"What's New" Medical Pharmaceutical Policy February 2019 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 (**Xeomin** only) are:

1. Sialorrhea
   - Documentation that patient is at least 18 years of age **AND**
   - Medical record documentation of a diagnosis of chronic sialorrhea resulting from Parkinson's disease, atypical parkinsonism, stroke, or traumatic brain injury

MBP 49.0 Erythropoietin and Darbepoetin Therapy - Updated policy

DESCRIPTION:
Erythropoietin therapy (e.g., EPO, Epogen [epoetin alfa], Retacrit [epoetin alfa-epbx], Procrit [epoetin beta]) and darbepoetin alfa therapy (Aranesp) is used to stimulate red blood cell production in the bone marrow, with the goal of correcting anemia, minimizing the need for transfusion requirements, and improving the anemic insured individual's quality of life.

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

Erythropoietin therapy is considered medically necessary for the following indications when reversible or correctable conditions including but not limited to, vitamin B12 deficiency, hemolysis, iron or folate deficiency, underlying hematological disease, underlying infection or inflammatory process, and blood loss have been ruled out and when all of the indication specific criteria are met.

1. Treatment of symptomatic anemia of chronic renal insufficiency, chronic renal failure, including end stage renal disease either requiring or not requiring dialysis when all of the following criteria are met:
   - For New starts: Hgb less than or equal to 10 g/dL OR
   - For Continuation of therapy: Hgb less than 11 g/dL OR medical record documentation that the dose will be reduced or interrupted if Hgb is greater than or equal to 11g/d

   AND
   - Ferritin greater than or equal to 100 ng/mL or transferrin saturation level greater than or equal to 20%, or a history of chelation therapy for iron~~;~~

2. Treatment of symptomatic anemia in zidovudine-treated HIV infected insured individuals when all of the following criteria are met:
   - Endogenous erythropoietin levels of 500 MU/mL or less; AND
   - Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron; AND
   - Zidovudine doses of 4200 mg or less per week; AND
   - Hgb less than or equal to 10 g/dL for new starts OR Hgb less than 12 g/dL for continuation of therapy

Treatment should not last longer than 3 months following the discontinuation of zidovudine

3. Treatment of anemia secondary to myelosuppressive chemotherapy in *non-myeloid malignancies when all of the following criteria are met:
   - Hgb less than or equal to 10 g/dL for new starts OR Hgb less than 12 g/dL for continuation of therapy AND
   - Insured individual is currently on anemia-inducing chemotherapy and there is a minimum of two additional months of planned chemotherapy; AND
   - Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron

*Non-myeloid malignancies include all types of carcinoma, sarcoma, melanoma, multiple myeloma, lymphoma and lymphocytic leukemia

4. Treatment of symptomatic anemia secondary to myelodysplastic syndrome (MDS) when all of the following criteria are met:

- Hgb less than or equal to 10 g/dL for new starts OR Hgb less than 12 g/dL for continuation of therapy AND
- Ferritin greater than or equal to 100ng/dL or transferrin level saturation greater than or equal to 20% OR a history of chelation therapy for iron; AND
- Baseline endogenous erythropoietin levels of 500 MU/mL or less (NCCN Clinical Practice Guidelines in Oncology – Myelodysplastic Syndromes v2.2010)

5. Treatment of symptomatic anemia of chronic disease (rheumatoid arthritis, inflammatory bowel disease, systemic lupus erythematosis, and hepatitis C undergoing treatment) when all of the following criteria are met:
- Hgb less than or equal to 10g/dL for new starts OR less than 12g/dL for continuation of therapy AND
- Ferritin greater than or equal to 100ng/dL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron; AND
- Insured individual has a severe comorbidity (e.g. severe angina, pulmonary disease, heart failure, cerebrovascular disease causing transient ischemic attacks, lymphoma, myeloma, etc.); AND
- Insured individual's anemia is manifested by impairments such as, but not limited to, exercise intolerance, tachycardia or shortness of breath with minimal activity, or inability to perform activities of daily living

6. Reduction of allogeneic blood transfusion in anemic insured individuals undergoing surgery when all of the following criteria are met:
- Hgb less than 13 g/dL AND
- Ferritin greater than or equal to 100ng/dL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron; AND
- Anemia is related to chronic disease state (limited to rheumatoid arthritis, inflammatory bowel disease, systemic lupus erythematosis, and hepatitis C undergoing treatment); AND
- Insured individual is scheduled to undergo elective, non-cardiac, non-vascular surgery in which anticipated blood loss is greater than 2 units and the need for allogeneic blood transfusion is anticipated.

  Note: Authorization will be for a duration of 1 month. Request for use beyond 4 weeks will require medical record documentation indicating medical necessity.

  Note: Erythropoietin therapy (epoetin alfa) is not indicated for anemic patients who are able and willing to donate autologous blood.

AUTHORIZATION DURATION: Except for the indication of use in anemic surgical patients, approval for Epogen, Retacrit, Procrit or Aranesp therapy will be given for an initial duration of 12 months. Subsequent authorizations will be considered based on the stated criteria.

GENERAL GUIDEANCE:
- For continuation of therapy, a repeat hgb should be submitted after 3 12 months of therapy.
- In individuals whose Hgb is greater than or equal to 12gm/dL or rises by 1gm/dl in any two-week period, additional doses should be withheld. (In insured individuals with Hgb of greater than or equal to12 gm/dL Erythropoietin or Darbepoetin therapy will not be covered according to FDA recommendations, except when being used for reduction of allogeneic blood transfusion in anemic insured individuals undergoing surgery).
- For initiation or continuation of therapy, a ferritin level no greater than 3 months old and/ or transferrin saturation level no greater than 6 months old should be submitted.
- The member should receive supplemental iron if serum ferritin is less than 100ng/ml and transferrin saturation is less than 20 percent.

MBP 59.0 White Blood Cell Stimulating Factors- Updated policy

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

Neupogen, Neulasta, Fulphila, Zarxio, Leukine, Granix:

The use of white blood cell stimulating factor [Neupogen (filgrastim), Neulasta (pegfilgrastim), Fulphila (pegfilgrastim-jmdb), Granix (tbo-filgrastim), Zarxio (filgrastim-sndz), or Leukine (sargramostim)] is considered medically necessary in insured individuals with a diagnosis of cancer, and when any of the following FDA labeled indications or uses supported by clinical guidelines are present:

1. Primary Prophylaxis - the prevention of febrile neutropenia (FN) when the risk of FN due to the myelosuppressive chemotherapy regimen is 20% or greater. Those regimens include but are not limited to:

- TC (paclitaxel/cisplatin, or cyclophosphamide/docetaxel or docetaxel/cisplatin or paclitaxel/carboplatin)
- MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
- AC (doxorubicin, cyclophosphamide, docetaxel)
- AT (doxorubicin, paclitaxel)
- TIC (paclitaxel, ifosfamide, mesna, cisplatin)
- VAPEC-B (vincristine, doxorubicin, prednisolone, etopside, cyclophosphamide, bleomycin)
- A(N)CVB (doxorubicin or mitoxantrone, cyclophosphamide, vindesine, bleomycin)
- DHAP (dexamethasone, cisplatin, cytarabine)

NOTE: Regimens not specified in this document must be listed on a nationally recognized guideline stating risk of FN of greater than 20%.

OR

For the prevention of FN when the risk of developing FN is less than 20%, but any other risk factor listed below is present:

- Age 65 years or greater
- Poor performance status
- Previous history of FN
- Extensive prior radiation or chemotherapy treatment
- Poor nutritional status
- Recent surgery or Open wounds or active infection
- Advanced cancer
- Persistent neutropenia
- Bone marrow involvement by tumor
- Liver dysfunction (bilirubin >2.0)
- Renal dysfunction (CrCl <50)

Neupogen, Neulasta, Fulphila, Zarxio, or Leukine: May also be considered medically necessary for any of the following:

2. Secondary Prophylaxis – prevention of FN when a previous cycle of chemotherapy resulted in a neutropenic complication and for which primary prophylaxis was not received, and a dose reduction will compromise disease-free or overall survival or treatment outcome.

3. Treatment of Febrile Neutropenia - as an adjunct to antibiotics in high-risk individuals with FN who are at high risk for infection related complications or when **any** of the following prognostic factors are documented:

- Age 65 years or greater
- Anticipated prolonged and profound neutropenia
- Uncontrolled primary disease
- Pneumonia
- Invasive fungal infection
- Hypotension
- Multi-organ dysfunction
- Hospitalized at the time of development of the fever

4. Dose Dense Therapy – specifically in the treatment of node positive breast cancer, small cell lung cancer, and diffuse aggressive non-Hodgkin's lymphoma.

5. Stem Cell Transplantation- when one of the following is met:

- Bone Marrow Transplant (BMT)-
  - Documentation of a non-myeloid malignancy undergoing myeloablative chemotherapy followed by autologous or allogenic bone marrow transplant (G-CSF is given after BMT)

OR

- Peripheral Blood Progenitor Cell (Mobilization)Transplant (PBPC)
  - Used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. (G-CSF is given prior to and throughout leukaphersis)

Note: Neulasta and Fulphila are considered off-label for PBPC mobilization

6. Leukemia or Myelodysplastic Syndromes – insured individuals with any of the following conditions:

- Acute myeloid leukemia (AML) receiving induction or consolidation chemotherapy

- Acute lymphoblastic leukemia (ALL) after completion of the first few days of chemotherapy of the initial induction or the first post-remission course
- Myelodysplastic syndrome with less than 15% blasts in the bone marrow, or recurrent neutropenic infections are experienced.

7. Lymphoma – Age 65 years or greater treated with curative chemotherapy, e.g., CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)

8. Radiation therapy – with any of the following conditions

- If prolonged delays secondary to neutropenia are anticipated.
- As treatment for radiation injury secondary to doses of 3-10 Grays (Gy) or greater

Note: Fulphila is not indicated for radiation injury syndrome

Neupogen, Zarxio: May also be considered medically necessary for the following:

9. Severe Chronic Neutropenia – when the following criteria are met

- Diagnosis of Congenital, Cyclic, or Idiopathic Neutropenia AND
- Documentation of an Absolute Neutrophil Count (ANC) <500 cells/mm^3 on three separate occasions during a 6 month period (for Congential or Idiopathic Neutropenia) OR five consecutive days of ANC <500 cells/mm^3 per cycle (for Cyclic Neutropenia) AND
- Documentation that the member experienced a clinical significant infection, fever, or oropharyngeal ulcer during the past 12 months.

Leukine: May also be considered medically necessary for the following:

10. **Delayed Neutrophil Recovery or Graft Failure**

- Medical record documentation that the member has had an allogeneic or autologous bone marrow transplant and neutrophil recovery* has not occurred.

  *Note to reviewer: Neutrophil engraftment is defined as the first day of three consecutive days where the neutrophil count (ANC) is 500 cells/mm^3 or greater.

MBP 74.0 Cimzia (certolizumab pegol)- Updated policy

5. Plaque Psoriasis

- Prescription written by a dermatologist **AND**
- Medical record documentation of age greater than 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of a therapeutic failure of, contraindication to, or intolerance of a minimum 3-month trial of Humira* AND Cosentyx*

QUANTITY LIMIT (FOR PLAQUE PSORISIS ONLY): 2 kits per 28 days

Note: This product is billed per kit. Each kit contains two 200mg syringes.

AUTHORIZATION DURATION:
Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of plaque psoriasis at six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of plaque psoriasis while on Cimzia therapy.

MBP 106.0 Injectable Antipsychotic Medications- Updated policy

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

~~Prior authorization requirement applies only to new starts. Insured individuals who have been on Invega Trinza, Invega Sustenna, Aristada, Aristada Initio, Abilify Maintena, Zyprexa Relprevv, or Risperdal Consta IM Injection prior to coming on to the Plan will be grandfathered and can continue to receive therapy.~~

The following Injectable Antipsychotic Medications (on Invega Trinza, Invega Sustenna, Aristada, Aristada Initio, Abilify Maintena, Zyprexa Relprevv, or Risperdal Consta) will be considered medically necessary when the following criteria are met:

- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of a history of poor adherence to oral medications and documentation that education to improve adherence has been attempted **AND**
- Medical record documentation of use for an FDA approved indication.
    - Abilify Maintena – Schizophrenia or maintenance monotherapy treatment of Bipolar I Disorder
    - Aristada – Schizophrenia
    - Aristada Initio – Initiation of Aristada (in combination with oral aripiprazole) to treat schizophrenia
    - Invega Sustenna – Schizophrenia or Schizoaffective disorders as monotherapy and as an adjunct to mood stabilizers or antidepressants
    - Invega Trinza – Schizophrenia
    - Risperdal Consta – Schizophrenia or Bipolar I Disorder as monotherapy or as adjunctive therapy to lithium or valproate
    - Zyprexa Relprevv – Schizophrenia
- In addition: The following criteria should apply to Invega Trinza:
    - Medical record documentation that the patient has been adequately treated with Invega Sustenna for at least 4 months.

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

LIMITATIONS:

The following quantity limits should apply (please enter claims payment note, when entering authorization)

- Abilify Maintena – One syringe or vial per 28 days
- Aristada – One syringe per 28 days (441mg/1.6ml, 662mg/2.4ml, 882mg/3.2ml strength), one syringe per 56 days (1064mg/3.9ml strength)
- Aristada Initio – Enter claims payment note as follows:
    - Aristada Initio – Rx Count of 1, quantity limit of 2.4mL (one syringe) per 28 days

- Aristada – Open-ended authorization with quantity limit: One syringe per 28 days (441mg/1.6ml, 662mg/2.4ml, 882mg/3.2ml strength), one syringe per 56 days (1064mg/3.9ml strength)

- Invega Sustenna –two syringes per 1 week, then one syringe per 28 days thereafter

  Enter claims payment note as follows to account for loading dose in the first week:

  - Rx Count of 1 approved by GPID for 234 mg, quantity limit 1
  - Rx Count of 1 approved by GPID for 156 mg, quantity limit 1
  - Open-ended authorization for quantity limit 1 syringe per month, request to be approved by GPID for the prescribed strength.
- Invega Trinza – One syringe per 84 days (3 months)
- Risperdal Consta – Two vials per 28 days
- Zyprexa Relprevv – Two vials per 28 days

Note: PA is not required for inpatient or ER use for any of these medications.

Note: Only members with documented adherence issues will be eligible for medications delivered via injection

Note: The FDA approved dosing of induction into treatment with Aristada includes oral aripiprazole, Aristada Initio and Aristada (outlined below) and it is appropriate for the member to receive all the mentioned products over the course of one month for treatment initiation.

- One 30mg dose of oral aripiprazole (given on Day 1)
- One 675mg dose of Aristada Initio (given on Day 1)
- One (first) dose of Aristada (441mg, 662mg, 882mg, or 1064mg) (given on Day 1 or up to 10 days after the dose of Aristada Initio)

AUTHORIZATION DURATION: ~~Approvals will be made for a lifetime authorization of the specific approved injectable.~~

For Aristada Initio: Approval will be for a one-time fill/visit (authorization duration of 1 month) of Aristada Initio AND a lifetime authorization of Aristada will also be entered.

All other approvals will be made for a lifetime authorization of the specific approved injectable.

MBP 130.0 Mircera (methoxy polyethylene glycol-epoetin beta)- Updated policy

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

Mircera (methoxy polyethylene glycol-epoetin beta) will be considered medically necessary when all of the following criteria are met:

For ~~new starts~~ initial authorization in adult patients:

- Medical record documentation of age 18 years or greater AND
- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease (CKD) in ~~adult~~ patients on dialysis and patients not on dialysis AND
- Hemoglobin (Hgb) less than 10 g/dL for new starts AND
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%

For initial authorization in pediatric patients:

- Medical record documentation of age 5 years or greater AND

- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease in patients on dialysis AND
- Medical record documentation that patient's hemoglobin has stabilized on and is converting to Mircera from another erythropoiesis-stimulating agent AND
- Hemoglobin (Hgb) less than 11 g/dL for new starts AND
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%

For continuation of therapy, a repeat Hgb should be submitted after 12 ~~3~~ months of therapy.

For continuation of therapy in adult patients:

- Medical record documentation of age 18 years or greater AND
- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease (CKD) in ~~adult~~ patients on dialysis and patients not on dialysis AND
- Hemoglobin (Hgb) less than ~~12~~ 11 g/dL for continuation of therapy AND
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%

For continuation of therapy in pediatric patients:

- Medical record documentation of age 5 years or greater AND
- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease in patients on dialysis AND
- Hemoglobin (Hgb) less than 11 g/dL for new starts AND
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%

In individuals whose Hgb is greater than or equal to 12gm/dL or rises by 1gm/dl in any two-week period, additional doses should be withheld.

AUTHORIZATION DURATION: Each authorization period (initial and re-authorization) will be defined as a period of ~~3~~ 12 months. Re-authorization will be considered based on continuation of therapy criteria listed above.

MBP 133.0 Signifor LAR (pasireotide LAR) - Updated policy

Signifor LAR (pasireotide LAR) will be considered medically necessary when all of the following criteria are met:

Acromegaly

- Medical record documentation of a diagnosis of acromegaly **AND**
- Must be prescribed by an endocrinologist **AND**
- Medical record documentation of an inadequate response to or inability to be treated with surgery and/or radiotherapy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Somatuline depot OR Sandostatin LAR **AND**
- **If the patient also has a diagnosis of diabetes**: there must be medical record documentation of diabetes control demonstrated by documentation that the member has met his/her personal HbA1c goal.

Cushing's Disease

- Medical record documentation of a diagnosis of Cushing's disease **AND**
- Prescription written by an endocrinologist **AND**
- Medical record documentation that pituitary surgery is not an option or has not been curative **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ketoconazole AND Metopirone*

AUTHORIZATION DURATION

For Acromegaly: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement in GH and IGF-1 levels on six (6) months of Signifor LAR therapy is required. After the initial six (6) month approval, subsequent approvals will be for a duration of six (6) months, requiring medical record documentation of continued or sustained improvement in signs and symptoms of acromegaly while on Signifor LAR therapy.

For Cushing's Disease: If approved, approval will be given for a period of six (6) months. Re-authorization will require medical record documentation that urinary free cortisol levels are within normal limits.

LIMITATIONS: a quantity limit 1 dose every 28 days should be applied

MBP 184.0 Azedra (iobenguane I 131)- New policy

DESCRIPTION:
Azedra (iobenguane I 131) is an I 131 labeled iobenguane. Iobenguane is similar in structure to the neurotransmitter norepinephrine (NE) and is subject to the same uptake and accumulation pathways as NE. Iobenguane is taken up by the NE transporter in adrenergic nerve terminals and accumulates in adrenergically innervated tissues, such as the heart, lungs, adrenal medulla, salivary glands, liver, and spleen as well as tumors of neural crest origin. Azedra is taken up and accumulates within pheochromocytoma and paraganglioma cells, and radiation resulting from radioactive decay of I 131 causes cell death and tumor necrosis.

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

Azedra (iobenguane I 131) will be considered medically necessary when ALL of the following criteria are met:

Pheochromocytoma/Paraganglioma

- Prescription is written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 12 years of age or older **AND**
- Medical record documentation of a diagnosis of unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma **AND**
- Medical record documentation of a positive iobenguane scan (ex. MIBG (metaiodobenzylguanidine) scan, iobenguane I 131)

AUTHORIZATION DURATION: Azedra will be approved for a one time authorization of three (3) total doses (one dosimetric dose and two therapeutic doses).

Note: After the member receives the initial dosimetric dose, a dosimetry and biodistribution assessment should occur to determine if a dose adjustment is needed prior to giving the therapeutic doses as follows:

- Acquire anterior/posterior whole body gamma camera images within 1 hour of the AZEDRA dosimetric dose and prior to patient voiding (Day 0; Scan 1).
- Acquire additional images on Day 1 or 2 following patient voiding (Scan 2).

- Acquire additional images between Days 2-5 following patient voiding (Scan 3).

For each individual patient, calculate the radiation dose estimates to normal organs and tissues per unit activity [D (organ)] of administered dose using data extracted from these 3 images. Calculate in accordance with the Medical Internal Radiation Dose (MIRD) schema or related methodology. Whenever possible, use patient-specific organ masses (e.g., estimated from imaging).

Based on dosimetry assessment determine if a dose adjustment is needed for therapeutic dose. Administer a total of 2 therapeutic doses intravenously a minimum of 90 days apart.

MBP 185.0 Poteligeo (mogamulizumab-kpkc)- New policy

DESCRIPTION:
Poteligeo (mogamulizumab-kpkc) is a first-in-class defucosylated, humanized IgG1 kappa monoclonal antibody which selectively binds to C-C chemokine receptor 4 (CCR4). CCR4 mediates cell trafficking of lymphocytes to skin and various organs and is consistently expressed on the surface of T-cell malignancies (eg, mycosis fungoides, Sézary syndrome, adult T-cell leukemia/lymphoma, peripheral T-cell lymphoma) (Kim 2018). Mogamulizumab-kpkc binding to CCR4 targets a cell for antibody-dependent cellular cytotoxicity (ADCC), resulting in target cell depletion.

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

Poteligeo (mogamulizumab-kpkc) will be considered medically necessary when ALL of the following criteria are met:

- Prescription is written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of relapsed or refractory mycosis fungoides or Sézary syndrome **AND**
- Medical record documentation of resistance or intolerance to one prior therapy

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 186.0 Libtayo (cemiplimab-rwlc)- New policy

DESCRIPTION:
Libtayo (cemiplimab-rwlc) is a recombinant human IgG4 monoclonal antibody that inhibits programmed death-1 (PD-1) activity by binding to PD-1 and blocking the interactions with the ligands PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of immune response, including anti-tumor response. PD-1 ligand upregulation may occur in some tumors and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors. Blocking PD-1 activity has resulted in decreased tumor growth.

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

Libtayo (cemiplimab-rwlc) will be considered medically necessary when ALL of the following criteria are met:

- Prescription written by a hematologist or oncologist **AND**

- Documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC **AND**
- Medical record documentation that the patient is not a candidate for curative surgery or curative radiation

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.