"What's New" Medical Pharmaceutical Policy Updates July 2017

MBP 61.0 Flolan or Veletri (epoprostenol)- Policy Revised

Flolan or Veletri (epoprostenol) will be considered medically necessary when all of the following criteria are met:

- Must be prescribed by a pulmonologist or cardiologist; **AND**
  - Physician provided documentation of a diagnosis of class 4 pulmonary arterial hypertension; **OR**
  - Physician provided documentation of a diagnosis of class 2 or 3 pulmonary arterial hypertension with therapeutic failure on, intolerance to or contraindication to Revatio ~~and Ventavis~~

MBP 67.0 Supprelin LA (histrelin acetate implant) - Policy Revised

Supprelin LA (histrelin acetate implant) will be considered medically necessary for Central Precocious Puberty when all of the following criteria are met:

- Medical record documentation of a diagnosis of central precocious puberty; **AND**
- Therapeutic failure on, intolerance to or contraindication to Lupron Depot – Ped

Supprelin LA (histrelin acetate implant) will be considered medically necessary for Gender Confirmation Treatment when all of the following criteria are met:

- Psychological evaluation for gender dysphoria by a behavioral health professional with a minimum of a master's degree or equivalent who is capable of evaluating the member in accordance with WPATH Guidelines:
  1. A master's degree or its equivalent in a clinical behavioral science field. This degree or a more advanced one should be granted by an institution accredited by the appropriate national or regional accrediting board. The mental health professional should have documented credentials from a relevant licensing board or equivalent for that country.
  2. Competence in using the *Diagnostic Statistical Manual of Mental Disorders* and/or the *International Classification of Diseases* for diagnostic purposes.
  3. Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria.
  4. Documented supervised training and competence in psychotherapy or counseling.
  5. Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria.
  6. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.
- The use of medical intervention for gender dysphoria is age dependent. For use of a gonadotropin-releasing hormone (GnRH) analogs, the member must be peri-pubertal and a minimum of Tanner Stage 2, as documented by the provider. GnRH analogs are not medically necessary once the individual is post-pubertal.

INFORMATIONAL ONLY:

- **Pre-pubertal** - no medical treatment

- **Peri-pubertal** – gonadotropin-releasing hormone (GnRH) analogs to achieve suppression of pubertal hormones may be considered once the member reaches Tanner Stage* 2

  *The Tanner Scale is measurement of physical development in children, adolescents and adults. http://www.childgrowthfoundation.org/CMS/FILES/Puberty_and_the_Tanner_Stages.pdf

  Between 14 – 16 yrs of age –pubertal development of the desired opposite sex can be using a gradually increasing dose schedule of cross-gender hormone.

  Adolescents should be treated with GnRH analogues, progestins (e.g., medroxyprogesterone) or other medications that block and/or neutralize testosterone, estrogens and progesterone secretion.

- **Post-pubertal** – continuous hormone replacement therapy

  Female to male: IM testosterone or topical testosterone

  Male to female: Anti-androgen therapy (e.g., Spironolactone, GnRH agonists, plus estrogen)

  Age 40 yrs or older – estrogen cream, patch or injectable

MBP 77.0 Ilaris (canakinumab)- Policy Revised

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

1. **Cryopyrin-Associated Periodic Syndrome**

Ilaris® (canakinumab) may be considered to be medically necessary in individuals 4 years of age and older with Cryopyrin-Associated Periodic Syndrome when the following criteria are met:

- Physician provided documentation of diagnosis of Cryopyrin-Associated Periodic Syndrome (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) supported by documentation of genetic testing to identify the CIAS1/NLRP-3 gene mutation.
- Must be prescribed by an immunologist, rheumatologist, or allergist. **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on Kineret
- ~~Patient must be evaluated by expert in a contracted Center of Excellence as chosen by Geisinger Health Plan Medical Director in collaboration with the requesting physician.~~

AUTHORIZATION DURATION: The initial approval will be for a time period of ~~12 weeks~~ 6 months, requiring medical record documentation of improvement in signs and symptoms of CAPS. Ilaris will then require approval on a yearly basis.

For a neonatal-onset multisystem inflammatory disease (NOMID) the Geisinger Health Plan would require failure on Anakinra.

2. **Systemic Juvenile Idiopathic Arthritis**

Ilaris® (canakinumab) may be considered to be medically necessary in individuals 2 years of age and older with Systemic Juvenile Idiopathic Arthritis when the following criteria are met

- Must be prescribed by a rheumatologist **AND**
- **Must not be used in conjunction with tumor necrosis factor inhibitors AND**
- Medical record documentation of active Systemic Juvenile Idiopathic Arthritis (SJIA) diagnosed prior to age 16 years~~, characterized by~~ **AND**
  - ~~≥ 2 joints with active arthritis **AND**~~
  - ~~Spiking, intermittent fever (> 38°C) without infectious cause **AND**~~
  - ~~CRP > 30 mg/dL; **AND**~~
- Medical record documentation of contraindication to, intolerance to or therapeutic failure on Actemra

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 a lack of progression in the signs and symptoms of the targeted disease state at six (6) months of Ilaris therapy is required.

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

~~Initial approval will be for 6 months with annual review thereafter. For continuation of coverage, medical record documentation of at least 30% sustained improvement in ACR score (ACR30) from baseline.~~

3. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)

Ilaris® (canakinumab) may be considered to be medically necessary in pediatric and adult patients with Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) when the following criteria are met:

- Physician provided documentation of diagnosis of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) supported by documentation of genetic testing to identify the *TNFRSF1A* gene mutation.
- Must be prescribed by an immunologist, rheumatologist, or allergist.

4. Hyperimmunoglobulin D Syndrome (HIDS)/ Mevalonate Kinase Deficiency (MKD)

Ilaris® (canakinumab) may be considered to be medically necessary in pediatric and adult patients with Hyperimmunoglobulin D Syndrome (HIDS)/ Mevalonate Kinase Deficiency (MKD) when the following criteria are met:

- Physician provided documentation of diagnosis of Hyperimmunoglobulin D Syndrome (HIDS)/ Mevalonate Kinase Deficiency (MKD) supported by documentation of elevated immunoglobulin D level or genetic testing to identify the *MVK* gene mutation.
- Must be prescribed by an immunologist, rheumatologist, or allergist.

5. Familial Mediterranean Fever (FMF)

Ilaris® (canakinumab) may be considered to be medically necessary in pediatric and adult patients with Familial Mediterranean Fever (FMF) when the following criteria are met:

- Physician provided documentation of diagnosis of Familial Mediterranean Fever (FMF) as confirmed by genetic testing to identify the *MEFV* gene mutation.
- Must be prescribed by an immunologist, rheumatologist, or allergist.
- Medical record documentation of contraindication to, intolerance to or therapeutic failure on colchicine.

AUTHORIZATION DURATION (for all indications): The initial approval will be for a time period of 6 months, requiring medical record documentation of improvement in signs and symptoms of disease. Ilaris will then require approval on a yearly basis.

MBP 84.0 Berinert (C1 esterase inhibitor, human)- Policy Revised

Berinert (C1 esterase inhibitor, human) will be considered medically necessary for the treatment of acute abdominal, facial, or laryngeal attacks of hereditary angioedema in adults and ~~adolescents~~ pediatrics when the following criteria are met:

- ~~Member is 13 years of age or older; and~~
- Prescription is written by an allergist, immunologist, hematologist or dermatologist; and
- Medication is being used for the treatment of an acute attack of hereditary angioedema; and
- Not used in combination with other approved treatments for acute HAE attacks; and
- Physician provided documentation of a diagnosis of hereditary angioedema evidenced by:
    - Recurrent, self-limiting non-inflammatory subcutaneous angioedema without urticarial, lasting more than 12 hours; or
    - Laryngeal edema; or
    - Recurrent, self-remitting abdominal pain lasting more than 6 hours, without clear organic etiology

And

- the presence of specific abnormalities in complement proteins, in the setting of a suggestive clinical history of episodic angioedema without urticaria; supported by
    - Medical record documentation of 2 or more sets of complement studies, separated by one month or more, showing consistent results of
        - Low C4 levels and
        - Less than 50% of the lower limit of normal C1-INH antigenic protein levels OR
        - Less than 50% of the lower limit of normal C1-INH function levels

AND

- Physician provided documentation of concurrent or failure on, intolerance to, or contraindication to prophylactic therapy (danazol).*

*Only applies to patients with more than one severe episode of angioedema per month, or those with a history of laryngeal attacks

MBP 116.0 Aveed (testosterone undecanoate)- Policy Revised

Aveed (testosterone undecanoate) will be considered medically necessary when all of the following criteria are met:

- Medical record documentation of use for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:
    - Primary hypogonadism (congenital or acquired) OR
    - Hypogonadotropic hypogonadism (congenital or acquired) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to testosterone cypionate **AND** testosterone enanthate

For Gender Dysphoria:

- Psychological evaluation for gender dysphoria by a behavioral health professional with a minimum of a master's degree or equivalent who is capable of evaluating the member in accordance with WPATH Guidelines:
    7. A master's degree or its equivalent in a clinical behavioral science field. This degree or a more advanced one should be granted by an institution accredited by the appropriate national or regional accrediting board. The mental health professional should have documented credentials from a relevant licensing board or equivalent for that country.
    8. Competence in using the *Diagnostic Statistical Manual of Mental Disorders* and/or the *International Classification of Diseases* for diagnostic purposes.
    9. Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria.
    10. Documented supervised training and competence in psychotherapy or counseling.
    11. Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria.
    12. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.
- The member must be post-pubertal as documented by the treating provider
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to testosterone cypionate **AND** testosterone enanthate

MBP 119.0 Keytruda (pembrolizumab)- New Indication

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

1. **Unresectable or Metastatic Melanoma**
    - 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 unresectable or metastatic melanoma **AND**
    - Medical record documentation that Keytruda is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma.

2. **Metastatic Non-Small Cell Lung Cancer**
    - 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 metastatic NSCLC meeting <u>one</u> of the following situations:
        - Medical record documentation that tumors have high PD-L1 expression (Tumor Proportion Score (TPS)≥50% as determined by an FDA-approved test **AND**
        - Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations

      OR
        - Medical record documentation that tumors express PD-L1 (TPS)≥1% as determined by an FDA-approved test **AND**
        - Medical record documentation of disease progression on or after platinum-containing chemotherapy **AND**
        - For patients with EGFR or ALK genomic tumor aberrations: medical record documentation of disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda.

3. **Head and Neck Squamous Cell Carcinoma**

- 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 Head and Neck Squamous Cell Carcinoma that is recurrent or metastatic and had disease progression on or after platinum-containing chemotherapy

4. **Classical Hodgkin Lymphoma**
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of Classical Hodgkin Lymphoma **AND**
- One of the following:
    a. Medical record documentation of a diagnosis of refractory Classical Hodgkin Lymphoma **OR**
    b. Medical record documentation of relapse following three (3) or more prior lines of therapy

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 ~~6~~ **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 126.0 Opdivo (nivolumab)- New Indication

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

1. ~~*Metastatic*~~ *Melanoma*
- 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 unresectable or metastatic melanoma **AND**
- Medical record documentation that Opdivo is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma (with the exception of ipilimumab).

2. ~~*Metastatic Squamous*~~ *Non-Small Cell Lung Cancer (NSCLC)*
- 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 metastatic non-small cell lung cancer (NSCLC) with disease progression while on or after platinum-based chemotherapy **AND**
- Medical record documentation that Opdivo is not being used in combination with any other agents for the treatment of metastatic non-small cell lung cancer (NSCLC)

3. ~~*Metastatic*~~ *Renal Cell Carcinoma*
- Medical record documentation of use as a single agent for relapse or for surgically unresectable advanced or metastatic renal cell carcinoma ~~with predominant clear-cell histology~~ **AND**
- Medical record documentation of a therapeutic failure on or intolerance to prior anti-angiogenic therapy, including, but not limited to, Sutent (sunitinib), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib), Avastin (bevacizumab), Afinitor (everolimus), or Torisel (temsirolimus).

4. *Classical Hodgkin Lymphoma (CHL)*
- 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 classical Hodgkin lymphoma (CHL) that has relapsed or progressed after autologous hematopoietic stem cell transplantation and post-transplantation brentuximab vedotin (Adcetris).

5. *Squamous Cell Carcinoma of the Head and Neck (SCCHN)*
- 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 recurrent or metastatic squamous cell carcinoma of the head and neck **AND**
  Medical record documentation of disease progression while on or after receiving a platinum-based therapy

6. Urothelial Carcinoma
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient > 18 years of age **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma AND 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

  AND
- Medical record documentation that Opdivo is NOT being used in combination with any other agent

MBP 144.0 Tecentriq (atezolizumab) Policy Revision

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

1. **Locally Advanced or Metastatic Urothelial Carcinoma:**
- Prescription written by an oncologist **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on platinum-containing chemotherapy
- ~~Medical record documentation that the patient has had either:~~
  - ~~Disease progression during or following platinum-containing chemotherapy **OR**~~
  - ~~Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy~~

2. **Non-Small Cell Lung Cancer:**
- Prescription written by an oncologist **AND**
- Medical record documentation of a diagnosis of non-small cell lung cancer **AND**
- Medical record documentation that the patient has had either:
  - Disease progression during or following platinum-containing chemotherapy **OR**
  - Disease progression on at least one FDA-approved therapy targeting EGFR or ALK if the patient has EGFR or ALK genomic tumor aberrations (e.g. mutation, deletion, insertion, etc.).

Notes to reviewer:

- In clinical trials, contraindications to cisplatin-containing chemotherapy included: impaired renal function (CrCl greater than 30mL/min but less than 60mL/min), grade 2 or higher hearing loss or peripheral neuropathy, or ECOG performance status of 2.
- A therapeutic failure of platinum-containing chemotherapy is defined as disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant treatment.

MBP 152.0 Bavencio (avelumab)- New Policy

Bavencio (avelumab) is a fully human monoclonal antibody that binds to programmed death ligand 1 (PD-L1) to selectively prevent the interaction between the programmed cell death-1 (PD-1) and B7.1 receptors, while still allowing interaction between PD-L2 and PD-1.2 PD-L1 is an immune check point protein expressed on tumor cells and tumor infiltrating cells and down regulates antitumor T-cell function by binding to PD-1 and B7.1; blocking PD-1 and B7.1 interactions restores antitumor T-cell function.

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

Bavencio (avelumab) will be considered medically necessary when ALL of the following criteria are met:
- Prescribed by a hematologist/oncologist AND
- Medical record documentation of a diagnosis of metastatic Merkel Cell Carcinoma (MCC) AND
- Medical record documentation of age ≥12 years

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 continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

The following policies were reviewed with no changes:

- MBP 13.0 Viscosupplementation
- MBP 24.0 Aloxi (palonosetron)
- MBP 85.0 Cinryze (C1 esterase inhibitor, human)
- MBP 92.0 Off-label Drug Use for Oncologic Indications
- MBP 106.0 Injectable Antipsychotic Medications
- MBP 113.0 Gazyva (obinutuzumab)
- MBP 115.0 Cyramza (ramucirumab)
- MBP 124.0 Ruconest (C1 esterase inhibitor, recombinant)
- MBP 131.0 Cosentyx (secukinumab) vials
- MBP 133.0 Signifor LAR (pasireotide LAR)