P&T Committee Meeting Minutes
Medicaid
November 16, 2021

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Holly Bones, Pharm.D.
Megan Ammon, Pharm.D.	Alyssa Cilia, RPh
Kristen Bender, Pharm.D.	Michael Evans, RPh
Jeremy Bennett, MD	Jason Howay, Pharm.D.
Kim Castelnovo	Kelli Hunsicker, Pharm.D.
Dean Christian, MD	Perry Meadows, MD
Kimberly Clark, Pharm.D.	Jonas Pearson, RPh
Rajneel Farley, Pharm.D.	William Seavey, Pharm.D.
Kelly Faust Pharm.D.	Michael Shepherd, MD
Tricia Heitzman, Pharm.D.	
Nichole Hossler, MD	
Keith Hunsicker, Pharm.D.	
Derek Hunt, Pharm.D.	
Phillip Krebs, R.EEG T	
Jamie Miller, RPh	
Austin Paisley, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Renn, Pharm.D.	
Angela Scarantino	
Kristen Scheib, Pharm.D.	
Leslie Shumlas, Pharm.D.	
Richard Silbert, MD	
Aubrielle Smith Pharm.D.	
Michael Spishock, RPh	
Todd Sponenberg, Pharm.D.	
Jill Stone, Pharm.D.	
Robert Strony, MD MBA	
Kevin Szczecina, RPh	
Amanda Taylor, MD	
Brandon Whiteash, Pharm.D.	
Adam Root (non-voting participant)	
Nicole Hughes, Pharm.D. (Pharmacy Resident)	
Samantha Matchock, Pharm.D. (Pharmacy Resident)	
MeiLing Montross, Pharm.D. (Pharmacy Resident)	
Alison Walck, Pharm.D. (Pharmacy Resident)	

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, November 16, 2021.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the September, 2021 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Kerendia (finerenone)

Review: Kerendia is a non-steroidal MRA indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with CKD associated with T2D. Kerendia is supplied as 10 mg and 20 mg tablets. Serum potassium levels and estimated glomerular filtration rate (eGFR) need to be measured before initiation. Treatment should not be initiated if serum potassium is > 5.0 mEq/L or eGFR < 25 mL/min/1.73m2. Depending on eGFR and serum potassium, the starting dose can be 10 mg or 20 mg once daily. The target daily dose of Kerendia is 20 mg once daily. Kerendia is the first mineralocorticoid receptor antagonist and the third medication approved for the treatment of chronic kidney disease in patients with type 2 diabetes. Kerendia will directly complete with Invokana and Farxiga. Although the Farxiga indication does not call out chronic kidney disease with type 2 diabetes, 68% of patients in the clinical trials had type 2 diabetes. Jardiance is expected to complete its trial in patients with CKD with or without type 2 diabetes in 2022. Kerendia will likely be reserved for patients who cannot use or have failed a SLGT2 inhibitor. Kerendia was studied in the FIDELIO-DKD trial, which was a randomized, double-blind, placebo-controlled trial in adult patients (n=5,674) with CKD associated with T2D. Patients were to be receiving standard of care background therapy, including a maximum tolerated ACEi or ARB (99.8%). Patients were excluded with chronic heart failure with reduced ejection fraction and persistent symptoms (NYHA class II to IV). Approximately 5% were on an SLGT2 inhibitor. Patients received Kerendia or placebo and were followed for 2.6 years. Kerendia reduced the incidence of the primary composite endpoint of sustained decline in eGFR of ≥40%, kidney failure, or renal death (HR 0.82, 95% CI 0.73-0.93, p=0.001). Kerendia reduced the incidence of the composite endpoint of cardiovascular (CV) death, non-fatal myocardial infarction (MI), non-fatal stroke or hospitalization for heart failure (HR 0.86, 95% CI 0.75-0.99, p=0.034). The treatment effect on the primary and secondary composite endpoints was generally consistent across subgroups. Kerendia was also studied in a Phase 3 trial, which investigated the efficacy and safety versus placebo in addition to an ACEI or ARB in the reduction of cardiovascular morbidity and mortality in an additional 7,437 patients with CKD and T2D. Compared with FIDELIO-DKD the trial included more patients at earlier stages of CKD. Patients in the trial were on a maximal tolerated renin-angiotensin system blocker. Approximately 8% were on an SGLT2 inhibitor. Patients with heart failure with reduced ejection fraction with NYHA class II-IV were excluded. Patients were randomized to finerenone or placebo for 3.4 years. The primary endpoint was time to first occurrence of the compositive endpoint of cardiovascular death and nonfatal cardiovascular events (myocardial infarction, stroke, or hospitalization for heart failure) and the composite endpoint occurred in 12.4% of patients in the finerenone group compared to 14.2% in placebo group (HR 0.87, 95% CI 0.76-0.98, p=0.03). Results from the pooled analysis from both trials, indicate that finerenone is efficacious for CV outcomes for patients with T2D and CKD, who are on background RAS blockade therapy, mostly due to the reduction in hospitalization for heart failure. There was also reduction in end stage renal disease and a higher incidence of hyperkalemia. Patients with symptomatic heart failure were excluded from both trials. Kerendia is contraindicated in patients who are receiving concomitant treatment with strong CYP3A4 inhibitors and with adrenal insufficiency. Adverse reactions occurring in ≥ 1% of patients on Kerendia and more frequently than placebo are hyperkalemia, hypotension, and hyponatremia. Hyperkalemia led to permanent discontinuation of treatment in 2.3% of patients receiving Kerendia and was the most frequent adverse reaction (18.3%) in the study overall. The safety and efficacy of Kerendia have not been established in patients below 18 years of age.

According to the American Diabetes Association (ADA), patients with type 2 diabetes and kidney disease, the use of a SGLT2 inhibitor should be considered in those with an eGFR ≥ 30 mL/min/1.73m2 and UACR > 300 mg/g (Level of Evidence A). According to the Kidney Disease: Improving Global Outcomes (KDIGO), treatment with an ACEI or an ARB may be initiated in patients with diabetes, hypertension, and albuminuria (Level of Evidence 1B). In patients with type 2 diabetes, CKD, an eGFR ≥ 30 mL/min per 1.73m2, treatment with a SLGT2 inhibitor should be considered (1A).

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Kerendia will be a pharmacy benefit. It is recommended to not add Kerendia to the GHP Family formulary. The following prior authorization criteria will apply.

- Medical record documentation of a diagnosis of chronic kidney disease associated with type 2 diabetes AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of serum potassium ≤ 5.0 mEq/L AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) of the preferred sodium-glucose cotransporter 2 (SGLT-2) inhibitors FDA-approved for the member's diagnosis

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

Tivdak (tisotumab vedotin-tftv)

Review: Tivdak is the first tissue factor (TF)-directed antibody drug conjugate (ADC) approved for recurrent or metastatic cervical cancer. Tivdak is indicated as a second-line or later treatment option following platinum-containing chemotherapies, which are the preferred agents for first line treatment of recurrent or metastatic disease. NCCN recommends Keytruda and Opdivo as preferred treatment options in the second-line or later setting, but only in select patients (PD-L1 positive or MSI-H/dMMR tumors for Keytruda and PD-L1 positive tumors for Opdivo). The efficacy of Tivdak was evaluated in innovaTV 204, an open-label, single-arm trial that treated 101 patients with recurrent or metastatic cervical cancer who had received no more than two prior systemic regimens, including one prior platinum-based chemotherapy regimen. Patients received Tivdak 2 mg/kg intravenously every 3 weeks until disease progression or unacceptable toxicity. The major efficacy outcome measuring overall response rate was 24%, with 7% of patients having a complete response and 17% having a partial response. The median duration of response was 8.3 months. There are no black box warnings or contraindications for Tivdak. Warnings and precautions include ocular adverse reactions, peripheral neuropathy, hemorrhage, pneumonitis, and embryo fetal toxicity. During clinical trials of Tivdak, serious adverse reactions occurred in 43% of patients and fatal adverse reactions occurred in 4% of patients, including septic shock, pneumonitis, sudden death, and multisystem organ failure. Adverse reactions led to permanent discontinuation in 13% of patients. Dose interruptions occurred in 47% of patients and dose reductions occurred in 23% of patients. The most common adverse reactions were decreased hemoglobin, fatigue, decreased lymphocytes, nausea, peripheral neuropathy, alopecia, epistaxis, conjunctival adverse reactions, hemorrhage, decreased leukocytes, increased creatinine, dry eye, increased prothrombin international normalized ration, prolonged active partial thromboplastin time, diarrhea, and rash.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Tivdak is a medical benefit and should not be added to GHP Family pharmacy formulary. The following prior authorization criteria should apply:

- Medical record documentation that Tivdak is prescribed by a hematologist or oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND

- Medical record documentation recurrent or metastatic cervical cancer AND
- Medical record documentation that member has disease progression on or after chemotherapy

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.

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

Kimyrsa (oritavancin)

Review: Kimyrsa is a single dose IV infusion of oritavancin, used for the treatment of ABSSSI caused by susceptible Gram-positive microorganisms. It exhibits concentration-dependent bactericidal activity by inhibiting the polymerization and crosslinking involved in cell wall biosynthesis and causing disruption of bacterial membrane integrity. Kimyrsa is the second available product of oritavancin, the other being Orbactiv, a single dose IV infusion of oritavancin. The key difference between the two products is total infusion time, as well as other differences including dose strengths, reconstitution and dilution instructions, and compatible diluents. Treatment options that offer one-time dosing regimens for ABSSSI include oritavancin (Kimyrsa and Orbactiv) and dalbavancin (Dalvance). Kimyrsa is infused over 1 hour, Orbactiv is infused over 3 hours and Dalvance is infused over 30 minutes. All three intravenous options offer the potential to provide treatment without hospital admission. Due to high costs and concerns about safety, these agents are generally reserved for second-line therapy behind vancomycin for the empiric treatment of severe ABSSSI where methicillin-resistant *Staphylococcus aureus* (MRSA) is suspected or as targeted therapy when MRSA infection is confirmed. The Infectious Disease Society of America (IDSA) does not include oritavancin or dalbavancin in the treatment algorithm for management of Skin and Soft Tissue Infections, created in 2014, before FDA approval of these medications.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Kimyrsa is a medical benefit that will be GHP managed. Kimyrsa should not be added to the GHP Family pharmacy formulary. The following prior authorization criteria will apply:

1. Medical record documentation that patient is ≥ 18 years of age AND
2. 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
3. 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 intolerance to or contraindication to Orbactiv (oritavancin)

AUTHORIZATION DURATION: Approval will be for one (1) week and will be limited to one (1) treatment course (up to 1,200 mg as a single dose)

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

InPen (insulin delivery system)

Review: InPen is a reusable pen injector for single-patient home use by people with diabetes under the supervision of an adult caregiver, or by a patient age 7 and older for the self-injection of a desired dose of insulin. The pen injector is compatible with Lilly Humalog U-100 3.0 mL cartridges, Novo Nordisk Novolog U-100 3.0 mL cartridges, and Novo Nordisk Fiasp U-100 3.0 mL cartridges and single-use detachable and disposable pen needles (not included). The pen injector allows the user to dial the desired dose from 0.5 to 30 units in one-half (1/2) unit increments. The InPen dose calculator, a component of the InPen App, is indicated for the management of diabetes by people with diabetes under the supervision of an adult caregiver, or by a patient age 7 and older for calculating an insulin dose or carbohydrate intake based on user entered data. For an insulin dose based on amount of carbohydrates, a healthcare professional must provide patient specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the software prior to use. For an insulin dose based on fixed/variable meal sizes, a healthcare professional must provide patient specific fixed doses/meal sizes to be programmed into the software prior to use.

Key Features:

- Reusable for one year - no charging needed
- Keeps track of user's active insulin
- Reminds user to dose
- Monitors insulin temperature
- Automatically logs doses
- Integrates with CGMs
- Creates shareable reports with time-based meal analysis
- Integrates with Bluetooth-connected glucose meters
- Helps user make decisions based on their data

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Although InPen is labeled as a device it is not available via DME. The only option for procurement is through a pharmacy. It is recommended that InPen not be added to the prescription drug formulary. The following prior authorization criteria should apply:

- Medical record documentation of a diagnosis of diabetes mellitus **AND**
- Medical record documentation that InPen is prescribed by or in consultation with an endocrinologist **AND**
- Medical record documentation of age greater than or equal to 7 years **OR** age less than 7 years and documentation that InPen will be utilized with adult supervision **AND**
- Medical record documentation that member has access to a device with the ability to install and use the InPen app (e.g. smartphone, tablet, etc. with iOS 10 or later or Android 6 or later) **AND**

- Medical record documentation that member has utilized multiple daily injections of insulin (i.e. at least 3 injections per day), with frequent self-adjustments of insulin dose for at least 6 months **AND**
- Medical record documentation that member has suboptimal blood sugar control despite appropriate management as demonstrated by at least one of the following:
    - Glycosylated hemoglobin level (HbA1c) > 7.0 %
    - History of recurring hypoglycemia
    - Wide fluctuations in blood glucose before mealtime
    - History of severe glycemic excursions

Quantity Limit: 1 pen per 365 days

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

FAST FACTS

Briviact

Updated Indication: Briviact is indicated for the treatment of partial-onset seizures in patients 1 month of age and older.

Recommendation: No changes are needed to the formulary placement of Briviact. It is recommended to update the age requirement in the Briviact policy from 4 years to 1 month.

Outcome: The committee unanimously voted to accept the recommendations.

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

Erbitux

Updated Indication: Erbitux is now indicated, in combination with encorafenib, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy.

Recommendation: No changes are recommended to the formulary placement of Erbitux. Currently, Erbitux is available without a prior authorization and no changes are needed to incorporate the new indication.

Outcome: The committee unanimously voted to accept the recommendations.

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

Keytruda

Updated Indication: Keytruda now has an indicated for combination with chemotherapy, with or without bevacizumab, for the treatment of patients with persistent, recurrent or metastatic cervical cancer whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test

Recommendation: There are no changes recommended to the formulary placement or authorization duration of Keytruda. The following changes are recommended to the criteria in the policy:

8. Cervical Cancer

- Prescription written by a hematologist/oncologist AND
- One of the following:
    - Medical record documentation of recurrent or metastatic cervical cancer AND
    - Medical record documentation that tumors express PD-L1 (CPS≥1) AND
    - Medical record documentation of disease progression after receiving at least one prior line of therapy

OR

- Medical record documentation of persistent, recurrent or metastatic cervical cancer AND
- Medical record documentation that tumors express PD-L1 (CPS≥1) AND
- Medical record documentation that Keytruda will be used in combination with chemotherapy (paclitaxel, cisplatin or carboplatin), with or without bevacizumab

Outcome: The committee unanimously voted to accept the recommendations.

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

Tecartus

Updated Indication: Tecartus is now indicated for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

Recommendation: No changes are recommended to the formulary placement of Tecartus. It is recommended that the criteria are updaed to:

Mantle Cell Lymphoma (MCL)

- Medical record documentation that Tecartus is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed or refractory mantle cell lymphoma (MCL)

Acute Lymphoblastic Leukemia (ALL)

- Medical record documentation that Tecartus is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

Outcome: The committee unanimously voted to accept the recommendations.

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

Trikafta

Updated Indication: Trikafta is indicated for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who have at least one *F508del* mutation in the *CFTR* gene or a mutation in the *CFTR* gene that is responsive based on *in vitro* data. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one *F508del* mutation or a mutation that is responsive based on *in vitro* data.

Recommendation: No changes are recommended to the formulary placement of Trikafta. It is recommended that the age requirment in the policy be updated from 12 years to 6 years.

Outcome: The committee unanimously voted to accept the recommendations.

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

October Electronic Vote

Due to the volume of full drug reviews, fast facts, and updates that must reviewed by the P&T Committee an additional electronic vote was held from October 20, 2021 to October 27, 2021. Responses were received from 22 members (out of 39) and all voted to approve.

The following was approved for GHP Family:

Drug	Recommendation
Empaveli	Empaveli is a medical or a pharmacy benefit and should be added to the Brand tier of GHP Family pharmacy formulary. The following criteria will apply: • Medical record documentation of a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) • 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: o 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 o 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

Dalvance	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 ≥ 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 cutanenous 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).

Opdivo	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 radial 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 (≥ 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 (≥ 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.
Ultomiris	There are no changes recommended for the formulary placement or authorization duration. The following change is recommended for Medical Benefit Policy 196.0 for Ultomiris. **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.
Tecentriq	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 AND ○ Medical record documentation that tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 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 Cotelliq (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.

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

Meeting adjourned at 4:15 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on January 18th, 2022 at 1:00 p.m.

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 or will be held virtually