“What’s New” Medical Pharmaceutical Policy February 2018 Updates

MBP 11.0 Botulinum Toxin and Derivatives (Botox, Dysport, Myobloc, Xeomin)- Updated policy

Geisinger Health Plan approved FDA labeled indications for Botulinum Toxin Type A (Dysport) are:
1. Cervical dystonia
   OR
2. Upper Limb Spasticity
   • Medical record documentation that Dysport is being used for the treatment of upper limb AND
   • Documentation that the patient is at least 18 years of age.
   OR
3. Pediatric Lower Limb Spasticity
   • Medical record documentation that Dysport is being used for the treatment of the lower limb(s) AND
   • Documentation that the member is between 2 and 17 years of age ≥ 2 years of age.

**Note: Adult lower limb spasticity is indicated under Botox Only, NOT Dysport.

Geisinger Health Plan approved FDA labeled indications for Botulinum Toxin Type B (Myobloc):
1. Cervical dystonia

The following applies to all botulinum toxin products (Botox, Dysport, Myobloc, Xeomin):

**Quantity Limit:** One (1) visit per 12 weeks (3 months)*

*Note: Patients utilizing botulinum toxin products for more than one indication may require additional visits. The following cumulative doses should not be exceeded if being used for 1 (or more) indication(s):

- Botox – 400 units per 12 weeks (3 months)
- Dysport – 1500 units per 12 weeks (3 months)
- Myobloc – 5000 units per 12 weeks (3 months)
- Xeomin – 400 units per 12 weeks (3 months)

**AUTHORIZATION DURATION:** Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:

- Medical record documentation of continued disease improvement or lack of disease progression** AND
- Medical record documentation of one of the following:
  - Repeated administrations are not being given more frequently than once every 12 weeks OR
  - Peer-reviewed literature citing well-designed clinical trials to indicate that the member’s healthcare outcome will be improved by dosing more frequently than every 12 weeks.

**Note: The requested medication will no longer be covered if the patient fails to present clinical benefit after two sequential therapies using maximum doses.

Botulinum toxin is considered investigational for
- headache or migraine other than chronic migraine
- myofascial pain syndrome
• tremors such as benign essential tremor, chronic motor tic disorder, and tics associated with Tourette syndrome
• treatment of upper limb spasticity in pediatric patients
• treatment of lower limb spasticity pediatric patients (with exception of Dysport)

MBP 119.0 Keytruda (pembrolizumab)- New Indication

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

*Note to reviewer: Current recommendations intend Keytruda to be used as third-line treatment (i.e., patient is to have 2 prior lines of therapy, one of which must include HER2/neu-targeted therapy if the patient has HER-2 positive disease)

MBP 126.0 Opdivo (nivolumab)- New Indication

Opdivo (nivolumab) will be considered medically necessary when all of the following criteria are met:

8. Hepatocellular Carcinoma (HCC)
• Prescription written by a hematologist/oncologist AND
• Medical record documentation of a diagnosis of hepatocellular carcinoma AND
• Medical record documentation of a therapeutic failure on or intolerance to sorafenib (Nexavar)

MBP 159.0 Kymriah (tisagenlecleucel)- New Policy

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

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

Acute Lymphoblastic Leukemia (ALL)
• Prescription written by a hematologist/oncologist AND
• Medical record documentation that patient is less than 26 years of age AND
• Medical record documentation of a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second (or later) relapse

Note: The indication of Kymriah is intended to treat patients up to the age of 25 years 364 days. Upon reaching 26 years of age the patient is no longer a candidate for Kymriah treatment. Per Novartis, Kymriah will not be manufactured for any patient who does not meet the specific FDA approved indication, including these age restrictions.

AUTHORIZATION DURATION: Approved requests will be for a One-time authorization for one administration of Kymriah.
MBP 160.0 Besponsa (inotuzumab ozogamicin)- New Policy

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Besponsa (inotuzumab ozogamicin) will be considered medically necessary when ALL of the following criteria are met:

**Acute Lymphoblastic Leukemia (ALL)**
- 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 relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

**AUTHORIZATION DURATION:** An initial authorization duration of 3 cycles (3 months) should be approved.

**Reauthorization:** One subsequent authorization will be for an additional 3 cycles (3 months) and will require medical record documentation of the following:
- Medical record documentation that patient is not receiving hematopoietic stem cell transplant (HSCT) **AND**
- Medical record documentation that patient has achieved complete remission or complete remission with incomplete hematologic recovery and minimal residual disease (MRD) **AND**
- Medical record documentation that the patient is not experiencing toxicity or worsening of disease.

MBP 161.0 Aliqopa (copanlisib)- New Policy

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Aliqopa (copanlisib) will be considered medically necessary when ALL of the following criteria are met:
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed follicular B-cell non-Hodgkin lymphoma (FL) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to or contraindication to at least two prior systemic therapies

**Quantity Limit:** 180 mg (3 vials) per 28 days

**AUTHORIZATION DURATION:** Each treatment period will be defined as 12 months. Re-review will occur every 12 months. Aliqopa will no longer be considered medically necessary if there is medical record documentation of disease progression.