"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)
- ~~treatment of hyperhidrosis in body areas other an axillary~~

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 <u>less than</u> 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, Kymiah will <u>not</u> 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 <u>one</u> 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.