

P&T Committee Meeting Minutes
Commercial/Exchange/CHIP
October 20, 2021 e-vote

DRUG REVIEWS

EMPAVELI (pegcetacoplan)

Review: Empaveli binds to complement protein C3, regulating the cleavage of C3 and the generation of downstream effectors of complement activation. It is the first self-administered subcutaneous therapy approved for PNH, and will compete with C5 inhibitors, Soliris and Ultomiris, which are administered via intravenous infusion. Empaveli has an advantage with inhibition of both intravascular and extravascular hemolysis, compared to C5 inhibitors which only affect intravascular hemolysis.

Based on clinical trials, Empaveli was shown to be effective for treatment in patients with an inadequate response to Soliris. The PRINCE trial, an ongoing trial evaluating Empaveli in treatment naïve patients, is expected to be completed in 2Q 2021 and will help determine the role of Empaveli as first line treatment for PNH. A biosimilar for Soliris, a subcutaneous formulation of Ultomiris, and several oral complement inhibitors are in development.

The efficacy and safety of Empaveli in patients with paroxysmal nocturnal hemoglobinuria was evaluated in the PEGASUS trial, a 16-week, randomized, open-label, active comparator-controlled study. The study included patients with PNH who had been treated with a stable dose of eculizumab for at least the previous 3 months and with hemoglobin levels less than 10.5 g/dL. Patients had a 4-week run-in period during which all patients received Empaveli in addition to their stable dose of eculizumab after which they were randomized 1:1 to receive Empaveli 1,080 mg twice weekly (n=41) or their current dose of eculizumab (n=39) through the duration of the 16-week randomized controlled period. Empaveli was superior to change from baseline in hemoglobin level at week 16. The adjusted mean change from baseline in the hemoglobin level was 2.37 g/dL in the Empaveli group compared to -1.47 g/dL in the eculizumab group. Non-inferiority was demonstrated in the endpoints of transfusion avoidance and change from baseline in ARC

Empaveli has a black box warning for risk of serious infections caused by encapsulated bacteria. It is contraindicated in patients with a hypersensitivity to any of the excipients, patients who are not currently vaccinated against certain encapsulated bacteria, and patients with unresolved serious infection caused by encapsulated bacteria. Other warnings include infusion-related reactions, PNH manifestations after discontinuation of Empaveli, and interference with laboratory test (artificially prolonged activated partial thromboplastin time (aPTT)). During the PEGASUS trial, serious adverse events were reported in 7 patients receiving Empaveli, most commonly infections. The most common adverse reactions with Empaveli were injection site reactions, infections, diarrhea, abdominal pain, respiratory tract infection, viral infection, and fatigue.

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 voted to accept the recommendations as presented. None were opposed.

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

Outcome: Empaveli is a medical benefit which is also available via specialty vendor. When processed at a specialty pharmacy, Empaveli will process at the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. Empaveli will require prior authorization with the following criteria:

- Medical record documentation of a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) **AND**
- Medical record documentation of flow cytometry confirming diagnosis **AND**
- Medical record documentation that Empaveli is prescribed by a hematologist **AND**
- Medical record documentation that member has received vaccinations against encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae type B* **AND**
- Medical record 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 pegcetacoplan due to documented hemoglobin less than 7 g/dL in persons without anemic symptoms or less than 9 g/dL in persons with symptoms from anemia) prior to initiation of pegcetacoplan treatment; **OR**
 - there is a significant adverse impact on the insured individual's health such as end organ damage or thrombosis without other cause

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent authorizations will be for 6 months and will require of:

- Medical record documentation:
 - Hemolysis control measured by lactic acid dehydrogenase (LDH) level less than 1.5 times the upper limit of normal (ULN) **AND**
 - Reduced need or elimination of transfusion requirements **OR**
 - Stabilization of hemoglobin levels

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

WELIREG (belzutifan)

Review: Welireg inhibits hypoxia-inducible factor 2 alpha (HIF-2 α), a transcription factor which plays a role in oxygen sensing and regulation of genes that promote adaptation to hypoxia. With a lack of functional von Hippel-Lindau (VHL) protein, an accumulation of HIF-2 α is translocated to the nucleus where it forms a transcriptional complex with hypoxia-inducible factor 1 beta (HIF-1 β) which can induce the expression of downstream genes, including those associated with cellular proliferation, angiogenesis, and tumor growth. Welireg binds HIF-2 α and blocks the HIF-2 α and HIF-1 β interaction, leading to reduced transcription of target genes. In vivo, Welireg demonstrated anti-tumor activity in mouse xenograft models of renal cell carcinoma.

Welireg is the first HIF-2 α inhibitor approved in the United States and the first FDA approved treatment for select types of tumors associated with VHL disease. There are several ongoing clinical studies evaluating Welireg in other cancer types, as monotherapy and in combination with other medications such as Keytruda and Lenvima.

The efficacy of Welireg was evaluated in Study 004, an open-label clinical trial in 61 patients with VHL-associated RCC diagnosed based on VHL germline alteration and with at least one measurable solid tumor localized to kidney as defined by response evaluation criteria in solid tumors (RECIST) v1.1. The major efficacy endpoint for the treatment of VHL-associated RCC showed an overall response rate (ORR) of 49% with all patients demonstrating a partial response. The median duration of response was not reached, but 56% of patients had a response lasting at least 12 months.

Other efficacy results showed an overall response rate of 63% for patients with VHL-associated CNS hemangioblastomas and 83% for patients with pNET, with a majority of patients demonstrating a partial response. Median duration of response was not reached, but 73% and 50% of patients, respectively, had a duration of response lasting at least 12 months.

Welireg has a black box warning for embryo-fetal toxicity. Welireg has warnings for severe anemia that can require blood transfusion, hypoxia, and embryo-fetal toxicity. During Study 004, serious adverse reactions occurred in 15% of patients, including anemia, hypoxia, anaphylaxis reaction, retinal detachment, and central retinal vein occlusion. Permanent discontinuation occurred in 3.3% of patients, included dizziness and opioid overdose. Dose interruptions and reductions occurred in 39% and 13% of patients. Th most common adverse reactions included decreased hemoglobin, anemia, fatigue, increased creatinine, headache, dizziness, increased glucose, and nausea.

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 voted to accept the recommendations as presented. None were opposed.

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

Outcome: Welireg is a pharmacy benefit will be added to the Oral Oncology Brand Non-Preferred Tier (\$0 Copay). Welireg will require prior authorization with the following criteria:

- Medical record documentation that Welireg is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of von Hippel-Lindau (VHL) disease confirmed with a germline VHL alteration and at least one of the following:
 - associated renal cell carcinoma (RCC) **OR**
 - associated central nervous system (CNS) hemangioblastomas **OR**
 - associated pancreatic neuroendocrine tumors (pNET)

AND

- Medical record documentation that patient does not require immediate surgery

QUANTITY LIMIT: 90 tablets per 30 days

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

FAST FACTS

DALVANCE (dalbavancin)

Updated Indication: Dalvance is now indicated for the treatment of adult and pediatric patients with acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of Gram-positive microorganisms.

Dalvance was previously indicated for acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of Gram-positive microorganisms.

Current formulary status: Dalvance is a medical benefit requiring prior authorization and is not on the Commercial, Exchange, and CHIP pharmacy formularies. When Dalvance is processed at a specialty pharmacy, it should be processed on the Specialty tier or the Brand Non-preferred tier for members with a three-tier benefit.

Recommendation: There are no changes recommended to the formulary placement of Dalvance. It is recommended that the authorization duration be changed and prior authorization criteria be removed and added for medical benefit policy (MBP) 121.0.

1. ~~Medical record documentation that patient is \geq 18 years of age AND~~

1. 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 dysgalactiae*, *Streptococcus anginosus*, *Streptococcus intermedius*, *Streptococcus constellatus*, or *Enterococcus faecalis* (vancomycin susceptible strains) which has been diagnosed and documented with Infectious Disease consultation **AND**
2. 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**
3. If Dalvance 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 **AND**
4. Medical record documentation of a prescribed dose of Dalvance (dalbavancin) that is consistent with the Food and Drug Administration (FDA) approved package labeling **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds FDA approved labeling.

AUTHORIZATION LIMIT: ~~If approved, Dalvance will be authorized for a treatment course of 2 doses within a 2-week period.~~

AUTHORIZATION DURATION/QUANTITY LIMIT:

For SINGLE dose regimen: Approval will be for **one (1) week** and will be limited to **one (1) treatment course** (up to 1,500 mg as a single dose) (Facets RX count 300, Darwin RX count 1).

For TWO-dose regimen: Approval will be for **two (2) weeks** and will be limited to **two (2) treatment courses** (up to 1,500 mg divided among two doses) (Facets RX count 300, Darwin RX count 2).

Discussion: No comments or questions.

Outcome: The committee 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.

FARXIGA (dapagliflozin)

Updated indication: Farxiga is now indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.

Previously, Farxiga was indicated for adults with type 2 diabetes as an adjunct to diet and exercise to improve glycemic control. Also, to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes and established cardiovascular disease or multiple cardiovascular risk factors. Farxiga is also indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (NYHA class II-IV).

Limitations of Use:

- Not recommended for patients with type 1 diabetes.
- Not recommended for use to improve glycemic control in adults with type 2 diabetes with an eGFR less than 45 mL/min/1.73m².
- Not recommended for treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for kidney disease.

Current formulary status: Farxiga is a pharmacy benefit and is currently non-formulary requiring a prior authorization.

Recommendations: There are no changes to formulary status at this time. However, it is recommended to add a section to the policy for the new indication. There will be no changes to quantity limits at this time.

Chronic Kidney Disease:

- Medical record documentation of age greater than or equal to 18 years of age **AND**
- Medical record documentation of a diagnosis of chronic kidney disease **AND**
- Medical record documentation that Farxiga will be used in combination with angiotensin-converting enzyme/ angiotensin II receptor blocker (ACEi/ARB) unless contraindicated or not tolerated

Discussion: No comments or questions.

Outcome: The committee 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.

FERRIPROX (deferiprone)

Updated indication: Ferriprox is an iron chelator now indicated for the treatment of transfusional iron overload in adult and pediatric patients 3 years and older with sickle cell disease and other anemias.

Previously, Ferriprox was indicated for the treatment of transfusional iron overload in adult and pediatric patients 3 years and older with thalassemia syndromes.

Limitations of Use: Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with myelodysplastic syndrome or in patients with Diamond Blackfan anemia.

Current formulary status: Specialty tier or Brand NP tier for members with a three tier benefit, requires a PA

Recommendations: No changes are needed to the formulary placement or authorization duration of Ferriprox. It is recommended that the following changes be made to Commercial Policy 244.0 to incorporate the new indication:

- Medical record documentation that Ferriprox is prescribed by a hematologist **AND**

- Medical record documentation of being used for the treatment of transfusional iron overload due to **one of the following:**
 - Thalassemia syndromes **OR**
 - **Sickle cell disease and other anemias***

AND

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to deferasirox (generic Exjade) **AND**
- Medical record documentation of absolute neutrophil count (ANC) greater than $1.5 \times 10^9/L$

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 serum ferritin level > 300 mcg/L.

***NOTE:** Safety and effectiveness of Ferriprox have not been established for the treatment of transfusional iron overload in patients with myelodysplastic syndrome or in patients with Diamond Blackfan anemia.

Discussion: No comments or questions.

Outcome: The committee 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.

NURTEC ODT (rimegepant)

Updated indication: Nurtec ODT is a calcitonin gene-related peptide receptor antagonist now indicated for the preventive treatment of episodic migraine in adults.

Previously, Nurtec ODT was only indicated for the acute treatment of migraine with or without aura in adults.

Current formulary status: Nurtec ODT is a pharmacy benefit and is currently not on formulary. Nurtec ODT requires a prior authorization.

Recommendations: It is recommended to add Nurtec ODT to the Brand Preferred tier. The prior authorization criteria should be updated to the following for both indications. It is also recommended to update the quantity limits for both indications.

Acute Migraine Treatment

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Nurtec ODT will be used for the acute treatment of migraine with or without aura **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary triptans **AND**
- Medical record documentation that Nurtec ODT will not be used concomitantly with another CGRP antagonist indicated for the acute treatment of migraine (e.g. Ubrelvy).

Preventive Migraine Treatment

- Medical record documentation that Nurtec ODT is prescribed by or in consultation with a neurologist or headache specialist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of migraine with or without aura, based on the International Classification of Headache Disorders (ICHD)-III diagnostic criteria AND
- Medical record documentation of number of baseline migraine or headache days per month AND
- Medical record documentation of diagnosis of episodic migraine (no more than 14 headache days per month) AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three (3) of the following:
 - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
 - Topiramate
 - Divalproex/sodium valproate
 - Amitriptyline
 - Venlafaxine AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig AND Emgality AND
- Medical record documentation that Nurtec ODT will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g., Aimovig, Ajovy, Emgality, Vyepti) AND
- Medical record documentation that Nurtec ODT will not be used in combination with botulinum toxin for preventive treatment OR
 - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox AND
 - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

Authorization Duration for Preventive Treatment: Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine AND
- Medical record documentation that Nurtec ODT will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g., Aimovig, Ajovy, Emgality, Vyepti) AND
- Medical record documentation that Nurtec ODT will not be used in combination with botulinum toxin for preventive treatment OR
 - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox AND
 - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

Quantity Limit: 18 tablets per 30 days

ICHD-III Diagnostic Criteria ³	
Migraine without Aura:	Migraine with Aura:
A) At least five (5) attacks fulfilling criteria B through D below:	A) At least two (2) attacks fulfilling criteria B through C below:

<p>B) Headache lasting 4 to 72 hours (untreated or unsuccessfully treated)</p>	<p>B) One (1) or more of the following fully reversible aura symptoms:</p> <ul style="list-style-type: none"> ○ Visual ○ Sensory ○ Speech and/or language ○ Motor ○ Brainstem ○ Retinal
<p>C) Headache with at least two (2) of the following characteristics:</p> <ul style="list-style-type: none"> ○ unilateral location ○ pulsating quality ○ moderate to severe pain intensity ○ aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs) 	<p>C) At least three (3) of the following:</p> <ul style="list-style-type: none"> ○ at least one (1) aura symptom spreads over 5 or more minutes ○ two (2) or more aura symptoms occur in succession ○ each individual aura symptom lasts 5 to 60 minutes¹ ○ at least one (1) aura symptom is unilateral² ○ at least one (1) aura symptom is positive³ ○ the aura is accompanied, or followed within 60 minutes, by a headache
<p>D) At least one of the following during the headache:</p> <ul style="list-style-type: none"> ○ nausea and/or vomiting ○ photophobia and phonophobia 	<p>D) Not better accounted for by another ICHD-3 diagnosis</p>
<p>E) Not better accounted for by another ICHD-3 diagnosis</p>	

Other Recommendations:

Ubrelvy:

Commercial/Marketplace/CHIP: It is recommended to add Ubrelvy to the Brand Preferred tier. It is recommended to update the prior authorization criteria to the following.

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Ubrelvy will be used for the acute treatment of migraine with or without aura **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary triptans **AND**
- Medical record documentation that Ubrelvy will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the acute treatment of migraine (e.g. Nurtec ODT)

Reyvow:

Commercial/Marketplace/CHIP: Reyvow is non-formulary. There are no changes to formulary status at this time, however it is recommended to update the prior authorization criteria to the following.

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Reyvow will be used for the acute treatment of migraine with or without aura **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to nonsteroidal anti-inflammatory drug (NSAID) therapy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary triptans **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Ubrelvy and Nurtec ODT for acute treatment

Discussion: No comments or questions.

Outcome: The committee 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.

OPDIVO (nivolumab)

Updated Indication: Opdivo is now indicated for adjuvant treatment of patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection of UC.

Current formulary status: Medical Benefit, requires a PA; when processed at specialty pharmacy, process on Specialty or Brand NP tier for members with three-tier benefit

Recommendations: There are no changes recommended for the formulary placement of Opdivo. The following changes are recommended to the prior authorization criteria and authorization duration in Medical Benefit Policy 126.0:

6. Urothelial Carcinoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient ≥ 18 years of age **AND**
- Medical record documentation of one of the following:
 - 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

OR

- Medical record documentation that Opdivo is being used in the adjuvant setting for a diagnosis of urothelial carcinoma **AND** both of the following:
 - Medical record documentation of radical resection of urothelial carcinoma **AND**
 - Medical record documentation of high risk of recurrence of urothelial carcinoma*

AND

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

**Note in clinical trials high risk of recurrence of urothelial carcinoma was defined as pathological stage of ypT2-ypT4a or ypN⁺ for patients who received neoadjuvant cisplatin or pathological stage of pT3-pT4a or pN⁺ for patients who did not receive neoadjuvant cisplatin due to ineligibility for or refusal of adjuvant cisplatin.*

Authorization duration:

****For adjuvant treatment of metastatic melanoma (completely resected melanoma), adjuvant treatment of resected esophageal or gastroesophageal junction cancer, and adjuvant urothelial carcinoma:**

Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. One subsequent approval 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.

Authorization of Opdivo for the adjuvant treatment of metastatic melanoma, adjuvant treatment of resected esophageal or gastroesophageal junction cancer, **or adjuvant treatment of urothelial carcinoma** should not exceed the FDA-approved treatment duration of 1 year (12 months). For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

****For first line-treatment of metastatic NSCLC expressing PD-L1 ($\geq 1\%$), for first-line treatment of metastatic or recurrent NSCLC, and first line treatment of unresectable malignant pleural mesothelioma and treatment of gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma:**

Initial approval:

Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be for an additional **18 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.

Authorization of Opdivo for the first line-treatment of metastatic NSCLC expressing PD-L1 ($\geq 1\%$), for first-line treatment of metastatic or recurrent NSCLC, and first line treatment of unresectable malignant pleural mesothelioma and treatment of gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma: should not exceed the FDA-approved treatment duration of 2 years (24 months) in patients without disease progression. For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

For all other indications:

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.

Discussion: No comments or questions.

Outcome: The committee 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 now indicated for adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH).

Previously this was only indicated in adult patients for PNH and for adult and pediatric patients one month and older with atypical hemolytic uremic syndrome (aHUS).

Current formulary status: Medical Benefit, requires PA, at specialty pharmacy, processed on Specialty or Brand NP tier for members with a three tier benefit

Recommendations: There are no changes recommended for the formulary placement or authorization duration. The following change is recommended for Medical Benefit Policy 196.0:

Paroxysmal Nocturnal Hemoglobinuria (PNH)

- Prescription is written by a hematologist AND
- Medical record documentation of ~~18 years of age or older~~ **1 month 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 according to the most current Advisory Committee on Immunization Practices (ACIP) recommendations AND
- 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.

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent authorizations will be for 6 months and will require:

- Medical record documentation:
 - Hemolysis control measured by lactic acid dehydrogenase (LDH) level less than 1.5 times the upper limit of normal (ULN) AND
 - Reduced need or elimination of transfusion requirements OR
 - Stabilization of hemoglobin levels

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 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

TECENTRIQ

Tecentriq has two indications previously approved through accelerated approval that have been voluntarily withdrawn.

Roche voluntarily withdrew the US Indication for Tecentriq in prior-platinum treated metastatic urothelial carcinoma based on results from the confirmatory trial IMvigor211 which did not meet the primary endpoint of overall survival in the PD-L1 high patient population^{1,2}.

Roche also voluntarily withdrew the indication for Tecentriq in combination with chemotherapy for the treatment of adults with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) whose tumors express PD-L1, as determined by an FDA approved test. Continued approval was contingent on the results of IMpassion131 which did not meet its primary endpoint of PFS for the initiation treatment of people with mTNBC in the PD-L1-positive population.

Recommendations: The following updates are recommended to Medical Benefit Policy 144.0:

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 one of the following:
 - Disease progression during or following platinum-containing chemotherapy
 - OR**
 - Patient is not eligible for cisplatin-containing therapy **AND**
 - Tumors express PD-L1 (greater than or equal to 5%) as determined by an FDA-approved test
 - OR**
 - Patient is not eligible for any platinum-containing chemotherapy (regardless of PD-L1 status)
2. Non-Small Cell Lung Cancer:
 - Prescription written by an oncologist **AND**
 - Medical record documentation of a diagnosis of non-small cell lung cancer meeting one of the following situations:
 - Medical record documentation of disease progression during or following platinum-containing chemotherapy
 - OR**
 - Medical record documentation of 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.)
 - OR**
 - Medical record documentation of a non-squamous histologic subtype **AND**
 - Medical record documentation that Tecentriq will be given as first-line treatment **AND**
 - Medical record documentation that Tecentriq will be given in combination with bevacizumab, paclitaxel, **AND** carboplatin **OR** paclitaxel protein-bound **AND** carboplatin **AND**
 - Medical record documentation that the patient does not have an EGFR or ALK genomic tumor aberration

OR

- Medical record documentation that Tecentriq will be given as first-line treatment for metastatic disease B
- Medical record documentation that tumors have high PD-L1 expression (PD-L1 stained $\geq 50\%$ of tumor cells [TC $\geq 50\%$] or PD-L1 stained tumor-infiltrating immune cells [IC] covering $\geq 10\%$ of the tumor area [IC $\geq 10\%$]) as determined by an FDA-approved test **AND**
- Medical record documentation that the patient does not have an EGFR or ALK genomic tumor aberration

3. **Breast Cancer:**

- Prescription written by an oncologist **AND**
- Medical record documentation of a diagnosis of advanced or metastatic triple negative (ER-negative, PR-negative, HER2-negative) breast cancer **AND**
- Medical record documentation that tumors express PD-L1 (greater than or equal to 1%) as determined by an FDA-approved test **AND**
- Medical record documentation that Tecentriq will be used in combination with protein-bound paclitaxel (Abraxane)

4. Small Cell Lung Cancer (SCLC):

- Prescription written by an oncologist **AND**
- Medical record documentation of a diagnosis of extensive stage small cell lung cancer (ES-SCLC) **AND**
- Medical record documentation that Tecentriq will be used in combination with carboplatin and etoposide **AND**
- Medical record documentation of use as first-line treatment of extensive-stage disease

5. Unresectable or Metastatic Hepatocellular Carcinoma (HCC)

- Prescription written by an oncologist **AND**
- Medical record documentation of diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) **AND**
- Medical record documentation that Tecentriq will be given in combination with bevacizumab **AND**
- Medical record documentation that patient has not received prior systemic treatment for hepatocellular carcinoma

6. Melanoma

- Medical record documentation of unresectable or metastatic melanoma **AND**
- Medical record documentation of BRAF V600 mutation as determined by an FDA-approved test **AND**
- Medical record documentation that Tecentriq will be given in combination with Cotellicq (cobimetinib) and Zelboraf (vemurafenib)

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.

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.

Discussion: No comments or questions.

Outcome: The committee 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.

DESCOVY USPSTF PrEP COVERAGE UPDATE

Background: The United States Preventive Services Task Force (USPSTF) currently recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition. Presently, emtricitabine/tenofovir (F/TDF) as well as Descovy (F/TAF) are Food and Drug Administration (FDA) approved for this indication. Geisinger currently operationalizes this requirement by covering emtricitabine/tenofovir as well as its component parts for \$0 at point-of-sale when the pharmacy enters an appropriate submission clarification code (SCC).

GHP recently consulted with Dr. Darrell McBride and Dr. Stan Martin, both infectious disease physicians, regarding the coverage of Descovy for PrEP. Dr. McBride offered several merits of Descovy when compared to generic Truvada:

- Descovy is the preferential option for patients who may remain on PrEP therapy for an extended period of time of those who are elderly.
- Descovy has less impact on bone mineral density (BMD).
- Descovy has the advantage of requiring no dosage adjustment down to a creatinine clearance (CrCl) of 30 mL/min. Generic Truvada requires dose adjustment for a CrCl less than 50 mL/min.
- Descovy has less impact on markers of renal function.

Recommendations: There are no changes recommended to the current quantity limits or formulary placement of Descovy when used for the treatment of HIV. It is recommended that Descovy is covered for \$0 when utilized for PrEP. The logic currently in place for generic Truvada which requires pharmacy submission of an SCC code to indicate HIV treatment vs. PrEP will be added to Descovy.

Discussion: No comments or questions.

Outcome: The committee 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.

Voting responses were received from 22 of 39 members. The vote was unanimously approved.

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on Tuesday, November 16, 2021

Meeting will be via phone/Microsoft Teams.