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

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

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

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the medication is prescribed by or in consultation with a neurologist **AND**
- Documented evidence of focal or symmetric neurologic deficits that are slowly progressive or relapsing over 2 months or longer **AND**
- Physician provided documentation of EMG abnormalities consistent with the diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy with the presence of at least ONE of the following:
    - Motor distal latency prolongation ≥ 50% above upper limit of normal (ULN) in two nerves (excluding median neuropathy at the wrist from carpal tunnel syndrome) **OR**
    - Reduction of motor conduction velocity ≥ 30% below lower limit of normal (LLN) in two nerves **OR**
    - Prolongation of F-wave latency ≥ 20% above ULN in two nerves (> 50% if amplitude of distal negative peak compound muscle action potential (CMAP) <80% of LLN values) **OR**
    - Absence of F-waves in two nerves if these nerves have distal negative peak CMAP amplitudes ≥ 20% of LLN + ≥ 1 other demyelinating parameter in ≥ 1 other nerve **OR**
    - Partial motor conduction block: ≥ 30% amplitude reduction of the proximal negative peak CMAP relative to distal, if distal negative peak CMAP ≥ 20% of LLN, in two nerves, or in one nerve + ≥1 other demyelinating parameter in ≥ 1 other nerve **OR**
    - Abnormal temporal dispersion (>30% duration increase between the proximal and distal negative peak CMAP) in ≥ 2 nerves **OR**
    - Distal CMAP duration (interval between onset of the first negative peak and return to baseline of the last negative peak) increase in ≥ 1 nerve (median ≥ 6.6 ms, ulnar ≥ 6.7 ms, peroneal ≥ 7.6 ms, tibial ≥ 8.8 ms) + ≥ 1 other demyelinating parameter in ≥ 1 other nerve

AND

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one (1) intravenous or subcutaneous immune globulin (IVIG/SCIG) therapy, one (1) corticosteroid therapy, OR plasma exchange (PLEX) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one (1) non-steroidal immunosuppressive therapy (can include but is not limited to azathioprine, cyclophosphamide, cyclosporine, methotrexate, mycophenolate) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab

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 290.0 Epkinly (epcoritamab-bysp) – Updated Policy

Follicular Lymphoma

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Epkinly is written by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of relapsed or refractory follicular lymphoma (FL) **AND**
- Medical record documentation of prior therapy with at least two lines of systemic therapy

MBP 156.0 Imfinzi (durvalumab) – Updated Policy

1. Neoadjuvant/Adjuvant Non-Small Cell Lung Cancer (NSCLC)

- Medical record documentation that Imfinzi 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 resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation that Imfinzi is being used in the neoadjuvant setting in combination with platinum containing chemotherapy then continued as a single agent in the adjuvant setting following surgery **AND**
- Medical record documentation of no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.

AUTHORIZATION DURATION (Neoadjuvant/Adjuvant NSCLC): One approval for 18 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Imfinzi for the neoadjuvant/adjuvant treatment of NSCLC should not exceed the FDA-approved treatment duration of 4 cycles of neoadjuvant treatment prior to surgery and 12 cycles of adjuvant treatment following surgery. 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.

6. dMMR Endometrial Cancer

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Imfinzi is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of a diagnosis of primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR) **AND**
- Medical record documentation that Imfinzi will be used in combination with carboplatin and paclitaxel for 6 cycles, followed by continuation of Imfinzi as a single agent

AUTHORIZATION DURATION (dMMR Endometrial Cancer): 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 119.0 Keytruda (pembrolizumab) – Updated Policy

11. Hepatocellular Carcinoma (HCC)

- 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 hepatocellular carcinoma secondary to Hepatitis B **AND**

- Medical record documentation of at least one (1) prior systemic therapy other than a PD-1 and PD-L1 containing regimen ~~a therapeutic failure on or intolerance to sorafenib (Nexavar)~~

15. Endometrial Carcinoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of a diagnosis of primary advanced or recurrent endometrial carcinoma **AND**
    - Medical record documentation that Keytruda will be used in combination with carboplatin and paclitaxel followed by Keytruda as a single agent

OR

- Medical record documentation of a diagnosis of advanced endometrial carcinoma **AND**
- Medical record documentation of disease progression following at least one prior systemic therapy **AND**
- Medical record documentation that patient is not a candidate for curative surgery or radiation **AND**
- Medical record documentation of one of the following:
    - Medical record documentation that tumors are **not** microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) **AND**
    - Medical record documentation that Keytruda will be given in combination with lenvatinib (Lenvima)

OR

- Medical record documentation that Keytruda will be used as a single agent for treatment of tumors that are microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

19. Malignant Pleural Mesothelioma (MPM)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of unresectable advanced or metastatic malignant pleural mesothelioma (MPM) **AND**
- Medical record documentation that Keytruda is being used as first-line treatment in combination with pemetrexed and platinum chemotherapy.

MBP 196.0 Ultomiris (ravulizumab-cwvz) – Updated Policy

Neuromyelitis Optica Spectrum Disorder (NMOSD)

- Prescribed by or in consultation with a neurologist **AND**
- Medical record documentation that member is 18 years or older **AND**
- Medical record documentation of diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) **AND**
- Medical record documentation that member is anti-Aquaporin-4 (AQP4) antibody positive **AND**
- Medical record documentation of failure on intolerance to, or contraindication to rituximab or rituximab biosimilar **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Enspryng **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to eculizumab or biosimilar.

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.

MBP 134.0 Cresemba IV (isavuconazonium sulfate) – Updated Policy

- Medical record documentation that the patient is ~~18 years~~ 1 year of age or older **AND**
    - Medical record documentation that Cresemba is being used for the treatment of invasive aspergillosis **OR** for the treatment of invasive mucormycosis

    OR
- Medical record documentation that the patient is 18 years of age or older **AND**
    - Medical record documentation that Cresemba is prescribed by an oncologist, hematologist, infectious disease specialist, or transplant service provider **AND**
    - Medical record documentation of use for prophylaxis of invasive Aspergillus or Candida infections in patients at high risk of developing these infections due to being severely immunocompromised **AND**
    - Medical record documentation that member requires treatment with an anti-cancer medication that interacts with posaconazole

MBP 307.0 Elevidys (delandistrogene moxeparvovec-rokl) – Updated Policy

- Medical record documentation of a diagnosis of Duchenne Muscular Dystrophy confirmed by a genetic mutation in the Duchenne Muscular Dystrophy gene **AND**
- One of the following:
    - Medical record documentation that the member is a male based on assigned sex at birth

    OR
    - Medical record documentation that the member is a female based on assigned sex at birth AND
    - Medical record documentation that the member has a confirmed X-inactivation of the unmutated X-chromosome OR confirmed biallelic variants in the *DMD* gene (cytogenetic or molecular) alteration involving the Xp21 locus

  AND
- Medical record documentation of patient age of at least 4~~, but no older than 5,~~ years of age **AND**
- Medical record documentation that the patient does NOT have a deletion in exon 8 and/or exon 9 in the Duchenne Muscular Dystrophy gene **AND**
- Medical record documentation that the patient has anti-adeno-associated virus serotype rh74 (anti-AAVrh74) antibody titers <1:400 **AND**
- Medical record documentation of provider attestation that the member is ambulatory (e.g., able to walk with or without assistance, not wheelchair dependent) **AND**
- Medical record documentation that Elevidys is prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation that patient has been initiated on corticosteroids for Duchenne muscular dystrophy one day prior to Elevidys infusion and medical documentation that patient will continue the regimen after for 60 days* **AND**
- Medical record documentation that the patient is on the appropriate weight-based dose **AND**
- Medical record documentation that the patient has never received Elevidys treatment in their lifetime **AND**
- Medical record documentation that the member has not received any previous gene therapy for Duchenne muscular dystrophy **AND**
- Medical record documentation that the patient will not receive exon-skipping therapies for Duchenne Muscular Dystrophy [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)] concomitantly with Elevidys treatment. (Note: Any current authorizations for exon-skipping therapy will be terminated upon Elevidys approval.)

***** Deflazacort is <u>not</u> recommended for use as a peri-Elevidys infusion corticosteroid

AUTHORIZATION DURATION: One (1) time approval (auth duration: 2 months) 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.

Elevidys (delandistrogene moxeparvovec-rokl) is considered unproven for:
- Use in non-ambulatory patients

MBP 160.0 Besponsa (inotuzumab ozogamicin)– Updated Policy
Acute Lymphoblastic Leukemia (ALL)
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ~~≥18 years~~ 1 year of age or older **AND**
- Medical record documentation of a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

The following policy was retired (for all lines of business):
- MBP 95.0 Erwinaze

The following policy was retired (for Medicaid only):
- MBP 201.0 Zulresso [PDL policy applies]

The following policies were reviewed with no changes:
- MBP 33.0 Medical Benefit Pharmaceutical Administrative Policy
- MBP 54.0 Soliris
- MBP 58.0 Prialt
- MBP 64.0 Arranon
- MBP 65.0 Torisel
- MBP 78.0 Istodax
- MBP 97.0 Kyprolis
- MBP 117.0 Beleodaq
- MBP 121.0 Dalvance
- MBP 137.0 Yondelis
- MBP 203.0 Nuzyra
- MBP 205.0 Zerbaxa
- MBP 221.0 Monjuvi
- MBP 222.0 Zepzelca
- MBP 244.0 Rylaze
- MBP 266.0 Jelmyto
- MBP 286.0 Hemgenix

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

MBP 304.0 Altuviiio (antihemophilic factor (Recombinant [Fc-VWF-XTEN)-ehtl) – New Policy
- Medical record documentation of a diagnosis of hemophilia A **AND**
- Prescribed by or in consultation with a hematologist **AND**
- Medical record documentation for use as a treatment for one of the following:
  - Routine prophylaxis to reduce the frequency of bleeding episodes
  - On-demand treatment and control of bleeding episodes
  - Perioperative management of bleeding

  AND

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Advate **AND**
- If being used for routine prophylaxis of Hemophilia A, medical record documentation of therapeutic failure on, intolerance to, or contraindication to Hemlibra.

The following drugs were added to/edited within the Part B Step Therapy Program (effective 1/1/24):

- Zilretta
- Khapzory
- Rituxan, Truxima, Ruxience, Riabni