"What's New" Medical Pharmaceutical Policy February 2024 Updates
The following policy updates and reviews apply to all GHP members (Commercial, Marketplace, TPA, Medicare and Medicaid):

MBP 126.0 Opdivo (nivolumab) – Updated Policy

Melanoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 12 years of age **AND**
- Medical record documentation of one of the following:
  - A diagnosis of unresectable or metastatic melanoma **AND**
  - Opdivo is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma (with the exception of ipilimumab).

  OR
  - A diagnosis of completely resected (no evidence of disease) ~~metastatic melanoma with distant metastases, which may include lymph nodes~~ Stage IIB, Stage IIC, Stage III, or Stage IV melanoma **AND**
  - ~~Medical record documentation of complete resection of distant metastases **AND**~~
  - Opdivo is being used in the adjuvant setting **AND**
  - Opdivo is being used as a single agent

    ***(*Note: The FDA-approved treatment duration for use of Opdivo in the adjuvant setting for completely resected ~~metastatic~~ stage IIB, stage IIC, stage III, and stage IV melanoma is for up to 1 year, see specific reauthorization criteria below.)*

****For adjuvant treatment of ~~metastatic~~ melanoma *(completely resected melanoma)*, adjuvant treatment of resected esophageal or gastroesophageal junction cancer, and adjuvant urothelial carcinoma:**
Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. One subsequent approval 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.

Authorization of Opdivo for the adjuvant treatment of ~~metastatic~~ melanoma, adjuvant treatment of resected esophageal or gastroesophageal junction cancer, or adjuvant treatment of urothelial carcinoma should not exceed the FDA-approved treatment duration of 1 year (12 months). For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

MBP 236.0 Jemperli (dostarlimab-gxly) – Updated Policy

Endometrial Cancer

- Medical record documentation that Jemperli 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 one of the following:
  - Medical record documentation of a diagnosis of recurrent or advanced endometrial cancer **AND**
  - Medical record documentation of mismatch repair deficient (dMMR) as determined by an FDA approved test **AND**
  - Medical record documentation of disease progression on or following prior treatment with a platinum-containing regimen **AND**
  - Medical record documentation that member is not a candidate for curative surgery or radiation

OR

- Medical record documentation of primary advanced or recurrent endometrial cancer **AND**
- Medical record documentation that Jemperli will be used in combination with carboplatin and paclitaxel for 6 doses, followed by Jemperli as a single agent **AND**
- Medical record documentation of mismatch repair deficient (dMMR) as determined by an FDA approved test OR microsatellite instability-high (MSI-H)

MBP 260.0 Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (Efgartigimod Alfa and Hyaluronidase Injection) – Updated Policy

Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (Efgartigimod Alfa and Hyaluronidase Injection) will be considered medically necessary when all of the following criteria are met:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Vyvgart is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AChR) antibody positive **AND**
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IV **AND***
- Medical record documentation of a baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL) score of 5 or more **AND****
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND**
- Medical record documentation of therapeutic failure on intolerance to, or contraindication to at least two (2) non-steroidal immunosuppressive therapies OR has failed at least one (1) immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) **AND**
- Medical record documentation of failure on intolerance to, or contraindication to intravenous immunoglobulin (IVIG)

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent approvals will be for 6 months and will require:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is responding positively to therapy as evidenced by a 2-point reduction from baseline in Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score**

The medication will no longer be covered if patient experiences toxicity or worsening of disease.

MBP 301.0 Elrexfio (elranatamab-bcmm) – New Policy

Elrexfio (elranatamab-bcmm) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Elrexfio is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of relapsed or refractory multiple myeloma **AND**
- Medical record documentation of treatment with at least four (4) prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

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 the member experiences unacceptable toxicity or worsening of disease.

MBP 302.0 Talvey (talquetamab-tgvs) – New Policy

Talvey (talquetamab-tgvs) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Talvey is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of relapsed or refractory multiple myeloma **AND**
- Medical record documentation of treatment with at least four (4) prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

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 the member experiences unacceptable toxicity or worsening of disease.

MBP 303.0 Adstiladrin (nadofaragene Firadenov-vncg) – New Policy

Adstiladrin (nadofaragene firadenov-vncg) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of an age greater than or equal to 18 **AND**
- Medical record documentation that Adstiladrin is being prescribed by or in consultation with a hematologist, oncologist, or urologist **AND**
- Medical record documentation of high-risk Bacillus Calmette-Guerin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

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 of 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 305.0 Rystiggo (rozanolixizumab-noli) – New Policy

Rystiggo (rozanolixizumab-noli) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of age 18 years or older **AND**
- Medical record documentation that Rystiggo is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AChR) positive OR anti-muscle-specific tyrosine kinase (MuSK) antibody positive **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IVa **AND**
- Medical record documentation of a baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL) score greater than or equal to 3 (with at least 3 points being non-ocular) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND**

- Medical record documentation of therapeutic failure on intolerance to, or contraindication to at least two (2) non-steroidal immunosuppressive therapies OR has failed at least one (1) immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to intravenous immunoglobulin (IVIG).

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 and will require:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is responding positively to therapy as evidenced by an improvement of Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score from baseline.

The medication will no longer be covered if patient experiences toxicity or worsening of disease.

MBP 306.0 Vyjuvek (beremagene geperpavec-svdt) – New Policy

Vyjuvek (beremagene geperpavec-svdt) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation that Vyjuvek is prescribed by or in consultation with a dermatologist who specializes in epidermolysis bullosa (EB) management **AND**
- Medical record documentation of age greater than or equal to 6 months **AND**
- Medical record documentation of diagnosis of dystrophic epidermolysis bullosa (DEB) **AND**
- Medical record documentation of genetic testing confirming mutation(s) in the COL7A1 gene **AND**
- Medical record documentation of at least one open dystrophic epidermolysis bullosa (DEB) wound **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

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 and will require medical record documentation of clinical response to prior dystrophic epidermolysis bullosa (DEB) wounds treated with Vyjuvek therapy and lack of toxicity. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

QUANTITY LIMIT: 2.5 mL (1 vial) per week, or 10 mL (4 vials) every 28 days

MBP 308.0 Roctavian (valoctocogene roxaparvovec-rvox) – New Policy

Roctavian (valoctocogene roxaparvovec-rvox) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation that the patient is a male based on assigned sex at birth and age greater than or equal to 18 years **AND**
- Medical record documentation that the patient is diagnosed with severe hemophilia A* **AND**
- Medical record documentation that Roctavian is being dosed according to the Food and Drug Administration approved labeling for hemophilia A **AND**
- Medical record documentation that the member has not received any previous gene therapy for hemophilia A **AND**
- The prescription must be written with consultation from or by a Hematologist **AND**
- Medical record documentation showing lack of pre-existing antibodies to AAV5 using the FDA approved companion diagnostic **AND**
- Medical record documentation of factor VIII inhibitor titer testing showing lack of factor VIII inhibitor **AND**

- Medical record documentation whether a patient can receive corticosteroids and/or other immunosuppressive therapy that may be required for an extended period. **AND**
- Medical record documentation that the patient DOES NOT have active acute or uncontrolled chronic infections, known significant hepatic fibrosis (stage 3 or 4 on the Batts-Ludwig scale or equivalent) or cirrhosis, or mannitol hypersensitivity

***Note:** Severe hemophilia A is defined as Factor VIII activity <1% (<0.01 units/mL) with spontaneous bleeding into joints or muscles

AUTHORIZATION DURATION: One (1) time approval per lifetime. Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

The following policies were reviewed with no changes:

- MBP 63.0 Ixempra (ixabepilone)
- MBP 79.0 Provenge (sipuleucel-T)
- MBP 83.0 Lumizyme (alglucosidase alfa)
- MBP 99.0 Sandostatin LAR (Octreotide acetate)
- MBP 101.0 Zaltrap (ziv-aflibercept)
- MBP 102.0 Synribo (omacetaxine mepesuccinate)
- MBP 166.0 Adcetris (brentuximab vedotin)
- MBP 174.0 Luxturna (voretigene-neparvovec-rzyl)
- MBP 175.0 Mepsevii (vestronidase alfa-vjbk)
- MBP 178.0 Zilretta (triamcinolone acetonide ER injection)
- MBP 186.0 Libtayo (cemiplimab-rwlc)
- MBP 208.0 Enhertu (fam-trastuzumab deruxtecan-nxki)
- MBP 268.0 Amvuttra (vutrisiran)

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

The following policies were reviewed with no changes:

- MBP 47.0 Lucentis (ranibizumab), Byooviz (ranibizumab-nuna), and Cimerli (ranibizumab-eqrn)
- MBP 60.0 Cerezyme (imiglucerase)
- MBP 67.0 Supprelin LA (histrelin acetate implant)
- MBP 74.0 Cimzia (certolizumab pegol)
- MBP 75.0 Stelara (ustekinumab)
- MBP 86.0 Kalbitor (ecallantide)
- MBP 89.0 Xgeva (denosumab)
- MBP 100.0 Elelyso (taliglucerase alfa)
- MBP 105.0 VPRIV (velaglucerase alfa)
- MBP 116.0 Aveed (testosterone undecanoate)
- MBP 124.0 Ruconest (C1 esterase inhibitor, recombinant)
- MBP 125.0 Lemtrada (alemtuzumab)
- MBP 129.0 Iluvien (fluocinolone acetonide)
- MBP 153.0 Zinplava (bezlotoxumab)
- MBP 171.0 Varubi IV (rolapitant)
- MBP 179.0 Hemlibra (emicizumab-kxwh)
- MBP 190.0 Ilumya (tildrakizumab-asmn)
- MBP 191.0 Cinvanti (aprepitant)
- MBP 192.0 Akynzeo IV (fosnetupitant-palonosetron)
- MBP 272.0 Krystexxa (pegloticase)