**“What’s New” Medical Pharmaceutical Policy August 2021 Updates**
**The following policy updates and reviews apply to all GHP members (Commercial, Marketplace, TPA, Medicare and Medicaid):**

## MBP 91.0 Yervoy (ipilimumab) – Updated policy

**1. Melanoma**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of unresectable ~~stage III or IV~~ or metastatic melanoma **AND**
- One of the following:
    - Medical record documentation of use in combination with nivolumab for first line therapy **OR**
    - Medical record documentation of use as a single agent or in combination with nivolumab as second-line or subsequent therapy for disease progression if not previously used **OR**
    - Medical record documentation of use as a single-agent reinduction therapy in select patients who experienced no significant systemic toxicity during prior ipilimumab therapy and who relapse after initial clinical response or progress after stable disease >3 months

**OR**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of use as a single agent for adjuvant therapy:
    - For Stage IIIA with metastases > 1 mm, or Stage IIIB or Stage IIIC cutaneous melanoma with nodal metastases following a complete lymph node dissection or resection **OR**
    - Following complete lymph node dissection and/or complete resection of nodal recurrence

## MBP 119.0 Keytruda (pembrolizumab) – Updated policy

**Gastric Cancer**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of a diagnosis of recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma **AND**
    - Medical record documentation that tumors express PD-L1 (combined positive score [CPS] greater than or equal to 1) as determined by an FDA-approved test **AND**
    - Medical record documentation of disease progression on or after two or more prior lines of therapy (including fluoropyrimidine- and platinum-containing chemotherapy)* **AND**
    - If patient has HER2-positive disease, medical record documentation of disease progression on or after HER2/neu-targeted therapy (including but not limited to trastuzumab (Herceptin)*

    **OR**

    - Medical record documentation of a diagnosis of locally advanced unresectable or metastatic HER-2 positive gastric or gastroesophageal junction adenocarcinoma **AND**
    - Medical record documentation that Keytruda will be used as first-line treatment **AND**
    - Medical record documentation that Keytruda will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy

**Cutaneous Squamous Cell Carcinoma (cSCC)**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of locally advanced, recurrent, OR metastatic cutaneous squamous cell carcinoma **AND**
- Medical record documentation that the patient’s disease is not curable by surgery **AND**
- Medical record documentation that the patient’s disease is not curable by radiation.

## MBP 237.0 Zynlonta (loncastuximab tesirine-lpyl) – New policy

Zynlonta (loncastuximab tesirine-lpyl) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation that Zynlonta is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of relapsed or refractory large B-cell lymphoma including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma **AND**
- Medical record documentation of prior treatment with two or more lines of systemic therapy

**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 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.

## MBP 238.0 Nulibry (fosdenopterin) – New policy

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

- Medical record documentation that Nulibry is prescribed by a neonatologist, geneticist, or pediatric neurologist **AND**
- Medical record documentation of a diagnosis of molybdenum cofactor deficiency (MoCD) Type A as confirmed by genetic testing indicating a mutation in the molybdenum cofactor synthesis gene 1 (MOCS1) gene **OR**
- Medical record documentation of both of the following:
    - Documentation of biochemical and clinical features consistent with a diagnosis of molybdenum cofactor deficiency (MoCD) Type A, including but not limited to encephalopathy, intractable seizures, elevated urinary S-sulfocysteine levels, and decreased uric acid levels **AND**
    - Documentation that the member will be treated presumptively while awaiting genetic confirmation

**AUTHORIZATION DURATION:**

**For patients with a presumptive diagnosis of molybdenum cofactor deficiency (MoCD) Type A awaiting genetic confirmation:**

Approval will be given for an **initial duration of one (1) month** or less if the reviewing provider feels it is medically appropriate and will require:

- Medical record documentation of genetic testing confirming a diagnosis of molybdenum cofactor deficiency (MoCD) Type A.

**For patients with genetically confirmed MoCD Type A diagnosis:**

Approval will be given for an **initial duration of twelve (12) months**. Subsequent approvals will be for a **duration of twelve (12) months** or less if the reviewing provider feels it is medically appropriate and will require:

- Medical record documentation of a clinically significant positive response or lack of disease progression with Nulibry treatment.

## MBP 239.0 Rybrevant (amivantamab-vmjw) – New policy

Rybrevant (amivantamab-vmjw) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation that Rybrevant is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of with locally advanced or metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of epidermal growth factor receptor (EGFR) exon 20 insertion mutations as determined by an FDA approved test* **AND**
- Medical record documentation of disease progression on or following prior treatment with a platinum-based chemotherapy.

**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 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 115.0 Cyramza (ramucirumab)
- MBP 138.0 Onivyde (irinotecan (liposomal))
- MBP 160.0 Besponsa (inotuzumab ozogamicin)

### 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 5.0 Remicade (infliximab), Inflectra (infliximab-dyyb), Renflexis (infliximab-abda), or Avsola (infliximab-axxq) – Updated policy

**For Treatment of Ulcerative Colitis:**

- Must be at least 6 years of age; **AND**
- Must be prescribed by a gastroenterologist; **AND**
- Physician provided documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Physician provided documentation of failure on, intolerance to, or contraindication to an adequate trials ~~of~~ to at least one conventional therapy~~:~~ ~~that include~~ corticosteroids, aminosalicylates, or ~~and~~ immunomodulators (eg, 6-mercaptopurine or azathioprine) **AND**
- Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent

**AND**

- Medical record documentation of one of the following:
  - Therapeutic failure on, intolerance to, or contraindication to at least a 12 week trial of Humira* **OR** ~~medical record documentation of age < 18 years~~ ~~**AND**~~
  - Medical record documentation that infliximab is being prescribed to induce disease remission

**AND**

- One of the following:
  - For infliximab biosimilar requests other than Avsola (e.g. Renflexis, Inflectra), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to infliximab-axxq (Avsola) **OR**
  - For infliximab reference product requests (i.e. Remicade), medical record

documentation of a therapeutic failure on, intolerance to, or contraindication to infliximab-axxq (Avsola) AND infliximab-abda (Renflexis), AND infliximab-dyyb (Inflectra).

## MBP 68.0 Nplate (romiplostim) – Updated policy

**Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS)**

- Medical record documentation of Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS) AND
- Medical record documentation of suspected or confirmed acute exposure to myelosuppressive doses of radiation (estimated as radiation levels greater than 2 gray [Gy]).

**AUTHORIZATION DURATION:** One-time authorization for one administration of Nplate

## MBP 118.0 Entyvio (vedolizumab) – Updated policy

**Ulcerative Colitis**

- Prescription written by a gastroenterologist **AND**
- Medical record documentation of age >18 years **AND**
- Medical record documentation of a diagnosis of moderate-to-severe ulcerative colitis **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to ~~azathioprine or 6-mercaptopurine (6-MP)~~ at least one conventional therapy: corticosteroids, aminosalicylates, or immunomodulators (e.g. 6-mercaptopurine or azathioprine)

## MBP 240.0 Fensolvi (leuprolide injection) – New policy

Fensolvi (leuprolide injection) will be considered medically necessary when all of the following criteria are met:

- Medical record documentation of a diagnosis of central precocious puberty (CPP) **AND**
- Prescription written by or in consultation with a pediatric endocrinologist **AND**
- Medical record documentation of age greater than or equal to 2 years of age **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Lupron Depot-Ped, Triptodur* and Supprelin LA*.

*Prior authorization required

**AUTHORIZATION DURATION:** None

**QUANTITY LIMITS:** One (1) Kit (45mg) per 6 months