

“What’s New” Medical Pharmaceutical Policy May 2020 Updates

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

5. Chronic Migraine Headache

Botulinum toxin A for the treatment of chronic migraine headache may be considered medically necessary when all of the following criteria are met:

- 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 of a completed Neurology consult and recommendation **AND**
 - Physician provided medical record documentation of **therapeutic failure on**, intolerance **to**, or contraindication to ~~an adequate trial of at least two different migraine prophylaxis medications (eg, beta-blockers, calcium channel blockers, tricyclic antidepressants or anticonvulsant medications)~~ at least three (3) 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

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 ~~≥18~~ **≥2** years of age.OR
3. **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 ≥ 2 years of age.

MBP 68.0 Nplate (romiplostim) - Updated policy

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

- Physician supplied documentation of a diagnosis of ~~chronic~~ immune (idiopathic) thrombocytopenia purpura (ITP); **AND**
- Physician supplied documentation of a therapeutic failure on, contraindication to corticosteroids, immunoglobulins, rituximab*, splenectomy, and eltrombopag (Promacta)*; **AND**
- Physician supplied documentation of:
 - symptomatic ITP with platelets less than 30,000/ μ L and bleeding symptoms; **OR**
 - a platelet count of less than 20,000/ μ and an increased risk of bleeding

*requires prior authorization

AUTHORIZATION DURATION:

If an exception is made, Nplate will be authorized for an **initial period of three (3) months** ~~and continued coverage will require medical record documentation of improvement in symptoms and/or platelet count response above 20,000/ μ L.~~ Subsequent authorizations will be for a period of **six (6) months** and will ~~then~~ require medical record documentation of platelet count greater than or equal to 50,000/microL and continued or sustained reduction in bleeding events.

MBP 119.0 Keytruda (pembrolizumab) - Updated policy

1. Urothelial Carcinoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is \geq 18 years of age **AND**
- 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 cisplatin-containing chemotherapy* **AND**
 - Tumors express PD-L1 (combined positive score [CPS] greater than or equal to 10) as determined by an FDA-approved test
OR
 - Patient is not eligible for any platinum-containing chemotherapy (regardless of PD-L1 status)
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:

- In clinical trials, patients who were not considered cisplatin-eligible had the following characteristics: baseline creatinine clearance of <60 mL/min, ECOG performance status of 2, ECOG 2 and baseline creatinine clearance of <60 mL/min, other reasons (Class III heart failure, Grade 2 or greater peripheral neuropathy, and Grade 2 or greater hearing loss).

**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 169.0 Baxdela IV (delafloxacin) - Updated policy

- Medical record documentation that patient is greater than or equal to 18 years of age **AND**
- Medical record documentation of one of the following:
 - ~~Medical record documentation of~~ A diagnosis of acute bacterial skin and skin structure infections (ABSSSI)* caused by: *Staphylococcus aureus* (including methicillin-resistant

[MRSA] and methicillin-susceptible [MSSA] isolates), *Staphylococcus haemolyticus*, *Staphylococcus lugdunensis*, *Streptococcus agalactiae*, *Streptococcus anginosus* Group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*), *Streptococcus pyogenes*, *Enterococcus faecalis*, *Escherichia coli*, *Enterobacter cloacae*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa* **OR**

- o A diagnosis of community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin susceptible [MSSA] isolates only), *Klebsiella pneumoniae*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Chlamydia pneumoniae*, *Legionella pneumophila*, and *Mycoplasma pneumoniae*

AND

- Prescription written by or in consultation with Infectious Disease **AND**
- If Baxdela was initiated during an inpatient stay, medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments OR a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity **AND**
- Medical record documentation of therapeutic failure on, intolerance to, contraindication to Baxdela tablets.

*Note to reviewer: ABSSSI is defined as a skin infection with a lesion surface area of at least 75 cm² and includes the three following types of infection: (1) cellulitis/erysipelas, (2) wound infections, and (3) major cutaneous abscesses.

AUTHORIZATION DURATION:

If approved for ABSSI, Baxdela IV will be authorized for 14 days, with a maximum of 28 doses.

If approved for CABP, Baxdela IV will be authorized for 10 days, with a maximum of 20 doses.

MBP 181.0 Site of Care – Product updates

II. Purpose/Objective:

To provide a policy of coverage regarding the use of hospital based outpatient facilities as a site of care for drugs that require administration via intravenous infusion or injection. This policy applies to these medications:

1. Abatacept (Orencia IV) [effective 5/1/20]
2. Belimumab (Benlysta IV) [effective 5/1/20]
3. Golimumab (Simponi Aria) [effective 5/1/20]
4. Immune Globulin (IVIG) [effective 10/1/19]
5. Infliximab (Remicade) & infliximab biosimilar products [effective 10/1/19]
6. Tocilizumab (Actemra IV) [effective 5/1/20]
7. Vedolizumab (Entyvio) [effective 5/1/20]
8. Denosumab (Prolia, Xgeva) [effective 7/1/20]

No changes to "Criteria for Use" within MBP 181.0.

MBP 208.0 Enhertu (fam-trastuzumab-nxki) – New policy

DESCRIPTION:

Enhertu (fam-trastuzumab deruxtecan-nxki) is a HER2-directed antibody and topoisomerase inhibitor conjugate that binds to HER2 on tumor cells, undergoes internalization and intracellular linker cleavage by lysosomal enzymes, and upon release, causes DNA damage and apoptotic cell death.

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

Enhertu (fam-trastuzumab deruxtecan-nxki) will be considered medically necessary when ALL of the following criteria are met:

- 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 breast cancer **AND**
- Medical record documentation of two or more prior anti-HER2 based therapies in the metastatic setting

AUTHORIZATION DURATION: 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 209.0 Padcev (enfortumab vedotin-ejfv) – New policy

DESCRIPTION:

Padcev (enfortumab vedotin-ejfv) is an antibody-drug conjugate consisting of human IgG1-kappa antibody, anti-Nectin-4, attached to a microtubule disrupting agent, monomethyl auristatin E (MMAE), by a cleavable maleimidocaproyl valine-citrulline linker. The antibody-drug conjugate binds to the Nectin-4 adhesion protein found on the cell surface and the entire complex is internalized. MMAE is cleaved from the complex resulting in the disruption of the microtubule network within the cell, leading to cell cycle arrest and apoptotic cell death.

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

Padcev (enfortumab vedotin-ejfv) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation that prescription is written by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of locally advanced or metastatic urothelial cancer **AND**
- Medical record documentation that member has received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting

AUTHORIZATION DURATION: 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.