Geisinger Health Plan

POLICIES AND PROCEDURE MANUAL

"What's New" Medical Pharmaceutical Policy September 2020 Updates

MBP 47.0 Lucentis (ranibizumab)- New policy

DESCRIPTION:
Lucentis (ranibizumab) is a recombinant humanized monoclonal antibody fragment which binds to and inhibits human vascular endothelial growth factor A (VEGF-A). Ranibizumab inhibits VEGF from binding to its receptors and thereby suppressing neovascularization and slowing vision loss.

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

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

- Medical record documentation of a diagnosis of neovascular age-related macular degeneration **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Avastin

OR

- Medical record documentation of a diagnosis of diabetic retinopathy with or without macular edema **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Avastin

OR

- Medical record documentation of a diagnosis of macular edema following retinal vein occlusion **OR** myopic choroidal neovascularization

NOTE: Indicators of Avastin failure may include:
- Worse or unchanged intraretinal or subretinal fluid.
- Persistent subretinal or intraretinal fluid.
- Recurrent intraretinal or subretinal fluid at current interval or extended interval.
- New subretinal hemorrhage
- In the absence of subretinal fluid, intraretinal fluid, or subretinal hemorrhage a failure documented as evidence of growth of the neovascular membrane on clinical exam or multimodal imaging.
- Any ocular or systemic adverse event thought related to the use of intravitreal bevacizumab.

AUTHORIZATION DURATION: Approvals will be given for a lifetime duration.

MBP 94.0 Eylea (aflibercept)- New policy

DESCRIPTION:
Eylea (aflibercept) is a recombinant fusion protein that acts as a decoy receptor for vascular endothelial growth factor-A (VEGF-A) and placental growth factor (PLGF). Aflibercept binds to VEGF-A and PLGF and inhibits binding and activating of endothelial cell receptors, thereby suppressing neovascularization and slowing vision loss.

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

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

- Medical record documentation of a diagnosis of neovascular age-related macular degeneration **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Avastin

OR

- Medical record documentation of a diagnosis of diabetic retinopathy with or without macular edema **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Avastin **OR** medical record documentation of baseline visual acuity 20/50 or worse

OR

- Medical record documentation of a diagnosis of macular edema following retinal vein occlusion

NOTE: Indicators of Avastin failure may include:

- Worse or unchanged intraretinal or subretinal fluid.
- Persistent subretinal or intraretinal fluid.
- Recurrent intraretinal or subretinal fluid at current interval or extended interval.
- New subretinal hemorrhage
- In the absence of subretinal fluid, intraretinal fluid, or subretinal hemorrhage a failure documented as evidence of growth of the neovascular membrane on clinical exam or multimodal imaging.
- Any ocular or systemic adverse event thought related to the use of intravitreal bevacizumab.

AUTHORIZATION DURATION: Approvals will be given for a lifetime duration.

MBP 122.0 Sivextro (tedizolid phosphate) IV - Updated policy

Sivextro (tedizolid phosphate) IV will be considered medically necessary when all of the following criteria are met:

- Medical record documentation that patient is ~~> 18~~ ≥ 12 years of age **AND**
- Medical record documentation of a diagnosis of an acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutaneous abscess) caused by: Staphylococcus aureus, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus, or Enterococcus faecalis which has been diagnosed and documented with Infectious Disease consultation **AND**
- Medical record documentation of a 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 **OR**
- If Sivextro was initiated during an inpatient stay, medical record documentation of a 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

MBP 140.0 Empliciti (elotuzumab)- Updated policy

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

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of multiple myeloma **AND**
    - Medical record documentation of use in combination with lenalidomide (Revlimid) and dexamethasone **AND**
    - Medical record documentation that the patient has previously been treated with at least one prior therapy ~~for multiple myeloma~~

    OR

    - Medical record documentation of use in combination with pomalidomide and dexamethasone **AND**
    - Medical record documentation that the patient has previously been treated with at least two prior therapies including lenalidomide and a proteasome inhibitor.

MBP 152.0 Bavencio (avelumab)- Updated policy

Urothelial Carcinoma

- Prescribed by a hematologist/oncologist AND
- Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma AND
- Medical record documentation of one of the following:
    - Documentation that Bavencio will be used as maintenance treatment with no progression following first-line platinum-containing chemotherapy OR
    - Disease progression during or following platinum-containing chemotherapy OR
    - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

MBP 181.0 Site of Care Review Guidelines for Infusion Drugs and Specialty Medications- Updated policy

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)
2. Belimumab (Benlysta IV)
3. Benralizumab (Fasenra) [effective 12/1/20]
4. C1 esterase Inhibitor [Human] (Cinryze) [effective 10/1/20]
5. Denosumab (Prolia, Xgeva)
6. Golimumab (Simponi Aria)
7. Immune Globulin (IVIG)
8. Infliximab & infliximab biosimilar products
9. Mepolizumab (Nucala) [effective 12/1/20]
10. Omalizumab (Xolair) [effective 12/1/20]
11. Tocilizumab (Actemra IV)
12. Vedolizumab (Entyvio)

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

Administration in the hospital based outpatient setting will be considered medically necessary and LIMITED to a duration of 60 days when one of the following criteria are met:

- This is the initial medication infusion **OR**
- Member is reinitiating treatment after not receiving any treatments for at least 6 months.

AUTHORIZATION DURATION: Initial approval will be for a duration of 60 days. Administration in the hospital based outpatient setting for longer than 60 days will be required to meet the authorization criteria in the section below.

Administration in the hospital based outpatient setting will be considered medically necessary for a duration of greater than 60 days when one of the following criteria are met:

- The medication has a site of care restriction for administration per the FDA approved label **OR**
- Documented previous history of severe or potentially life-threatening adverse event during or following administration and the adverse event cannot be managed using pre-medication(s) or adjusting the rate of infusion **OR**
- ~~Both~~ All of the following:
    - All alternate non-hospital outpatient settings are not within a reasonable distance from the member's home (within 50 miles) **AND**
    - Home healthcare or infusion provider has determined that the patient, home caregiver, or home environment is not appropriate for home infusion or home infusion services are not available due to limited network access **AND**
    - For request of a provider administered drug, for which a self-administered formulation is available, including but not limited to abatacept, belimumab, benralizumab, golimumab, mepolizumab and tocilizumab: medical record documentation of a therapeutic failure of or intolerance to a 3 month trial of the self-administered formulation of the respective product.

OR

- For IVIG any of the above criteria **OR**

- Change of immune globulin products (one infusion will be permitted in the hospital outpatient setting) **OR**
- Laboratory confirmed immunoglobulin A (IgA) deficiency with anti-IgA antibodies

OR

- For Xgeva (denosumab) any of the above criteria **OR**
  0. Patient is receiving Xgeva concomitantly with intravenous chemotherapy as part of the same encounter

AUTHORIZATION DURATION: Initial approval will be for the same length of time as the authorization of the specific drug being administered. Subsequent approvals will be required if the specific drug requires subsequent authorizations.

NOTE: To prevent a delay in care and allow adequate transition time for members to an alternate infusion site, members already established on therapy who do not meet any of the above criteria will be given a 60-day transition auth to allow them to continue receiving therapy at their current hospital based outpatient facility while they transition to a different infusion site.

MBP 195.0 Spravato (esketamine)- Updated policy

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

For Treatment Resistant Depression

- Medical record documentation of age ≥ 18 AND
- Medical record documentation of diagnosis of major depression disorder (MDD) AND
- Medical record documentation of Spravato being used for treatment-resistant depression as defined by failure of at least two antidepressants from two different classes at an optimized dose for at least 6 weeks AND
- Medical record documentation that Spravato will be used in combination with a newly initiated antidepressant AND
- Medical record documentation of the patient's baseline depression status using an appropriate rating scale (e.g. PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D) AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to olanzapine/fluoxetine capsules AND
- Medical record documentation that all potential drug interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary about the risks associated with the use of both medications when they interact).

For acute suicidal ideation and behavior

- Medical record documentation of age ≥ 18 years AND
- Medical record documentation that Spravato will be used in combination with an oral antidepressant AND
- Medical record documentation of diagnosis of major depression disorder (MDD) AND
- Medical record documentation of a recent hospital admission (within 4 weeks) due to depressive symptoms with acute suicidal ideation and behavior AND
- Medical record documentation that Spravato was started inpatient AND
- Medical record documentation that Spravato will not exceed the FDA-approved duration of 4 weeks AND
- Medical record documentation that all potential drug interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug,

or counseling of the beneficiary about the risks associated with the use of both medications when they interact).

*Note to reviewer: The standard of care for patients with acute suicidal ideation and behavior is to hospitalize for safety. Spravato should be started inpatient for acute suicidal ideation requests.

Authorization Duration for treatment resistant depression:
Initial approval will be for 1 month or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following criteria is required.

- Medical record documentation of clinical improvement in depression symptoms as measured by an appropriate rating scale (compared to previous measurement).

Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following criteria is required.

- Medical record documentation of clinical improvement or lack of progression in depression symptoms as measured by an appropriate rating scale (compared to previous measurement).

Quantity Limits for treatment resistant depression:
For the initial 1 month authorization: 23 devices per 28 days
For subsequent authorizations: 12 devices per 28 days

Authorization Duration for depressive episodes with acute suidical ideation: Approval will be for one (1) 4 week approval for the FDA approved maximum of 24 devices. Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improvement by dosing beyond the FDA-approved treatment duration.

Quantity Limits for depressive episodes with acute suicidal ideation:
56 mg dose pack: 16 devices per 28 days
84 mg dose pack: 24 devices per 28 days

MBP 210.0 Reblozyl (luspatercept-aamt)- Updated policy

Reblozyl (luspatercept-aamt) will be considered medically necessary when ALL of the following criteria are met:

1. Anemia due to Beta thalassemia

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of beta thalassemia **AND**
- Medical record documentation that patient requires regular* red blood cell (RBC) transfusions **AND**
- Medical record documentation of baseline number of transfusions and red blood cell (RBC) units required for the previous six (6) months **AND**
- Medical record recommendation that Reblozyl is being dosed consistent with FDA-approved labeling**.

2. Anemia due to myelodysplastic syndromes or myelodysplastic/myeloproliferative neoplasm

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) with one of the following:
    - Documentation of greater than or equal to 15% ring sideroblasts **OR**
    - Documentation of greater than or equal to 5% ring sideroblasts AND an SF3B1 mutation **AND**

- Medical record documentation of very low to intermediate risk **AND**
- Medical record documentation that patient requires 2 or more red blood cell units over 8 weeks **AND**
- Medical record documentation of baseline number of transfusions and red blood cell (RBC) units required for the previous six (6) months **AND**
- Medical record documentation of therapeutic failure, intolerance to, or contraindication to an erythropoiesis stimulating agent **AND**
- Medical record recommendation that Reblozyl is being dosed consistent with FDA-approved labeling**.

AUTHORIZATION DURATION: Approval will be given for an **initial duration of six (6) months** or less if the reviewing provider feels it is medically appropriate. After the initial six (6) month approval, subsequent approvals will be for a **duration of six (6) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- a decrease in red blood cell (RBC) transfusion burden from baseline **AND**
- Reblozyl being dosed consistent with the FDA-approved labeling**

Ongoing subsequent approvals will be for a **duration of six (6) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- a sustained reduction of red blood cell (RBC) transfusion burden from baseline **AND**
- Reblozyl being dosed consistent with the FDA-approved labeling**

LIMITATIONS: Reblozyl will no longer be covered if the patient does not experience a decrease in transfusion burden after nine (9) weeks of treatment (administration of three (3) doses) at the maximum dose level or if unacceptable toxicity occurs at any time.

NOTES:
*In clinical trials For Beta Thalassemia, “regular red blood cell transfusions” was considered to be 6 to 20 red blood cell units per 24 weeks with no transfusion-free period greater than 35 days.

**Per current labeling: For Beta Thalassemia: 1mg/kg every 3 weeks increasing to a maximum of 1.25mg/kg every 3 weeks after two doses if a reduction in transfusion burden is not seen. Dose should not exceed 1.25mg/kg every 3 weeks

For MDS-RS and MDS/MPN-RS-T: 1mg/kg every 3 weeks increasing to a dose of 1.33 mg/kg every 3 weeks after two doses if a reduction in transfusion burden is not seen , then increasing up to a maximum of 1.75mg/kg every 3 weeks after two doses if a reduction in transfusion burden is not seen. Dose should not exceed 1.75mg/kg every 3 weeks

MBP 221.0 Monjuvi (tafasitamab-cxix)- New policy

DESCRIPTION:
Monjuvi (tafasitamab-cxix) is a humanized CD19-directed, Fc-modified monoclonal antibody that binds to CD19 antigen, which is expressed on the surface of pre-B and mature B lymphocytes and on several B-cell malignancies, including diffuse large B-cell lymphoma. After binding to CD19, tafasitamab mediates B-cell lysis through apoptosis and immune effector mechanisms, including antibody-dependent cellular cytotoxicity and phagocytosis. Administering in combination with lenalidomide results in increased antibody-dependent cellular cytotoxicity activity compared to either agent alone.

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

Monjuvi (tafasitamab-cxix) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Monjuvi is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma **AND**
- Medical record documentation that the member is not eligible for autologous stem cell transplant (ASCT) **AND**
- Medical record documentation that Monjuvi will be used in combination with Revlimid (lenalidomide)

AUTHORIZATION DURATION: Initial approval will be for **12 months**. Subsequent approvals will be for an additional 12 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

MBP 222.0 Zepzelca (lurbinectedin)- New policy

DESCRIPTION:
Zepzelca (lurbinectedin) is an alkylating agent and a selective inhibitor of oncogenic transcription which binds preferentially to guanine residues in the minor groove of DNA; this forms adducts and bends the DNA helix towards the major groove. Adduct formation affects the activities of DNA binding proteins, including some transcription factors and DNA repair pathways. Inhibition of oncogenic transcription results in tumor cell apoptosis.

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

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

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Zepzelca is written by a hematologist or oncologist **AND**
- Medical record documentation of metastatic small cell lung cancer (SCLC) **AND**
- Medical record documentation of disease progression on or after platinum-based chemotherapy

AUTHORIZATION DURATION: Initial approval will be for **6 months**. Subsequent approvals 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 the member experiences unacceptable toxicity or worsening of disease.

The following policies were reviewed with no changes:

- MBP 4.0 Intravenous Immune Globulin
- MBP 64.0 Arranon (nelarbine)
- MBP 65.0 Torisel (temsirolimus)
- MBP 93.0 Nulojix (belatacept)
- MBP 96.0 Voraxaze (glucarpidase)
- MBP 111.0 Marqibo (vincristine sulfate liposome injection)
- MBP 117.0 Beleodaq (belinostat)
- MBP 138.0 Onivyde (irinotecan liposome injection)
- MBP 140.0 Empliciti (elotuzumab)
- MBP 164.0 Vyxeos (daunorubicin-cytarabine liposomal)
- MBP 166.0 Adcetris (brentuximab vedotin)

- MBP 167.0 Vabomere (meropenem-vaborbactam)
- MBP 168.0 Parsabiv (etelcalcetide)
- MBP 172.0 Trisenox (arsenic trioxide)
- MBP 187.0 Zemdri (plazomicin)
- MBP 189.0 Lumoxiti (moxetumomab pasudotox-tdfk)
- MBP 202.0 Evenity (romosozumab-aqqg)