"What's New" Medical Pharmaceutical Policy March 2023 Updates

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

MBP 36.0 Abraxane (paclitaxel protein bound particles) – Updated Policy

- Medical record documentation that the member has a baseline neutrophil count > greater than or equal to 1,500 cells/mm^3 **AND**

MBP 156.0 Imfinzi (durvalumab) – Updated Policy

1. Stage III Non-Small Cell Lung Cancer (NSCLC)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of unresectable Stage III Non-Small Cell Lung Cancer (NSCLC) **AND**
- Medical record documentation that patient has received and has not progressed following a minimum of two cycles of concurrent platinum-based chemotherapy **AND** radiation therapy

AUTHORIZATION DURATION (Stage III NSCLC): ~~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**~~ One approval for **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.

Authorization of Imfinzi for the treatment of non-small cell lung cancer 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

2. Metastatic Non-Small Cell Lung Cancer (NSCLC)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations **AND**
- Medical record documentation that Imfinzi will be used in combination with tremelimumab-actl (Imjudo) **AND** platinum-based chemotherapy

AUTHORIZATION DURATION (Metastatic NSCLC): 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.

4. Unresectable Hepatocellular Carcinoma (uHCC)

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Imfinzi is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of unresectable hepatocellular carcinoma (uHCC) **AND**
- Medical record documentation that Imfinzi will be used in combination with tremelimumab-actl (Imjudo)

AUTHORIZATION DURATION (uHCC): 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.

5. Biliary Tract Cancer (BTC)

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Imfinzi is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of locally advanced or metastatic biliary tract cancer (BTC) **AND**
- Medical record documentation that Imfinzi will be used in combination with gemcitabine and cisplatin

AUTHORIZATION DURATION (BTC): 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 180.0 Kanuma (sebelipase alfa) – Updated Policy

QUANTITY LIMITS:

Rapidly progressing/Wolman disease (patients initially presenting within the first 6 months of life): Kanuma will initially be approved for quantity sufficient for up to ~~3~~ 5 mg/kg once weekly. These requests should be approved for a total of 4 visits per month.

Late onset/CESD: Patients 4 years of age and older will be approved for ~~1~~ up to 3 mg/kg every other week. These requests should be approved for a total of 2 visits per month.

The following policies were reviewed with no changes:

- MBP 53.0 Eraxis (anidulafungin)
- MBP 62.0 Remodulin IV (treprostinil)
- MBP 225.0 Uplizna (inebilizumab-cdon)
- MBP 226.0 Viltepso (viltolarsen)
- MBP 248.0 Nexviazyme (avalglucosidase alfa-ngpt)
- MBP 249.0 Saphnelo (anifrolumab-fnia)

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 274.0 Spevigo (spesolimab-sbzo) – New Policy

Spevigo (spesolimab-sbzo) 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 that Spevigo is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of generalized pustular psoriasis (GPP) **AND**
- Medical record documentation of a generalized pustular psoriasis (GPP) flare of moderate to severe intensity and all of the following:
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 3 (moderate to severe) **AND**
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation subscore ≥ 2 (moderate to very high-density pustules) **AND**
    - Presence of fresh pustules (new appearance or worsening of pustules) **AND**
    - ≥5% of body surface area covered with erythema and presence of pustules

AND

- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

QUANTITY LIMIT: 15 milliliters (2 vials) per claim (Darwin authorization by GPI-14)

AUTHORIZATION DURATION: Initial approval will be for **one dose** of 900 mg (2 vials) for one week. A subsequent approval of Spevigo will be given for **one dose** of 900 mg (2 vials) if the following criteria are met:

- Medical record documentation that member is experiencing persistent symptoms of an acute generalized pustular psoriasis (GPP) flare of moderate to severe intensity AND all of the following criteria:
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 2 (moderate to severe) **AND**
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation subscore ≥ 2 (moderate to very high-density pustules) **AND**
    - Spevigo will be administered no sooner than 1 week after the initial dosage was administered.

AND

- Medical record documentation that member has not already received two doses of Spevigo for treatment of the current generalized pustular psoriasis (GPP) flare

REAUTHORIZATION OF NEW GPP FLARES:

Treatment of new generalized pustular psoriasis (GPP) flares will require reevaluation of coverage for a new initial approval for **one dose** of 900 mg (2 vials) for a duration of one week and the following criteria will be required:

- Medical record documentation the member is being treated for a new generalized pustular psoriasis (GPP) flare of moderate to severe intensity AND all of the following
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 3 (moderate to severe) **AND**

- Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation subscore ≥ 2 (moderate to very high-density pustules) **AND**
- Presence of fresh pustules (new appearance or worsening of pustules) **AND**
- ≥5% of body surface area covered with erythema and presence of pustules **AND**
- At least 12 weeks have elapsed since the last dose of Spevigo

One subsequent approval of Spevigo for the treatment of persistent symptoms of a repeat generalized pustular psoriasis (GPP) flare will be given for **one dose** of 900 mg (2 vials) for a duration one week if the following reauthorization criteria are met:

- Medical record documentation that member is experiencing persistent symptoms of an acute generalized pustular psoriasis (GPP) flare of moderate to severe intensity AND all of the following criteria:
  - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 2 (moderate to severe) **AND**
  - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation subscore ≥ 2 (moderate to very high-density pustules) **AND**
  - Spevigo will be administered no sooner than 1 week after the initial dosage was administered.

The following policies were reviewed with no changes:

- MBP 74.0 Cimzia (certolizumab pegol)
- MBP 85.0 Cinryze (C1 esterase inhibitor, human)
- MBP 86.0 Kalbitor (ecallantide)
- MBP 89.0 Xgeva (denosumab)
- MBP 124.0 Ruconest (C1 esterase inhibitor, recombinant)
- MBP 191.0 Cinvanti (aprepitant)
- MBP 192.0 Akynzeo IV (fosnetupitant-palonosetron)