitivity, parasitic helminth infection, HIV infection, and non-hematologic malignancy

Quantity Limit: 1 vial (100mg) per 28 days (for eosinophilic asthma), 3 vials (300mg) per 28 days (for EGPA or HES)