P&T Committee Meeting Minutes
Commercial/Marketplace/GHP Kids E-vote
April 8, 2020

DRUG REVIEWS

PRETOMANID (pretomanid)

Review: Pretomanid is indicated, as part of a combination regimen with Sirturo (bedaquiline) and linezolid for the treatment of adults with pulmonary extensively drug resistant tuberculosis (XDR-TB) or treatment-intolerant or nonresponsive multidrug-resistant tuberculosis (TI/NR MDR-TB). Pretomanid Tablets are not indicated in patients with the following conditions: Drug-sensitive (DS) tuberculosis, Latent infection due to *Mycobacterium tuberculosis*, Extra-pulmonary infection due to *Mycobacterium tuberculosis*, or MDR-TB that is not treatment-intolerant or nonresponsive to standard therapy. The safety and effectiveness of Pretomanid Tablets have not been established for its use in combination with drugs other than Sirturo (bedaquiline) and linezolid.

Pretomanid is the first agent approved in the novel nitroimidazooxazine class, which inhibits mycolic acid biosynthesis & cell wall production. . The indication is limited to patient with one of the following forms of pulmonary tuberculosis TI/NR MDR-TB or XDR-TB. TI/NR MDR-TB are organisms that are resistant to rifampin and isoniazid. In addition, patients with MDR TB may fail or be intolerant to standard of care therapy. The standard of care for MDR TB is a customized regimen of usually 4 anti-tubercular agents to which the organism remains sensitive for a duration of 9 to 18 months or more. Agents may include moxi/levo-floxacin, bedaquiline, linezolid, clofazimine, cycloserine, ethambutol, pyrazinamide, mero/imi-penem, and aminoglycosides (amikacin, streptomycin). XDR-TB organisms meet the MDR criteria but are also resistant to a fluoroquinolone and either an aminoglycoside or capreomycin. Treatment options for XDR are poor, with a five-drug regimen of the previously mentioned agents being recommended, continuing for 6 months beyond sputum culture conversion. The recommended dosage of pretomanid is 200mg (1 tablet) orally once daily for 26 weeks. Dosing of the combination regimen may be extended beyond 26 weeks if necessary.

Pretomanid was approved based on a single, prospective, open-label study in patients with XDR, treatment-intolerant MDR, or non-responsive MDR pulmonary TB. The patients received a combination regimen of pretomanid tablets, bedaquiline, and linezolid for six months (extended to 9 months in two patients) with 24 months of follow-up. Treatment failure was defined as the incidence of bacteriologic failure (reinfection – culture conversion to positive status with different M. tuberculosis strain), bacteriological relapse (culture conversion to positive status with same M. tuberculosis strain), or clinical failure through follow-up until 6 months after the end of treatment. Of the 107 patients assessed, outcomes were classified as success for 95 (89%) patients and failure for 12 (11%) patients. The success rate significantly exceeded the historical success rates for XDR-TB. The outcomes were similar in both HIV negative and HIV positive patients.

There are no black box warnings associated with pretomanid. Several warnings and precautions are included in the pretomanid Prescribing Information. Because the drug was always given in combination with bedaquiline and linezolid in the NIX-TB trial, it is not possible to know what proportion of risk for these adverse events is due to pretomanid, but it appears that pretomanid confers little to no additive risk for the following adverse effects: hepatic adverse effects, myelosuppression, peripheral and optic neuropathy, QT prolongation, and lactic acidosis. One warning/precaution that is unique to pretomanid surround its reproductive effects. Pretomanid caused testicular atrophy and impaired fertility in male rats. The most common adverse reaction ($\geq$ 10%) are peripheral neuropathy, acne, anemia, nausea, vomiting, headache, increased transaminases, dyspepsia, decreased appetite, rash, pruritus, abdominal pain, pleuritic pain, increased gamma-glutamyltransferase, lower respiratory tract infection, hyperamylasemia, hemoptysis, back pain, cough, visual impairment, hypoglycemia, abnormal loss of weight, and diarrhea. The safety and effectiveness in pediatric patients have not been established.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Pretomanid will be a pharmacy benefit. It is recommended that Pretomanid be added to the formulary at the Brand Preferred tier. Pretomanid will require a prior authorization with the following criteria:

- Prescription written by a physician specializing in infectious disease **AND**
- Medical record documentation of age greater or equal to 18 years **AND**
- Medical record documentation of pulmonary infection due to *Mycobacterium tuberculosis* **AND**
- Medical record documentation of one of the following:
    - Extensively drug resistant tuberculosis (XDR-TB) **OR**
    - Treatment-intolerant or nonresponsive multidrug-resistant tuberculosis (TI/NR MDR-TB) **AND**
- Medical record documentation that Pretomanid will be used in combination with Sirturo (bedaquiline) and linezolid

AUTHORIZATION DURATION: 26 weeks

QUANTITY LIMIT: One (1) tablet per day

NOTE:

- TI/NR MDR-TB (Treatment-Intolerant or Nonresponsive Multi-Drug Resistant TB). MDR-TB organisms are resistant to rifampin and isoniazid and possibly additional agents.
- XDR-TB (Extensively Drug Resistant TB). These organisms are resistant to isoniazid, rifampin, and fluoroquinolones as well as either aminoglycosides and/or capreomycin.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

REBLOZYL (luspatercept-aamt)

Review: Reblozyl is a recombinant fusion protein which binds endogenous transforming growth factor (TGF)-beta super family ligands which leads to a decrease in Smad 2/3 signaling. Through inhibition of the Smad 2/3 pathway which is associated with impaired erythropoiesis, Reblozyl enhances the maturation of existing erythroid precursors. It is not a replacement for red blood cell transfusions but is intended to reduce the transfusion burden in patients with β-thalassemia major.

The efficacy of Reblozyl was investigated in the BELIEVE trial, a randomized, double blind, placebo-controlled trial in 336 adult patients with beta thalassemia requiring regular red blood cell transfusions (6-20 RBC units per 24 weeks) with no transfusion-free period greater than 35 days during that period. Patients were randomized 2:1 to receive Reblozyl or placebo plus best supportive care administered every three weeks as long as a reduction in transfusion requirement was observed.

Patients treated with Reblozyl had a statistically significant improvement in the primary efficacy endpoint, erythroid response defined as defined as ≥ 33% reduction from baseline in red blood cell transfusion burden with a reduction of at least two units from Week 13 to Week 24. Secondary endpoints measuring erythroid response at Week 37 to Week 48, and erythroid response with a ≥ 50% reduction from baseline in red blood cell transfusion burden at Week 13 to Week 24 and Week 37 to 48 also occurred in a statistically significant greater proportion of patients treated with Reblozyl compared to placebo.

During the BELIEVE trial, serious adverse reactions occurred in 3.6% of patients exposed to Reblozyl, including cerebrovascular accident and deep vein thrombosis. Permanent discontinuation due to adverse events occurred in 5.4% of patients, dosage reductions occurred in 2.7% of patients, and dose interruptions occurred in 15.2% of patients. The most common adverse events which occurred in at least 10% of patients were headache, bone pain, arthralgia, fatigue, cough, abdominal pain, diarrhea, and dizziness.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Reblozyl is a medical benefit that should not be added to the Commercial/Marketplace/GHP Kids pharmacy formularies. The following prior authorization criteria should apply:

- 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**.

NOTES:

*In clinical trials, 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: 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.

AUTHORIZATION DURATION: Approval will be given for an **initial duration of six (6) months**. After the initial six (6) month approval, subsequent approvals will be for a **duration of six (6) months**, requiring medical record documentation of:

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

Ongoing subsequent approvals will be for a **duration of six (6) months**, requiring medical record documentation of:

- A sustained reduction of red blood cell (RBC) transfusion burden AND
- Reblozyl is being dosed consistent with 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.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

VALTOCO (diazepam nasal spray)

Review: Valtoco is an intranasal formulation of diazepam that can be administered by the caregiver in the outpatient setting indicated for acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 6 years of age and older. Diazepam is thought to bind the benzodiazepine site of the GABA receptor, potentiating GABAergic neurotransmission. Valtoco is the third medication that is able to be used in emergency outpatient treatment of seizure clusters, following Nayzilam (midazolam nasal spray) and Diastat (diazepam rectal gel).

There were no clinical studies evaluating the efficacy of Valtoco. Approval of Valtoco was supported by the efficacy findings of clinical studies of diazepam rectal gel and pharmacokinetic studies comparing bioavailability of Valtoco to diazepam rectal gel and other formulations of diazepam. It was found that Valtoco is rapidly absorbed with comparable absorption between seizure and non-seizure periods and had a pharmacokinetic profile comparable to Diastat with less variability in the bioavailability.

The adverse event profile of Valtoco, apart from adverse events associated with the intranasal route of administration, is generally consistent with the known side effect profile of diazepam rectal gel and other antiepileptic medications. The most common reported adverse events during clinical trials were nasal congestion, nasal discomfort, epistaxis, and altered taste.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed

Outcome: Valtoco will be added to the Brand Preferred tier of the Commercial, Marketplace, and GHP Kids pharmacy formularies. No prior authorization will be required for patients 6 years of age and older, operationalized by an age-safety edit. For patients under 6 years of age, the following prior authorization criteria will apply. For all patients, the following quantity limits will apply:

- Medical record documentation age greater than or equal to 6 years
  OR
- 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 **AND**
- For patients at least 2 years of age: medical record documentation of why diazepam rectal gel cannot be used

QUANTITY LIMIT: 10 nasal spray units per 30 days

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

CAPLYTA (lumateperone)

Review: Caplyta (lumateperone) is a novel agent that was approved for treatment of schizophrenia from two clinical trials, and it is currently being investigated for the use in bipolar depression. Caplyta is categorized as an atypical antipsychotic, which currently consists of Abilify (aripiprazole), Clozaril (clozapine), Risperdal (risperidone), Seroquel (quetiapine), Zyprexa (olanzapine), Geodon (ziprasidone), Invega (paliperidone), Latuda (lurasidone), Rexulti (brexpiprazole), Saphris (asenapine), Fanapt (iloperidone), and Vraylar (cariprazine).

Caplyta has a unique mechanism of action with substantially greater affinity for 5-HT_2A receptors than D_2 receptors, and acts as a presynaptic partial agonist and postsynaptic antagonist at D_2 receptors with functional mesolimbic and mesocortical selectivity, inhibits reuptake of serotonin, and indirectly enhances glutamate neurotransmission.

Approval for use in schizophrenia was based from two 4-week, placebo-controlled, double-blinded trials that both had a primary outcome of change in baseline to day 28 in Positive and Negative Syndrome Scale (PANSS). Both trials assessed 2 strengths of Caplyta, but only 42 mg showed significance. One study included an active-control arm with risperidone 4 mg. Anecdotally, the efficacy of Caplyta 42 mg was just about that of risperidone and provided more benefit for negative and depressive symptoms, but the study was not designed to be a head to head trial. Caplyta side effects were comparable to placebo, except for causing more sedation/somnolence. The selective mechanism of action allows Caplyta to avoid the class wide adverse effects of antipsychotics such as tardive dyskinesia, extrapyramidal side effects, metabolic changes (diabetes, weight gain, dyslipidemia) and QTc interval prolongation. However, Caplyta has an extensive warnings/precautions list due to the medication class and a black boxed warning of increased mortality in elderly patients with dementia related psychosis.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Caplyta is a pharmacy benefit. Caplyta will be added to the Commercial, Marketplace, and GHP Kids formularies at the Brand Non-Preferred tier. Caplyta will require a prior authorization with the following criteria:

- Medical record documentation of schizophrenia **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two formulary atypical antipsychotics (olanzapine, risperidone, quetiapine, ziprasidone, aripiprazole)

QUANTITY LIMIT: 1 capsule per day

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

FAST FACTS

CRYSVITA (burosumab-twza)

Updated Indication: Crysvita is a fibroblast growth factor 23 (FGF23) blocking antibody indicated for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older.

Previously it was indicated in patients 1 year and older.

Current formulary status: Medical Benefit requiring a prior authorization

Recommendation: There are no changes needed to the current formulary placement, quantity limit, and authorization duration. The following changes are recommended to the prior authorization criteria to Medical Benefit Policy 182.0 to incorporate the new age indication.

- Medical record documentation that the patient is at least ~~1 year~~ 6 months of age or older **AND**

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

ORENITRAM (trepostinil)

Updated Indication: Orenitram is now indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to delay disease progression and to improve exercise capacity. The studies that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (66%) or PAH associated with connective tissue disease (26%).

Previously it was only indicated to improve exercise capacity in patients with pulmonary arterial hypertension (PAH) (WHO Group 1). The study that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (75%) or PAH associated with connective tissue disease (19%).

Current formulary status: Non-formulary

Recommendation: There are no changes to the dosage of Orenitram with the new indication, so no changes are recommended to the current quantity limits. There are no changes recommended to the formulary placement of Orenitram. It is recommended that the following changes be made to Commercial Policy 335.0 to incorporate the new indication for Orenitram:

- Medical record documentation that Orenitram is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of World Health Organization (WHO) Group 1 pulmonary arterial hypertension **AND**
- Medical record documentation of World Health Organization (WHO) functional class II or III symptoms **AND**
- Medical record documentation of a baseline 6-minute walking distance **AND**

- ~~Medical record documentation that Orenitram is not being used in combination with endothelin receptor antagonists (ambrisentan ([Letairis], bosentan [Tracleer], or macitentan [Opsumit]) or PDE5 inhibitors (sildenafil [Revatio] or tadalafil [Adcirca]) **AND**~~
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Uptravi*

QUANTITY LIMIT: 34 day supply per fill

AUTHORIZATION DURATION: If approved, Orenitram will require reauthorization every 6 months. At that point, the following criteria should apply:

- Medical record documentation of a 6-minute walking distance improved from baseline **OR**
- ~~Medical record documentation that Orenitram is not being used in combination with endothelin receptor antagonists (ambrisentan ([Letairis], bosentan [Tracleer], or macitentan [Opsumit]) or PDE5 inhibitors (sildenafil [Revatio] or tadalafil [Adcirca])~~
- Medical record documentation lack of progression in the signs and symptoms of pulmonary arterial hypertension on six (6) months of treprostinil therapy.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

SABRIL (vigabatrin)

Updated Indication: Sabril is now indicated for refractory complex partial seizures as adjunctive therapy in patients 2 years of age and older who have responded inadequately to several alternative treatments. Sabril is not indicated as a first-line agent.

Previously it was indicated for refractory complex partial seizures in patients at least 10 years of age and for infantile spasms in patients 1 month to 2 years of age.

Current formulary status: Vigabatrin is available on generic tier, requiring a prior authorization.

Recommendation: There are no changes needed to the formulary placement of Sabril/Vigabatrin. The Commercial Policy 201.0 for Vigabatrin should be updated as follows:

- Medical record documentation that vigabatrin is prescribed by a neurologist **AND**
- ~~Medical record documentation of therapeutic failure on, contraindication to or intolerance to all formulary alternatives **OR**~~
- Medical record documentation that vigabatrin is being used for Refractory Complex Partial Seizures and both of the following:
    - Documentation that vigabatrin is being used concomitantly with another seizure control medication **AND**
    - Documentation of therapeutic failure on, contraindication to or intolerance to three (3) formulary alternatives

OR

- Medical record documentation of use for infantile spasms

FORMULARY ALTERNATIVES:

Greater than or equal to 2 years: carbamazepine, carbamazepine ER, lamotrigine, phenytoin, topiramate
Greater than or equal to 3 years: gabapentin
Greater than or equal to 4 years: levetiracetam
Greater than or equal to 10 years: divalproex, divalproex ER, valproic acid
Greater than or equal to 12 years: tiagabine
Greater than or equal to 14 years: felbamate
Greater than or equal to 16 years: zonisamide

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

STELARA (ustekinumab)

Updated Indication: Stelara is a human interleukin-12 and -23 antagonist now indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

Previously, Stelara was indicated in adult patients with active psoriatic arthritis and moderately to severely active Crohn's disease and in adult and pediatric patients with moderate to severe plaque psoriasis.

Current formulary status: Medical Benefit requiring prior authorization (vial for IV infusion, single-dose vial for subcutaneous administration) or pharmacy benefit on Specialty tier requiring prior authorization (prefilled syringes)

Recommendation: No changes are recommended to the formulary placement of Stelara. It is recommended the following criteria, authorization duration, and quantity limit be added to Medical Benefit Policy 75.0 Stelara and Commercial Policy 318.0 Stelara to incorporate the ulcerative colitis indication:

- Medical record documentation that Stelara is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active ulcerative colitis **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of: Humira*, Entyvio*, and infliximab (or biosimilar)* **AND**
- Medical record documentation of Stelara 130 mg vials as IV infusion (for induction therapy) OR Stelara 90 mg syringes (for maintenance therapy) being prescribed **AND**
- Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

  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 ulcerative colitis on six (6) months of Stelara 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 ulcerative colitis while on Stelara therapy.

QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

Initial – One Time, RX count 1	Remainder/Subsequent
104 mL per 56 days	**QL: 1 mL per 56 days Max quantity supply:1 Min day supply: 56 Max day supply: 56**

NOTE: Stelara 45 mg syringe is not indicated for use in ulcerative colitis.

Other Recommendations:
It is recommended to update the quantity limits for Stelara for plaque psoriasis, psoriatic arthritits, and Crohn's disease in Medical Benefit Policy 75.0 as follows:

Medical Benefit Policy 75.0 Stelara

Quantity limit (Plaque Psoriasis):

If requesting a dose for patient weight:	Initial 6 month authorization	Subsequent 12 month authorization
Less than 60 kg	Facets RX Count: 135 MedImpact QL: One-time, one week authorization: 0.5 mL per 28 days Remainder of 6 month authorization: 0.5 mL per 84 days	Facets RX Count: 225 MedImpact QL: 0.5 mL per 84 days
Greater than or equal to 60 kg to 100 kg or less	Facets RX Count: 135 MedImpact QL: One-time, one week authorization: 0.5 mL per 28 days Remainder of 6 month authorization: 0.5 mL per 84 days	Facets RX Count: 225 MedImpact QL: 0.5 mL per 84 days
Greater than 100 kg	Facets RX Count: 270 MedImpact QL: One-time, one week authorization: 1 mL per 28 days Remainder of 6 month authorization: 1 mL per 84 days	Facets RX Count: 450 MedImpact QL: 1 mL per 84 days

Quantity limit (Psoriatic Arthritis):

If requesting a dose for patient weight:	Initial 6 month authorization	Subsequent 12 month authorization
100 kg or less	Facets RX Count: 135 MedImpact QL: One-time, one week authorization: 0.5 mL per 28 days Remainder of 6 month authorization: 0.5 mL per 84 days	Facets RX Count: 225 MedImpact QL: 0.5 mL per 84 days
Greater than 100 kg	Facets RX Count: 270 MedImpact QL: One-time, one week authorization: 1 mL per 28 days Remainder of 6 month authorization: 1 mL per 84 days	Facets RX Count: 450 MedImpact QL: 1 mL per 84 days

4. Crohn's Disease (CD)

- Prescription must be written by a gastroenterologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation of moderately to severely active Crohn's disease **AND**
- Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of three (3) of the following medications: Humira*, Cimzia*, Entyvio*, infliximab ~~(Remicade or Inflectra)~~ (or biosimilar) *, or Tysabri* **AND**
- Medical record documentation of Stelara 130mg vials as IV infusion (for induction therapy) OR Stelara 90mg syringes (for maintenance therapy) being prescribed.

Quantity limit (Crohn's disease):
Initial Authorization:

- One-time authorization:
  - Facets Rx Count: 520 (J3358 – Ustekinumab IV)
  - MedImpact Quantity Limit: 104 mL per 56 days GPID for Stelara 130 mg vial
- Remainder of initial authorization:
  - Facets RX Count: 270 (J3357 – Ustekinumab SQ [if requested through medical])
  - MedImpact Quantity limit: 1mL per 56 days GPID for Stelara 90mg Syringe

Subsequent Authorizations:

- Facets RX Count: 630 (J3357 – Ustekinumab SQ [if requested through medical])
- MedImpact Quantity limit: 1 mL per 56 days GPID for Stelara 90mg Syringe

It is recommended to update the quantity limits for Stelara for Crohn's disease for the Commercial Policy 318.0 as follows:
Commercial Policy 318.0 Stelara

Crohn's Disease

- Medical record documentation that Stelara is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active Crohn's disease **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of three (3) of the following medications: Humira*, Cimzia*, Entyvio*, infliximab ~~(Remicade or Inflectra)~~ (or biosimilar) *, or Tysabri* **AND**
- Medical record documentation of Stelara 130 mg vials as IV infusion (for induction therapy) OR Stelara 90 mg syringes (for maintenance therapy) being prescribed **AND**
- Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

Initial – One Time, RX count 1	Remainder/Subsequent
104 mL per 56 days	**QL: 1 mL per 56 days** **Max quantity supply:1** **Min day supply: 56** **Max day supply: 56**

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

ULTOMIRIS (ravulizumab-cwvz)

Updated Indication: Ultomiris is a complement inhibitor now indicated for the treatment of adults and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA).

Current formulary status: Medical Benefit requiring a prior authorization

Recommendation: There are no changes recommended to the current formulary placement of Ultomiris. It is recommended to add the following prior authorization criteria to incorporate the new indication:

Paroxysmal Nocturnal Hemoglobinuria (PNH)

- Prescription is written by a hematologist AND
- Medical record documentation of 18 years of age or older AND
- Medical record documentation of diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) AND
- Medical record documentation of patient being vaccinated with the meningococcal vaccine
- Physician documentation of one of the following:
    - member is transfusion-dependent (i.e., has at least 1 transfusion in the 24 months prior to initiation of ravulizumab due to documented hemoglobin less than 7 g/dL in persons without anemic symptoms or less than 10 g/dL in persons with symptoms from anemia) prior to initiation of ravulizumab treatment OR
    - there is a significant adverse impact on the insured individual's health such as end organ damage or thrombosis without other cause.

Atypical Hemolytic Uremic Syndrome (aHUS)

- Medical record documentation of a diagnosis of atypical hemolytic uremic syndrome (aHUS) *(Ultomiris is used to inhibit complement-mediated thrombotic microangiopathy)*

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 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.

Discussion: No comments or questions

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

UPDATES

VACCINE RECOMMENDATIONS

Pharmacists in the state of Pennsylvania are authorized to administer vaccines to patients 18 years and older (9 years and older for influenza vaccine). In order to improve accessibility, it is recommended that the following vaccines be set-up to pay as preventative services in the pharmacy claims system. Age and quantity limit restrictions are recommended for each product.

Recommendations:

VACCINE	AGE RESTRICTION RECOMMENDATIONS	QUANTITY LIMIT RECOMMENDATIONS
ADACEL TDAP (DIPH,PERTUSS(ACELL),TET VAC/PF	18 years up to and including 64 years	–
BEXSERO (MENINGOCOCCAL B VACCINE,4-COMP)	18 years up to and including 25 years	1 mL (2 doses) per lifetime
BOOSTRIX TDAP (DIPHTH,PERTUSS(ACELL),TET VAC)	18 years and up	–
ENGERIX-B ADULT (HEPATITIS B VIRUS VACCINE/PF)	20 years and up	8 mL (4 doses) per lifetime
ENGERIX-B PEDIATRIC-ADOLESCENT (HEPATITIS B VIRUS VACCINE/PF)	18 years up to and including 19 years	1.5 mL (3 doses) per lifetime
GARDASIL 9 (HPV VACCINE 9-VALENT/PF)	18 years up to and including 45 years	1.5 mL (3 doses) per lifetime
HAVRIX (HEPATITIS A VIRUS VACCINE/PF)	19 years and up	2 mL (2 doses) per lifetime
HAVRIX (HEPATITIS A VIRUS VACCINE/PF)	18 years only	1 mL (2 doses) per lifetime
HEPLISAV-B (HEPATITIS B VACCINE/CPG1018/PF)	18 years and up	1 mL (2 doses) per lifetime
MENACTRA (MENING VAC A,C,Y,W-135 DIP/PF)	18 years up to and including 55 years	1 mL (2 doses) per lifetime
MENVEO* (MENING VAC A,C,Y,W-135 DIP/PF) *SUPPLIED AS A KIT	18 years up to and including 55 years	2 kits (2 doses) per lifetime
M-M-R II VACCINE (MEASLES,MUMPS,RUBELLA VACC/PF)	18 years and up	1 mL (2 doses) per lifetime
PNEUMOVAX 23 (PNEUMOCOCCAL 23-VAL P-SAC VAC)	18 years and up	1.5 mL (3 doses) per lifetime
PREVNAR 13 (PNEUMOC 13-VAL CONJ-DIP CRM/PF)	18 years and up	0.5 mL (1 dose) per lifetime
RECOMBIVAX HB (HEPATITIS B VIRUS VACCINE/PF)	20 years and older	1.5 mL (3 doses) per lifetime
RECOMBIVAX HB (HEPATITIS B VIRUS VACCINE/PF)	18 up to and including 19 years	3 mL (3 doses) per lifetime
RECOMBIVAX HB DIALYSIS (HEPATITIS B VIRUS VACCINE/PF)	18 years and older	3 mL (3 doses) per lifetime
SHINGRIX* (VARICELLA-ZOSTER GE/AS01B/PF) *SUPPLIED AS A KIT	50 years and older	2 kits (2 doses) per lifetime
TDVAX (TETANUS, DIPHTHERIA TOX,ADULT)	18 years and up	–
TENIVAC (TETANUS-DIPHTHERIA TOXOIDS/PF)	18 years and up	–
TRUMENBA (N.MENINGITIDIS B,LIPID FHBP RC)	18 up to and including 25 years	1.5 mL (3 doses) per lifetime
TWINRIX (HEPATITIS A AND B VACCINE/PF)	18 years and up	4 mL (4 doses) per lifetime
VAQTA (HEPATITIS A VIRUS VACCINE/PF)	18 years only	1 mL per lifetime

VAQTA (HEPATITIS A VIRUS VACCINE/PF)	19 years and up	2 mL per lifetime
ZOSTAVAX* (ZOSTER VACCINE LIVE/PF) *SUPPLIED AS A KIT	50 years and up	1 kit (2 dose) per lifetime

Discussion: No comments or questions

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on Tuesday, May 19, 2020 at 1:00 HCN3A & 3B Conference room

All of these meetings are scheduled to be held at Geisinger Health Plan, Hughes Center North and South Buildings; 108 Woodbine Lane; Danville, PA 17821.