

## “What’s New” Medical Pharmaceutical Policy May 2026 Updates

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

### **MBP 357.0 Keytruda Qlex (pembrolizumab-berahyaluronidase alfa-pmph) – New Policy**

#### **1. Melanoma**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of one of the following:
  - **Unresectable or metastatic melanoma:**
    - Medical record documentation that patient is ≥ 18 years of age **AND**
    - A diagnosis of unresectable or metastatic melanoma **AND**
    - Keytruda Qlex is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma.

**OR**

#### **Adjuvant treatment of completely resected melanoma**

- Medical record documentation that patient is ≥ 12 years of age **AND**
- A diagnosis of Stage IIB, IIC, or III melanoma, which has been completely resected **AND**
- Keytruda Qlex is being used in the adjuvant setting (following complete resection) **AND**
- Keytruda Qlex is being used as a single agent.

#### **2. Neoadjuvant or Adjuvant Treatment of Non-Small Cell Lung Cancer (NSCLC)**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of Stage IB (T2a ≥ 4 cm), II, or IIIa non-small cell lung cancer (NSCLC) **AND**
  - Keytruda Qlex is being used in the adjuvant setting following resection and platinum-based chemotherapy **AND**
  - Keytruda Qlex is being used as a single agent

**OR**

- Medical record documentation of resectable (Tumors ≥ 4 cm or Node Positive) non-small cell lung cancer (NSCLC) **AND**
- Keytruda Qlex is being used in the neoadjuvant setting in combination with platinum containing chemotherapy then continued as a single agent in the adjuvant setting following resection

#### **3. Metastatic Non-Small Cell Lung Cancer (NSCLC)**

- 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 NSCLC meeting one of the following situations:
  - Medical record documentation of stage III NSCLC, metastatic NSCLC, OR that the member is not a candidate for surgical resection or definitive chemoradiation **AND**
  - Medical record documentation that Keytruda Qlex is being used as first-line treatment **AND**
  - Medical record documentation that Keytruda Qlex is being given as monotherapy **AND**
  - Medical record documentation that tumors express PD-L1 (TPS) ≥1% as determined by an FDA-approved test **AND**
  - Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations

**OR**

- Medical record documentation that Keytruda Qlex is being given as monotherapy **AND**
- Medical record documentation that tumors express PD-L1 (TPS) ≥1% as determined by an FDA-approved test **AND**
- Medical record documentation of disease progression on or after platinum-containing chemotherapy **AND**
- For patients with EGFR or ALK genomic tumor aberrations: medical record documentation of disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda Qlex.

**OR**

- Medical record documentation of metastatic nonsquamous NSCLC **AND**
- Medical record documentation that Keytruda Qlex will be given in combination with pemetrexed AND either carboplatin or cisplatin **AND**
- Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations

**OR**

- Medical record documentation of metastatic squamous NSCLC **AND**
- Medical record documentation that Keytruda Qlex will be given in combination with carboplatin **AND**

- either paclitaxel or nab-paclitaxel **AND**
- Medical record documentation that Keytruda Qlex, carboplatin, and paclitaxel (or nab-paclitaxel) are being used as first-line treatment **AND**
- Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations

#### 4. Head and Neck Squamous Cell Carcinoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of one of the following:
  - A diagnosis of Head and Neck Squamous Cell Carcinoma that is recurrent or metastatic **AND**
  - Disease progression on or after platinum-containing chemotherapy **AND**
  - Keytruda Qlex is being used as a single agent.

**OR**

- A diagnosis of metastatic or unresectable, recurrent Head and Neck Squamous Cell Carcinoma **AND**
- Keytruda Qlex is being used as a first-line treatment **AND**
- Keytruda Qlex is being used as a single agent **AND**
- Tumors express PD-L1 [Combined Positive Score (CPS) ≥ 1] as determined by an FDA-approved test

**OR**

- A diagnosis of metastatic or unresectable, recurrent Head and Neck Squamous Cell Carcinoma **AND**
- Keytruda Qlex is being used as a first-line treatment **AND**
- Keytruda Qlex is being administered in combination with platinum chemotherapy and fluorouracil (FU)

**OR**

- A diagnosis of resectable locally advanced Head and Neck Squamous Cell Carcinoma **AND**
- Tumors express PD-L1 [Combined Positive Score (CPS) ≥ 1] as determined by an FDA-approved test **AND**
- Keytruda Qlex is being used as a single agent for neoadjuvant treatment, followed by adjuvant treatment in combination with radiotherapy (RT) with or without cisplatin and then as a single agent

#### 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

#### 6. Urothelial Carcinoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of locally advanced or metastatic urothelial carcinoma **AND**
  - Medical record documentation of one of the following:
    - Disease progression during or following platinum-containing chemotherapy

**OR**

- Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

**OR**

- Patient is not eligible for any platinum-containing chemotherapy

**OR**

- Keytruda Qlex is being used in combination with Padcev

**OR**

- Medical record documentation of muscle invasive bladder cancer (MIBC) **AND**
- Medical record documentation that Keytruda Qlex will be prescribed in combination with Padcev **AND**
- Medical record documentation of use in the neoadjuvant setting and then continued after cystectomy as adjuvant treatment **AND**
- Medical record documentation that member is ineligible for cisplatin-containing chemotherapy

**OR**

- Patient has high-risk, non-muscle invasive bladder cancer (NMIBC)\*\* **AND**
- Patient's disease is unresponsive to an adequate trial of Bacillus Calmette-Guerin (BCG) therapy\*\* **AND**
- Patient is ineligible for or has elected not to undergo cystectomy

**\*\*Note:**

- BCG-unresponsive high-risk NMIBC is defined as persistent disease despite adequate BCG therapy, disease recurrence after an initial tumor-free state following adequate BCG therapy, or T1 disease following a single induction course of BCG.
- Adequate BCG therapy was defined as administration of at least five of six doses of an initial induction course plus either of: at least two of three doses of maintenance therapy or at least two of six doses of a second induction course.

**7. Gastric Cancer**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that Keytruda Qlex will be used as first-line treatment **AND**
- Medical record documentation of one of the following:
  - 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 tumors express PD-L1 (CPS $\geq$ 1) as approved by an FDA approved test **AND**
  - Medical record documentation that Keytruda Qlex will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy

**OR**

- Medical record documentation of locally advanced unresectable or metastatic HER-2 negative gastric or gastroesophageal junction (GEJ) adenocarcinoma **AND**
- Medical record documentation that tumors express PD-L1 (CPS $\geq$ 1) as approved by an FDA approved test **AND**
- Medical record documentation that Keytruda Qlex will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy

**8. Cervical Cancer**

- Prescription written by a hematologist/oncologist **AND**
- One of the following:
  - Medical record documentation of recurrent or metastatic cervical cancer **AND**
  - Medical record documentation that tumors express PD-L1 (CPS $\geq$ 1) **AND**
  - Medical record documentation of disease progression after receiving at least one prior line of therapy

**OR**

- Medical record documentation of persistent, recurrent or metastatic cervical cancer **AND**
- Medical record documentation that tumors express PD-L1 (CPS $\geq$ 1) **AND**
- Medical record documentation that Keytruda Qlex will be used in combination with chemotherapy (paclitaxel, cisplatin or carboplatin), with or without bevacizumab

**OR**

- Medical record documentation of FIGO 2014 Stage III-IVA cervical cancer **AND**
- Medical record documentation that Keytruda Qlex will be used in combination with chemoradiotherapy (cisplatin and external beam radiation therapy [EBRT] followed by brachytherapy [BT])

\*Note: FIGO 2014 Stage III-IVA includes patients with tumor involvement of the lower vagina with or without extension onto pelvic sidewall or hydronephrosis/non-functioning kidney or has spread to adjacent pelvic organs.

**9. Hepatocellular Carcinoma (HCC)**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is  $\geq$  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

**10. Merkel Cell Carcinoma (MCC)**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of Merkel Cell Carcinoma **AND**
- Medical record documentation of metastatic and/or recurrent disease

**11. Renal Cell Carcinoma (RCC)**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is  $\geq$  18 years of age **AND**
- Medical record documentation of one of the following:
  - **Advanced Renal Cell Carcinoma**
    - Medical record documentation of a diagnosis of advanced renal cell carcinoma **AND**
    - Medical record documentation that Keytruda Qlex is being used in combination with axitinib (Inlyta) OR lenvatinib (Lenvima) **AND**

- Medical record documentation that Keytruda Qlex in combination with axitinib (Inlyta) OR lenvatinib (Lenvima) is being used as first-line treatment for advanced disease

Note: In clinical trials, advanced disease included newly diagnosed or recurrent Stage IV renal cell carcinoma.

**OR**

**Adjuvant treatment of Renal Cell Carcinoma**

- A diagnosis of renal cell carcinoma **AND**
- Documentation of intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions **AND**
- Keytruda Qlex is being used in the adjuvant setting **AND**
- Keytruda Qlex is being used as a single agent

Note: In clinical trials, intermediate-high risk category included: pT2 with Grade 4 or sarcomatoid features; pT3, any Grade without nodal involvement (N0) or distant metastases (M0); and high risk included: pT4, any Grade N0 and M0; any pT, any Grade with nodal involvement and M0. The M1 no evidence of disease (NED) category includes patients with metastatic disease who had undergone complete resection of primary and metastatic lesions.

**12. Esophageal Cancer**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- One of the following:
  - Medical record documentation of a diagnosis of locally advanced or metastatic squamous cell carcinoma of the esophagus or gastroesophageal junction (GEJ) **AND**
  - Medical record documentation that tumors express PD-L1 (CPS ≥10) as determined by an FDA-approved test **AND**
  - Medical record documentation of disease progression after one or more prior lines of systemic therapy for advanced disease.

**OR**

- Medical record documentation of a diagnosis of locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) carcinoma not amenable to surgical resection or definitive chemoradiation **AND**
- Medical record documentation of use in combination with platinum (oxaliplatin or cisplatin) and fluoropyrimidine-based (fluorouracil or capecitabine) chemotherapy

**13. 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 Qlex will be used in combination with carboplatin and paclitaxel followed by Keytruda Qlex 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 Qlex will be given in combination with lenvatinib (Lenvima)

**OR**

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

**14. Tumor Mutational Burden – High (TMB-H) Solid Tumors**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of unresectable or metastatic solid tumors **AND**
- Medical record documentation that tumors are tumor mutational burden-high (TMB-H), defined as greater than or equal to 10 mutations per megabase (≥10 mut/Mb), determined by an FDA-approved test **AND**
- Medical record documentation of progression following prior treatment(s) **AND**
- Medical record documentation of no satisfactory alternative treatment options

#### 15. 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.

#### 16. Triple Negative Breast Cancer

- Prescription written 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:
  - Medical record documentation of locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) **AND** both of the following:
    - Medical record documentation that tumors express PD-L1 [Combined Positive Score (CPS) greater than or equal to 10] as determined by an FDA approved test **AND**
    - Medical record documentation that Keytruda Qlex will be given in combination with chemotherapy (paclitaxel, paclitaxel protein-bound, or gemcitabine and carboplatin).

**OR**

- Medical record documentation of high-risk, early-stage triple-negative breast cancer (TNBC) **AND**
- Medical record documentation that Keytruda Qlex will be given in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery

**LIMITATIONS:** The treatment of patients with multiple myeloma with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials.

#### 17. Biliary Tract Cancer

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of locally advanced unresectable or metastatic biliary tract cancer **AND**
- Medical record documentation that Keytruda Qlex will be used in combination with gemcitabine and cisplatin

#### 18. Malignant Pleural Mesothelioma (MPM)

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

#### **AUTHORIZATION DURATION:**

For adjuvant treatment of metastatic melanoma (completely resected melanoma), neoadjuvant/adjuvant treatment of early-stage triple negative breast cancer, neoadjuvant/adjuvant treatment of non-small cell lung cancer, and adjuvant treatment of renal cell carcinoma:

Initial approval will be for 6 months. One subsequent approval 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 patient experiences toxicity or worsening of disease.

- Authorization of Keytruda Qlex for the adjuvant treatment of metastatic melanoma, of non-small cell lung cancer, and of renal cell carcinoma should not exceed the FDA-approved treatment duration of 1 year (12 months).
- Authorization of Keytruda Qlex for the treatment of early-stage triple negative breast cancer should not exceed the approved treatment duration of 24 weeks for neoadjuvant therapy and 27 weeks for adjuvant therapy.
- Authorization for the treatment of neoadjuvant/adjuvant treatment of non-small cell lung cancer should not exceed the approved treatment duration of 12 weeks of neoadjuvant treatment and 39 weeks of adjuvant therapy.

For requests exceeding the above limits, 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

For neoadjuvant/adjuvant treatment of head and neck squamous cell carcinoma:

Initial approval will be for 6 months. Additional approval will be for up to an additional 12 months or less if determined medically appropriate by the reviewing provider 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 for the treatment of neoadjuvant/adjuvant treatment of head and neck squamous cell carcinoma should not exceed the approved treatment duration of 6 weeks of neoadjuvant treatment and 12 months of adjuvant treatment.

For requests exceeding the above limits, 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

For all other indications:

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 358.0 Tecentriq Hybreza (atezolizumab-hyaluronidase-tqjs) – New Policy**

### **1. Non-Small Cell Lung Cancer:**

- Prescription written by an oncologist **AND**
- Medical record documentation of a diagnosis of non-small cell lung cancer meeting one of the following situations:

- Medical record documentation of disease progression during or following platinum-containing chemotherapy

**OR**

- Medical record documentation of disease progression on at least one FDA-approved therapy targeting EGFR or ALK if the patient has EGFR or ALK genomic tumor aberrations (e.g. mutation, deletion, insertion, etc.)

**OR**

- Medical record documentation of a non-squamous histologic subtype **AND**
- Medical record documentation that Tecentriq Hybreza will be given as first-line treatment for metastatic disease **AND**
- Medical record documentation that Tecentriq Hybreza will be given in combination with bevacizumab, paclitaxel, AND carboplatin **OR** paclitaxel protein-bound AND carboplatin **AND**
- Medical record documentation that the patient does not have an EGFR or ALK genomic tumor aberration.

**OR**

- Medical record documentation that Tecentriq Hybreza will be given as first-line treatment for metastatic disease **AND**
- Medical record documentation that tumors have high PD-L1 expression (PD-L1 stained  $\geq 50\%$  of tumor cells [TC  $\geq 50\%$ ] or PD-L1 stained tumor-infiltrating immune cells [IC] covering  $\geq 10\%$  of the tumor area [IC  $\geq 10\%$ ]) as determined by an FDA-approved test **AND**
- Medical record documentation that the patient does not have an EGFR or ALK genomic tumor aberration.

**OR**

- Medical record documentation of stage II to IIIA disease **AND**
- Medical record documentation of use as adjuvant treatment following resection and platinum-based therapy **AND**
- Medical record documentation that tumors have PD-L1 expression on  $\geq 1\%$  of tumor cells as determined by an FDA-approved test **AND**
- Medical record documentation that Tecentriq Hybreza is being given as a single agent.

### **2. Small Cell Lung Cancer (SCLC):**

- Prescription written by an oncologist **AND**
- Medical record documentation of a diagnosis of extensive-stage small cell lung cancer (ES-SCLC) **AND**

- Medical record documentation that Tecentriq Hybreza will be used in combination with carboplatin and etoposide **AND**
  - Medical record documentation of use as first-line treatment of extensive-stage disease
- OR**
- Prescription written by an oncologist **AND**
  - Medical record documentation of a diagnosis of extensive stage small cell lung cancer (ES-SCLC) **AND**
  - Medical record documentation that Tecentriq Hybreza will be used in combination with lurbinectedin for maintenance treatment **AND**
  - Medical record documentation that the disease has not progressed after first-line induction therapy with Tecentriq or Tecentriq Hybreza, carboplatin and etoposide
- 3. Unresectable or Metastatic Hepatocellular Carcinoma (HCC)**
- Prescription written by an oncologist **AND**
  - Medical record documentation of diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) **AND**
  - Medical record documentation that Tecentriq Hybreza will be given in combination with bevacizumab **AND**
  - Medical record documentation that patient has not received prior systemic treatment for hepatocellular carcinoma
- 4. Melanoma**
- Medical record documentation of unresectable or metastatic melanoma **AND**
  - Medical record documentation of BRAF V600 mutation as determined by an FDA-approved test **AND**
  - Medical record documentation that Tecentriq Hybreza will be given in combination with Cotellicq (cobimetinib) and Zelboraf (vemurafenib)
- 5. Alveolar Soft Part Sarcoma (ASPS)**
- Prescription written by an oncologist **AND**
  - Medical record documentation of age greater than or equal to 12 years **AND**
  - Medical record documentation of a weight of 40 kg or greater **AND**
  - Medical record documentation of diagnosis of unresectable or metastatic alveolar soft part sarcoma (ASPS)

**AUTHORIZATION DURATION:**

**For adjuvant treatment of stage II to IIIA non-small cell lung cancer (NSCLC) following resection and platinum-based chemotherapy:** One approval will be given for 12 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 Tecentriq Hybreza for adjuvant treatment of stage II to IIIA non-small cell lung cancer (NSCLC) following resection and platinum-based chemotherapy should not exceed the FDA-approved treatment duration of 1 year (12 months) in patients. 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

**For all other indications:** 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.

**MBP 144.0 Tecentriq (atezolizumab) – Updated Policy**

**6. Small Cell Lung Cancer (SCLC):**

- Prescription written by an oncologist **AND**
- Medical record documentation of a diagnosis of extensive stage small cell lung cancer (ES-SCLC) **AND**

- Medical record documentation of one of the following:
    - Medical record documentation that Tecentriq will be used in combination with carboplatin and etoposide **AND**
    - Medical record documentation of use as first-line treatment of extensive-stage disease
- OR**
- Medical record documentation that Tecentriq will be used in combination with lurbinectedin **AND**
  - Medical record documentation that the disease has not progressed after first-line induction therapy with Tecentriq or atezolizumab and hyaluronidase-tqjs, carboplatin and etoposide

### **MBP 217.0 Tepezza (teprotumumab-trbw) – Updated Policy**

- Prescription written by an ophthalmologist **AND**
- Medical record documentation of the member being ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of Grave's disease **AND**
- Medical record documentation of moderate to severe Thyroid Eye Disease with documentation of one or more of the following: lid retraction of ≥ 2mm, moderate or severe soft-tissue involvement, proptosis ≥ 3 mm above normal values for race and sex, or periodic or constant diplopia **AND**
- Medical record documentation that the member is euthyroid or has mild hypo- or hyperthyroidism (free T4 and free T3 levels <50% above or below normal limits) prior to starting Tepezza therapy **OR** patient has been initiated on anti-thyroid medication **AND**
- Medical record documentation that the member is being prescribed an appropriate dose and duration of Tepezza (10 mg/kg as a single dose, followed by 20 mg/kg IV every 3 weeks for 7 additional doses) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to systemic steroids **OR** evidence of significant proptosis (≥ 3 mm above normal values for race and sex) and/or diplopia.

### **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:
    - 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)

\*IMDC Criteria risk factors include:

1. Less than one year from time of initial renal cell carcinoma diagnosis to randomization
2. Karnofsky performance status <80%
3. Hemoglobin less than the lower limit of normal
4. Corrected calcium of greater than 10 mg/dL
5. Platelet count greater than the upper limit of normal

- 6. Absolute neutrophil count greater than the upper limit of normal

## **MBP 119.0 Keytruda (pembrolizumab) – Updated Policy**

### **10. Urothelial Carcinoma**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- **Medical record documentation of one of the following:**
  - Medical record documentation of locally advanced or metastatic urothelial carcinoma **AND**
  - Medical record documentation of one of the following:
    - Disease progression during or following platinum-containing chemotherapy **OR**
    - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy **OR**
    - Patient is not eligible for any platinum-containing chemotherapy **OR**
    - ~~Patient has high-risk, non-muscle invasive bladder cancer (NMIBC)\*\* **AND**~~
    - ~~Patient's disease is unresponsive to an adequate trial of Bacillus Calmette-Guerin (BCG) therapy\*\* **AND**~~
    - ~~Patient is ineligible for or has elected not to undergo cystectomy~~
    - OR**
    - Keytruda is being used in combination with Padcev
  - OR**
  - **Medical record documentation of muscle invasive bladder cancer (MIBC) **AND****
  - **Medical record documentation that Keytruda will be prescribed in combination with Padcev **AND****
  - **Medical record documentation of use in the neoadjuvant setting and then continued after cystectomy as adjuvant treatment **AND****
  - **Medical record documentation that member is ineligible for cisplatin-containing chemotherapy**
  - OR**
  - **Patient has high-risk, non-muscle invasive bladder cancer (NMIBC)\*\* **AND****
  - **Patient's disease is unresponsive to an adequate trial of Bacillus Calmette-Guerin (BCG) therapy\*\* **AND****
  - **Patient is ineligible for or has elected not to undergo cystectomy**

\*\*Note:

- BCG-unresponsive high-risk NMIBC is defined as persistent disease despite adequate BCG therapy, disease recurrence after an initial tumor-free state following adequate BCG therapy, or T1 disease following a single induction course of BCG.
- Adequate BCG therapy was defined as administration of at least five of six doses of an initial induction course plus either of: at least two of three doses of maintenance therapy or at least two of six doses of a second induction course.

## **MBP 208.0 Enhertu (fam-trastuzumab deruxtecan-nxki) – Updated Policy**

- 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 (IHC 3+ or ISH positive) breast cancer **AND**
- Medical record documentation of one of the following:
  - Documentation of a prior anti-HER2 based therapy in the metastatic setting **OR**
  - Documentation of a prior anti-HER2 based therapy in the neoadjuvant or adjuvant setting **AND** documentation of disease recurrence during or within 6 months of completing therapy **OR**

o Documentation of first line treatment in combination with pertuzumab

**The following policies were reviewed with no changes:**

- MBP 15.0 Zevalin
- MBP 62.0 Remodulin
- MBP 90.0 Benlysta
- MBP 250.0 Kimmtrak
- MBP 337.0 Ziihera
- MBP 128.0 Blincyto
- MBP 50.0 Vectibix
- MBP 151.0 Spinraza
- MBP 108.0 Kadcyła
- MBP 283.0 Tziel
- MBP 258.0 Ryplazim
- MBP 257.0 Opdualag
- MBP 279.0 Korsuva

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

**MBP 359.0 Nexobrid (anacaulase-bcdb) – New Policy**

- Prescribed by or in consultation with a burn specialist, wound care specialist, or surgeon **AND**
- Medical record documentation that the member has deep partial thickness and/or full thickness thermal burns **AND**
- Medical record documentation of no contraindications such as allergies to pineapple, papain, bromelain, papaya, or any other ingredient listed as a potential for allergen **AND**
- Medical record documentation that Nexobrid will NOT be administered for treatment of any of the following:
  - o Burns on the face, perineum, or genitalia
  - o Burns on the feet of patients with diabetes mellitus
  - o Burns on the feet of patients with occlusive vascular disease
  - o Burns in patients with significant cardiopulmonary disease, including inhalation injury
  - o Burn wounds where medical devices (e.g., implants, pacemakers, shunts) or vital structures (e.g., large vessels) could become exposed during eschar removal
  - o Chemical or electrical burns
  - o Circumferential burns
  - o Wounds contaminated with radioactive and other hazardous substances **AND**
- Medical record documentation that the total body surface area (TBSA) being treated per session does NOT exceed 20% BSA over 2 applications applied 24 hours apart.

**AUTHORIZATION DURATION:** Initial approval will be for 2 days or less (from the planned administration date) if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 2 days (from the planned administration date) and will require:

- Medical record documentation that the additional application does not exceed the maximum total body surface area (TBSA) limits specified in the Initial Authorization criteria **AND**
- Medical record documentation that multiple wound areas on different body surfaces require additional treatment for logistical reasons, such as body position **AND**
- Medical record documentation that the member continues to meet all other initial authorization criteria.

**MBP 76.0 Actemra IV (tocilizumab), Tofidence IV (tocilizumab-bavi), Tyenne IV (tocilizumab-aazg), Avtozma IV (tocilizumab-anoh) – Updated Policy**

1. Adults with moderate to severe rheumatoid arthritis

- Medical record documentation that member is 18 years of age or greater **AND**
  - Prescription written by a rheumatologist **AND**
  - Physician provided documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification of Diagnosis of Rheumatoid Arthritis) **AND**
  - Medical record documentation that Actemra or tocilizumab biosimilars are 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 12 weeks of a preferred adalimumab product\*, Rinvoq\*, Enbrel\* OR Xeljanz\* **AND**
  - ~~For tocilizumab reference product requests (i.e. Actemra IV), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to tocilizumab-bavi (Tofidence\*) and tocilizumab-aazg (Tyenne\*).~~
  - For tocilizumab reference product requests (i.e. Actemra IV):
    - For members naïve to Actemra (tocilizumab) therapy: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to all of the following: tocilizumab-bavi (Tofidence\*), tocilizumab-aazg (Tyenne\*), and tocilizumab-anoh (Avtozma) **OR**
    - For members established on Actemra (tocilizumab) therapy: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one of the following tocilizumab biosimilars: tocilizumab-bavi (Tofidence\*), tocilizumab-aazg (Tyenne\*), or tocilizumab-anoh (Avtozma)
- \*Requires prior authorization

2. Active systemic juvenile idiopathic arthritis (SJIA)

- Prescription written by a rheumatologist **AND**
  - Patient is 2 years of age or older **AND**
  - Medical record documentation of a diagnosis of systemic juvenile idiopathic arthritis **AND**
  - Medical record documentation that Actemra or tocilizumab biosimilars are not being used concurrently with a TNF blocker or other biologic agent **AND**
  - ~~For tocilizumab reference product requests (i.e. Actemra IV), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to tocilizumab-bavi (Tofidence\*) and tocilizumab-aazg (Tyenne\*).~~
  - For tocilizumab reference product requests (i.e. Actemra IV):
    - For members naïve to Actemra (tocilizumab) therapy: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to all of the following: tocilizumab-bavi (Tofidence\*), tocilizumab-aazg (Tyenne\*), and tocilizumab-anoh (Avtozma) **OR**
    - For members established on Actemra (tocilizumab) therapy: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one of the following tocilizumab biosimilars: tocilizumab-bavi (Tofidence\*), tocilizumab-aazg (Tyenne\*), or tocilizumab-anoh (Avtozma)
- \*Requires prior authorization

3. Active polyarticular juvenile idiopathic arthritis (PJIA)

- Medical record documentation that member is 2 years of age or greater **AND**
- Prescription is written by a rheumatologist **AND**
- Medical record documentation of a diagnosis active polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND**
- Medical record documentation that Actemra or tocilizumab biosimilars are not being used concurrently with a TNF blocker or other biologic agent **AND**
- Physician provided documentation of a therapeutic failure on, contraindication to or intolerance to a minimum 3 month trial of two (2) preferred formulary biologics for the treatment of juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND**
- ~~For tocilizumab reference product requests (i.e. Actemra IV), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to tocilizumab-bavi (Tofidence\*)~~

and tocilizumab-aazg (Tyenne\*).

- For tocilizumab reference product requests (i.e. Actemra IV):
  - For members naïve to Actemra (tocilizumab) therapy: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to all of the following: tocilizumab-bavi (Tofidence\*), tocilizumab-aazg (Tyenne\*), and tocilizumab-anoh (Avtozma) **OR**
  - For members established on Actemra (tocilizumab) therapy: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one of the following tocilizumab biosimilars: tocilizumab-bavi (Tofidence\*), tocilizumab-aazg (Tyenne\*), or tocilizumab-anoh (Avtozma)

\*Requires prior authorization

#### 4. Giant Cell Arteritis

- Medical record documentation of a diagnosis of Giant Cell Arteritis **AND**
- Prescription written by a rheumatologist **AND**
- Patient is 18 years of age or older **AND**
- Medical record documentation that Actemra or tocilizumab biosimilars are not being used concurrently with a TNF blocker or other biologic agent **AND**
- ~~For tocilizumab reference product requests (i.e. Actemra IV), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to tocilizumab-bavi (Tofidence\*) and tocilizumab-aazg (Tyenne\*).~~
- For tocilizumab reference product requests (i.e. Actemra IV):
  - For members naïve to Actemra (tocilizumab) therapy: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to all of the following: tocilizumab-bavi (Tofidence\*), tocilizumab-aazg (Tyenne\*), and tocilizumab-anoh (Avtozma) **OR**
  - For members established on Actemra (tocilizumab) therapy: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one of the following tocilizumab biosimilars: tocilizumab-bavi (Tofidence\*), tocilizumab-aazg (Tyenne\*), or tocilizumab-anoh (Avtozma)

\*Requires prior authorization

### MBP 57.0 Natalizumab (Tysabri) and Biosimilars – Updated Policy

#### 1. Relapsing Multiple Sclerosis

Tysabri or Tyruko are considered medically necessary for the treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease when the following criteria are met:

- Medical record documentation of member being established on and responding to Tysabri or Tyruko **AND**
- For natalizumab reference product requests (i.e. Tysabri): Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to natalizumab-sztn (Tyruko)

**OR**

- Medical record documentation of a diagnosis of a relapsing form of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND**
- Medical record documentation that the patient 18 years or older **AND**
- Medical record documentation that Tysabri or Tyruko is being prescribed by a neurologist **AND**
- Physician documentation that Tysabri or Tyruko is being used as monotherapy is provided **AND**
- Medical record documentation that the member has been tested for anti-JCV antibody prior to start of Tysabri or Tyruko therapy

- If patient is anti-JCV antibody positive, medical record documentation that benefits of drug outweigh the risks of progressive multifocal leukoencephalopathy (PML) and patient is aware of increased PML risk

**AND**

- Medical record documentation of therapeutic failure on, contraindication to, or intolerance to two formulary alternatives OR medical record documentation of highly active disease course requiring aggressive treatment

**AND**

- For natalizumab reference product requests (i.e. Tysabri): Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to natalizumab-sztn (Tyruko)

## 2. Crohn's disease

Tysabri or Tyruko is considered medically necessary as a second line therapy after conventional therapy and TNF inhibitors, when the following criteria are met:

The insured individual

- Must be 18 years of age or older **AND**
- Has had a formal consultation with a gastroenterologist and recommendation for treatment with natalizumab **AND**
- Has a diagnosis of active Crohn's disease considered to be moderate or severe based on clinical signs and symptoms **AND** documented contraindication to, intolerance to, or failure on adequate conventional therapy; (corticosteroids, 5-aminosalicylates, and/or 6-mercaptopurine/azathioprine, methotrexate) **AND** an inadequate response to, contraindication to, or failure on 12 weeks of adalimumab (Humira) therapy and 12 weeks of infliximab (Remicade) therapy **AND**
- Is enrolled in a risk-minimization program, called the TOUCH™ Prescribing Program or Tyruko REMS Program **AND**
- For natalizumab reference product requests (i.e. Tysabri): Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to natalizumab-sztn (Tyruko)

## MBP 317.0 Omvoh (mirikizumab-mrkz) – Updated Policy

### Crohn's Disease

- Medical record documentation that Omvoh is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active Crohn's disease **AND**
- Medical record documentation that Omvoh is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of three (3) preferred formulary biologics for the treatment of Crohn's disease **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on Entyvio\* **AND** infliximab\* **AND**
- Medical record documentation that Omvoh 300 mg vials as intravenous (IV) infusion are being used for induction therapy

Note: Plan preferred formulary biologics include: Amjevita\*, Cimzia\*, Tremfya\*, Yesintek\*, Rinvoq\*

\*prior authorization required

## MBP 259.0 Tezspire (tezepelumab-ekko) – Updated Policy

### Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

- Medical record documentation that Tezspire is prescribed by or in consultation with an allergist, pulmonologist, immunologist, or otolaryngologist (ENT provider) **AND**

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) **AND**
- Medical record documentation that Tezspire will be used as add-on maintenance treatment **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) intranasal corticosteroids **AND**
- Medical record documentation that the medication will not be used in combination with Fasena (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Xolair (omalizumab), or Tezspire (tezepelumab)

### **MBP 252.0 Susvimo (ranibizumab implant) & 2026 Part B Step Therapy – Updated Policy**

- Medical record documentation of a diagnosis of neovascular age-related macular degeneration (nAMD) OR diabetic retinopathy (DR) with or without macular edema (DME) **AND**
- Medical record documentation patient has previously responded to at least two (2) intravitreal doses of a Vascular Endothelial Growth Factor (VEGF) inhibitor medication **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to an adequate trial of intravitreal bevacizumab (Avastin) given at every four (4) week dosing intervals **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) additional intravitreal VEGF inhibitors (e.g. a preferred aflibercept product, Beovu **indicated for nAMD and DME only**), or a preferred ranibizumab product)

#### **AND**

- Medical record documentation that Susvimo (ranibizumab) will not be given in combination with an intravitreal Vascular Endothelial Growth Factor (VEGF) inhibitor administration to the same eye **OR**
- If the request is for use in combination with an intravitreal VEGF inhibitor administration to the same eye, all of the following must be met:
  - Medical record documentation Susvimo (ranibizumab) will be given in combination with intravitreal ranibizumab injection (Lucentis) **AND**
  - Medical record documentation intravitreal ranibizumab injection will be administered on an as needed basis, as determined by the prescriber

**AUTHORIZATION DURATION:** Approval will be given for an initial duration of two (2) years or less if the reviewing provider feels it is medically appropriate. After the initial two (2) year approval, subsequent approvals will be for a **lifetime 12 month** duration or less if the reviewing provider feels it is medically appropriate, and will require:

- Medical record documentation that Susvimo (ranibizumab) will not be given in combination with an intravitreal Vascular Endothelial Growth (VEGF) inhibitor

#### **QUANTITY LIMIT:**

**Neovascular (Wet) Age-Related Macular Degeneration (AMD) or Diabetic Macular Edema (DME):**

0.2mL (2 vials) per 24 weeks (to allow 2mg per 24 weeks per treated eye)

**Diabetic Retinopathy (DR) without DME:**

0.2mL (2 vials) per 36 weeks (to allow 2mg per 24 weeks per treated eye)

### **MBP 254.0 Leqvio (inclisiran) – Updated Policy**

#### **AND**

- Medical record documentation of a baseline low-density lipoprotein (LDL) drawn within 3 months of the start of PCSK9 therapy showing:
  - Low-density lipoprotein (LDL) greater than 100 if the member is using Leqvio for primary prevention **OR**

- Low-density lipoprotein (LDL) greater than 70 55 if the member is using Leqvio for secondary prevention

**AND**

**MBP 242.0 Evkeeza (evinacumab-dgnb) – Updated Policy**

**AND**

- Medical record documentation of failure to adequately control low-density lipoprotein (LDL) levels with combination of maximum tolerated statin dose AND ezetimibe defined as:
  - Greater than or equal to 130 mg/dL in pediatric patients greater than or equal to 1 year of age and less than 18 years of age OR
  - Greater than or equal to 100 mg/dL in adult patients without cardiovascular disease OR
  - Greater than or equal to 70 55 mg/dL in adult patients with established cardiovascular disease **AND**

**The following policies were reviewed with no changes:**

- MBP 77.0 Ilaris
- MBP 106.0 Injectable Antipsychotic Medications
- MBP 118.0 Entyvio
- MBP 191.0 Cinvanti
- MBP 212.0 Adakveo
- MBP 276.0 Zynteglo

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

**The following policies were reviewed with no changes:**

- MBP 4.0 Intravenous Immune Globulin

**The following policies were retired:**

- MBP 287.0 Aduhelm

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

**MBP 13.0 Viscosupplementation using hyaluronan injections – Updated Policy**

Viscosupplementation products for Commercial, Exchange, and CHIP lines of business	
Preferred	Non-preferred
Durolane	Gel-One
Euflexxa	GenVisc 850
Gelsyn-3	Hymovis
Hyalgan	Monovisc
Supartz FX	Orthovisc
Synvisc	Synojynt
Synvisc One	Trilon
Visco-3	TriVisc

**NOTE: For commercial, exchange, and CHIP lines of business, Durolane, Euflexxa, Gelsyn-3, Supartz FX, Synvisc, and Synvisc One are preferred agents and DO NOT Require Prior Authorization**

**Gel-One, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Synjoynt, Triluron, TriVisc, and Visco-3** All viscosupplementation products will require Prior Authorization and will be considered medically necessary for the commercial, exchange and CHIP lines of business when all of the following criteria are met:

- Medical record documentation of **Physician-documented** symptomatic osteoarthritis of the knee, defined as knee pain associated with radiographic evidence of osteophytes in the knee joint provided the clinical presentation is not that of “bone-on-bone”, morning stiffness of less than or equal to 30 minutes in duration, crepitus on range of motion **AND**
- Medical record documentation of **Physician-documented** knee joint pain sufficient to interfere with ambulatory functional activities **AND**
- Medical record documentation of **Physician-documented** **an adequate trial** of non-pharmacologic modalities, e.g., weight loss, quadriceps muscle strengthening, other physical therapy modalities, or exercises that have not promoted satisfactory symptomatic relief **AND**
- Medical record documentation of **Physician-documented** that there has been no significant improvement following pharmacologic therapy with a full-dose nonsteroidal anti-inflammatory drug (NSAID) regimen, with or without supplemental acetaminophen, over a 10-12 week period of time or if NSAID’s are contraindicated, a failure of daily acetaminophen regimen over a 4 to 6 week period **AND**
- Medical record documentation of **Physician-documented** that there has been no significant improvement **within the 2 months** following standard dose intra-articular corticosteroid injection(s) ~~e.g., a satisfactory clinical response of greater than or equal to 3 months; this requirement does not apply if the use of corticosteroids might increase the risk of local or systemic bacterial infection, e.g., diabetes mellitus~~ **AND**
- **If the request is for a non-preferred product:** Medical record documentation of **Physician documented** of failure on, intolerance to or contraindication to **three (3) preferred products of the following: Durolane, Euflexxa, Gelsyn-3, Supartz-FX, Synvisc, and/or Synvisc-One**

**AUTHORIZATION DURATION/QUANTITY LIMIT:** Initial approval will be for six (6) months and will be limited to one (1) treatment course to the affected knee(s) (bilateral injections may be allowed if both knees meet the required coverage criteria). Subsequent approvals will be for six (6) months and will be limited to one (1) treatment course to the affected knee(s) when members meet the following criteria:

- Repeat treatment cycles are considered medically necessary when ALL of the following criteria are met:
  1. Medical record documentation ~~of~~ **that there was** significant improvement in pain and function **within the 3 months** following the **most recent Viscosupplementation injection** ~~previous injection~~ **AND**
  2. Documented reduction of the doses of nonsteroidals or analgesics during the **three six-** month period following the last injection in the previous series **AND as well as** no need for accompanying intra-articular steroid injections **AND**
  3. Six months or longer have elapsed **from since** the last injection in the previous series **to the next planned date of service.**

## **MBP 11.0 Botulinum Toxin and Derivatives (Botox, Daxxify, Dysport, Myobloc, Xeomin) – Updated Policy**

### **1. Chronic Migraine Headache**

- Physician provided medical record documentation of a history of 15 or more migraine headache days per month that last 4 or more hours per day **AND**
- Physician provided medical record documentation that Botox is prescribed by or in consultation with a neurologist or headache specialist **AND**
- Physician provided medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) of the following:
  - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
  - Topiramate
  - Divalproex/sodium valproate

- Amitriptyline
- Venlafaxine
- AND**
- ~~Medical record documentation that Botox will not be used in combination with a CGRP antagonist OR~~
- ~~If the request is for use in combination with a CGRP antagonist, all of the following must be met:~~
  - ~~Medical record documentation of a therapeutic failure on a minimum 3-month trial of at least one CGRP antagonists without the concomitant use of Botox AND~~
  - ~~Medical record documentation of therapeutic failure on a minimum 6-month trial of Botox without the concomitant use of a CGRP antagonist~~

The following policy updates and reviews apply to Medicare GHP members only:

**MBP 13.0 Viscosupplementation using hyaluronan injections & 2026 Part B Step Therapy Drugs List & Criteria – Updated Policy**

Viscosupplementation products for Medicare line of business	
Preferred	Non-preferred
Durolane	Gel-One
Euflexxa	GenVisc 850
Gelsyn-3	Hymovis
Hyalgan	Monovisc
Orthovisc	Triluron
Supartz FX	
Synojynt	
Synvisc	
Synvisc One	
TriVisc	
Visco-3	

**NOTE: For the Medicare line of business, Durolane, Euflexxa, Gelsyn-3, Hyalgan, Orthovisc, Supartz FX, Synojynt, Synvisc, Synvisc-One, TriVisc and Visco-3 are preferred agents and DO NOT require Prior Authorization.**

**Gel-One, GenVisc 850, Hymovis, Monovisc, and Triluron** require Prior Authorization and will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

- **Medical record documentation of** ~~Physician documented~~ symptomatic osteoarthritis of the knee, defined as knee pain associated with radiographic evidence of osteophytes in the knee joint provided the clinical presentation is not that of “bone-on-bone”, morning stiffness of less than or equal to 30 minutes in duration, crepitus on range of motion **AND**
- **Medical record documentation of** ~~Physician documented~~ knee joint pain sufficient to interfere with ambulatory functional activities **AND**
- **Medical record documentation of** ~~Physician documented~~ **an adequate trial** of non-pharmacologic modalities, e.g., weight loss, quadriceps muscle strengthening, other physical therapy modalities, or exercises that have not promoted satisfactory symptomatic relief **AND**
- **Medical record documentation of** ~~Physician documented~~ that there has been no significant improvement following pharmacologic therapy with a full-dose nonsteroidal anti-inflammatory drug (NSAID) regimen, with or without supplemental acetaminophen, over a 10-12 week period of time or if NSAID’s are contraindicated, a failure of daily acetaminophen regimen over a 4 to 6 week period **AND**
- **Medical record documentation of** ~~Physician documented~~ that there has been no significant

improvement **within the 2 months** following standard dose intra-articular corticosteroid injection(s) ~~e.g., a satisfactory clinical response of greater than or equal to 3 months; this requirement does not apply if the use of corticosteroids might increase the risk of local or systemic bacterial infection, e.g., diabetes mellitus~~ **AND**

- **If the request is for a non-preferred product:** Medical record documentation of **Physician documented** of failure on, intolerance to or contraindication to **two (2) preferred products** of the following: ~~Durolane, Euflexxa, Gelsyn-3, Hyalgan, Orthovisc, Supartz FX, Synjoynt, Synvise/Synvise One, TriVisc, and Visco-3~~

**AUTHORIZATION DURATION/QUANTITY LIMIT:** Initial approval will be for six (6) months and will be limited to one (1) treatment course to the affected knee(s) (bilateral injections may be allowed if both knees meet the required coverage criteria). Subsequent approvals will be for six (6) months and will be limited to one (1) treatment course to the affected knee(s) when members meet the following criteria:

- Repeat treatment cycles are considered medically necessary when ALL of the following criteria are met:
  1. Medical record documentation ~~of~~ **that there was** significant improvement in pain and function **within the 3 months** following the **most recent Viscosupplementation injection** ~~previous injection~~ **AND**
  2. Documented reduction of the doses of nonsteroidals or analgesics during the **three six-month** period following the last injection in the previous series **AND as well as** no need for accompanying intra-articular steroid injections **AND**
  3. Six months or longer have elapsed **from since** the last injection in the previous series **to the next planned date of service.**