P&T Committee Meeting Minutes
Medicaid
July 20, 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
Kim Castelnovo	Rajneel Farley, Pharm.D.
Dean Christian, MD	Kelly Faust Pharm.D.
Kimberly Clark, Pharm.D.	Keith Hunsicker, Pharm.D.
Tricia Heitzman, Pharm.D.	Kelli Hunsicker, Pharm.D.
Nichole Hossler, MD	Jonas Pearson, RPh
Jason Howay, Pharm.D.	William Seavey, Pharm.D.
Derek Hunt, Pharm.D.	Michael Shepherd, MD
Phillip Krebs, R.EEG T	Richard Silbert, MD
Perry Meadows, MD	Michael Spishock, RPh
Jamie Miller, RPh	Robert Strony, MD MBA
Austin Paisley, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Renn, Pharm.D.	
Angela Scarantino	
Kristen Scheib, Pharm.D.	
Leslie Shumlas, Pharm.D.	
Aubrielle Smith Pharm.D.	
Todd Sponenberg, Pharm.D.	
Jill Stone, Pharm.D.	
Kevin Szczecina, RPh	
Amanda Taylor, MD	
Brandon Whiteash, Pharm.D.	
Adam Root (non-voting participant)	

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:04 p.m., Tuesday, July 20, 2021.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the May 18, 2021 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Jemperli (dostarlimab-gxly)

Review: Jemperli is a programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer (EC), as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen. Jemperli is the third anti-PD-1 monoclonal antibody approved in the United States along with Keytruda and Opdivo. NCCN recommendations in uterine cancer recommend Jemperli, Keytruda, and Opdivo (off-label) as biomarker-directed systemic therapy for second-line treatment that is useful in certain circumstances

(category 2A for all). Other studies and cohorts of the GARNET trial are evaluating Jemperli for earlier lines of treatment in endometrial cancer and as monotherapy and combination therapy across multiple tumor types and other cancers, including ovarian cancer, non-small cell lung cancer, multiple myeloma, and melanoma.

The efficacy of Jemperli was evaluated in the GARNET study, a multi-cohort, open-label study in adult patients with advanced solid tumors. The efficacy population consisted of 71 patients with mismatch repair deficient (dMMR) recurrent or advanced EC who had progression on or after treatment with a platinum-containing regimen. Patients were treated with Jemperli 500 mg intravenously every 3 weeks for 4 doses followed by 1,000 mg intravenously every 6 weeks until disease progression or unacceptable toxicity. The major efficacy outcomes demonstrated an overall response rate (ORR) of 42.3% and a median duration of response (DOR) that was not reached at the time of analysis (range 2.6 months to 22.4+ months [ongoing]).

There are no black box warnings for Jemperli. There are warnings for immune-mediated adverse reactions, including immune-mediated pneumonitis, colitis, hepatitis, endocrinopathies, nephritis with renal dysfunction, and dermatologic adverse reactions. Other warnings include infusion-related reactions, embryo-fetal toxicity, and complications with allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/PD-L1 blocking antibody (graft-versus-host disease, hepatic veno-occlusive disease, and steroid-requiring febrile syndrome). The most common adverse reactions were fatigue/asthenia, nausea, diarrhea, anemia, and constipation.

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

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

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

- Medical record documentation that Jemperli 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 recurrent or advanced endometrial cancer **AND**
- Medical record documentation of mismatch repair deficient (dMMR) as determined by an FDA approved test **AND**
- Medical record documentation of disease progression on or following prior treatment with a platinum-containing regimen

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.

Zynlonta (loncastuximab tesirine-lpyl)

Review: Zynlonta is a CD19-directed antibody and alkylating agent conjugate indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade

lymphoma, and high-grade B-cell lymphoma. It will compete with other third-line or later treatment options which include CD19-directed CAR-T therapies Breyanzi, Kymriah, and Yescarta, and the nuclear export inhibitor Xpovio, and potentially with the second-line or later treatment options Polivy and Monjuvi (another CD19-directed antibody). Currently, there having been no trials directly comparing the different third-line treatment options and NCCN does not prefer one third-line option over another.

The efficacy of Zynlonta was evaluated in the LOTIS-2 trial, an open-label, single arm trial in 145 adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after at least 2 prior systemic regimens. Patients received Zynlonta 0.15 mg/ kg every 3 weeks for 2 cycles, then 0.0075 mg/kg every 3 weeks for subsequent cycles until disease progression or unacceptable toxicity. The primary efficacy endpoint evaluating overall response rate (ORR) as assessed by an independent review committee (IRC) using Lugano 2014 criteria demonstrated a 48.3% ORR with a median duration of response of 10.3 months.

There are no black box warnings for Zynlonta. Warnings and precautions include effusion (pleural and pericardial) and edema, myelosuppression, fatal and serious infections, cutaneous reactions, and embryo-fetal toxicity. In the pooled safety data in 215 patients from LOTIS-2 and another trial, the most common (>20%) adverse reactions were thrombocytopenia, increased gamma-glutamyltransferase, neutropenia, anemia, hyperglycemia, transaminase elevation, fatigue, hypoalbuminemia, rash, edema, nausea, and musculoskeletal pain.

Clinical Discussion: Dr. Yarczower asking if B-cell lymphoma is included in VIA Oncology Pathways? Unable to answer as this time. The committee unanimously voted to accept the recommendations.

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

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

- Medical record documentation that Zynlonta 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 relapsed or refractory large B-cell lymphoma including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma **AND**
- Medical record documentation of prior treatment with two or more lines of systemic therapy

Authorization Duration: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 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.

Nulibry (fosdenopterin)

Review: Nulibry is a substrate replacement therapy providing an exogenous source of cyclic pyranopterin monophosphate (cPMP) indicated to reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A. It is the first treatment approved for MoCD Type A. Prior to the approval of Nulibry, the

management of MoCD was mainly supportive to provide symptomatic relief and included antiepileptic medications and low sulfur diets with sulfate supplementation.

The efficacy of Nulibry for the treatment of MoCD Type A was established based on data from three clinical studies (Study 1, 2, and 3) that were compared to data from a natural history study. Efficacy was accessed in a combined analysis of 13 patients with genetically confirmed MoCD Type A from Study 1 (n=8), Study 2 (n=1), and Study 3 (n=4) who received Nulibry or rcPMP. The age of first dose was ≤ 14 days for 10 patients and ≥ 32 days and < 69 days for the remaining 3 patients. Efficacy compared overall survival in pediatric patients treated with Nulibry or rcPMP (n=13) with an untreated natural history cohort of pediatric patients with genetically confirmed MoCD Type A who were genotype matched to the treated patients (n=18). Patients treated with Nulibry or rcPMP had an improvement in overall survival compared to the untreated, genotype-matched, historical control group. Earlier initiation of treatment is associated with better outcomes however even in patients with severe pre-existing brain lesions appeared to have favorable responses, with decreased seizure activity, improved levels of consciousness, and clearly reduced irritability. Treatment with Nulibry resulted in reduced urine concentrations of SSC in patients with MoCD Type A and the reduction was sustained over 48 months. The CNS SSC levels were not measured in humans, but this animal data suggests that Nulibry is able to cross the blood brain barrier and that changes in the peripheral SSC levels will reflect reductions in brain SSC. During the clinical trials of Nulibry, the lack of efficacy of cPMP was documented in five neonates with MoCD type B.

There are no black box warnings for Nulibry. Nulibry has warnings for the potential for photosensitivity based on findings in animal studies. The most common adverse reactions included respiratory infections and complications related to the central venous catheter. Additional safety data evaluating rcPMP showed adverse reactions consistent with those in Nulibry-treated patients, but all included additional adverse reactions of sepsis, oral candidiasis, varicella, fungal skin infection, and eczema.

Clinical Discussion: Dr. Yarczower questioned the rationale for starting treatment even with a presumptive diagnosis. Treatment should be started as early as possible, even if diagnosis is only presumptive in order to stop progression. Is there a newborn screening test for MoCD? Some patients in trials had family history and had neonatal testing. Uncertain if it's included in all neonatal screenings at this time. Will investigate who can perform this testing and how long it takes to receive results. Is there a point at which treatment is futile or should everyone receive treatment? Clinical trials treated all patient and those patients did see improvements in seizure activity, etc. Even though it's only indicated to improve mortality, patients did have some other positive outcomesThe committee unanimously voted to accept the recommendations.

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

Outcome: Nulibry is a medical benefit or a pharmacy benefit that will be managed by GHP and should be added to the GHP Family formulary on the Brand Tier. The following prior authorization criteria will apply:

- Medical record documentation that Nulibry is prescribed by a neonatologist, geneticist, or pediatric neurologist **AND**
- Medical record documentation of a diagnosis of molybdenum cofactor deficiency (MoCD) Type A as confirmed by genetic testing indicating a mutation in the molybdenum cofactor synthesis gene 1 (MOCS1) gene **OR**
- Medical record documentation of both of the following:
    - Documentation of biochemical and clinical features consistent with a diagnosis of molybdenum cofactor deficiency (MoCD) Type A, including but not limited to encephalopathy, intractable seizures, elevated urinary S-sulfocysteine levels, and decreased uric acid levels **AND**
    - Documentation that the member will be treated presumptively while awaiting genetic confirmation

AUTHORIZATION DURATION:
For patients with a presumptive diagnosis of molybdenum cofactor deficiency (MoCD) Type A awaiting genetic confirmation:
Approval will be given for an **initial duration of one (1) month** or less if the reviewing provider feels it is medically appropriate and will require:

- Medical record documentation of genetic testing confirming a diagnosis of molybdenum cofactor deficiency (MoCD) Type A.

For patients with genetically confirmed MoCD Type A diagnosis:
Approval will be given for an initial **duration of twelve (12) months**. Subsequent approvals will be for a **duration of twelve (12) months** or less if the reviewing provider feels it is medically appropriate and will require:

- Medical record documentation of a clinically significant positive response or lack of disease progression with Nulibry treatment.

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

Evkeeza (evinacumab-dgnb)

Review: Evkeeza is a recombinant human monoclonal antibody that binds to and inhibits angiopoietin-like 3 (ANGPTL3) indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 12 years and older, with homozygous familial hypercholesterolemia (HoFH). It offers a new mechanism of action for the treatment of patients with HoFH who often require multiple intensive LDL-lowering therapies to reach their LDL goals. The treatment guidelines for the management of dyslipidemias and HoFH have not been updated since the approval of Evkeeza but it is expected that placement in therapy will be similar to Juxtapid which is also is reserved for patients who have failed other LDL-C lowering therapies and lipoprotein apheresis.

The efficacy of Evkeeza was evaluated in the ELIPSE-HoFH trial, a double-blind, randomized, placebo-controlled trial evaluating the efficacy and safety of Evkeeza compared to placebo in 65 patients 12 years of age and older with homozygous familial hypercholesterolemia (HoFH). During the 24-week, double-blind treatment period, patients were randomized to treatment with Evkeeza 15 mg/kg IV every 4 weeks (n=43) or placebo (n=22). After the double-blind treatment period, 64 of 65 patients entered a 24-week open-label extension period during which all patients received treatment with Evkeeza.

The primary efficacy endpoint was percent change in LDL-C from baseline to week 24. At week 24, the least mean squares difference between Evkeeza and placebo in mean percent change in LDL-C from baseline was -49%. After 24 weeks of open-label treatment (Week 24 to 48), the observed LDL-C reduction from baseline was similar in patients who crossed over from placebo to Evkeeza and was maintained in patients who remained on Evkeeza for 48 weeks. At Week 24, the observed reduction in LDL-C was consistent across all predefined subgroups, including age, limited LDLR activity, concomitant treatment with lipoprotein apheresis, and concomitant background lipid-lowering medications.

There are no black box warnings for Evkeeza. There are warnings for serious hypersensitivity reactions (including 1 case of anaphylaxis during clinical trials) and embryo fetal toxicity based on animal reproduction studies. During clinical trials, the most common adverse reactions which occurred in over 3% of patients treated

with Evkeeza and were greater than placebo included nasopharyngitis, influenza like illness, dizziness, rhinorrhea, nausea, pain in extremities and asthenia.

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

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

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

- Medical record documentation of a diagnosis of homozygous familial hypercholesterolemia that is caused by mutations of the low-density lipoprotein (LDL) receptor (LDLr) gene **AND**
- Medical record documentation that Evkeeza is prescribed by a lipidologist or cardiologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of failure to adequately control low-density lipoprotein (LDL) levels with combination of maximum tolerated statin dose and low-density lipoprotein (LDL) apheresis treatment defined as:
    - Greater than or equal to 135 mg/dL in pediatric patients greater than or equal to 12 years of age and less than 18 years of age OR
    - Greater than or equal to 100 mg/dL in adult patients without cardiovascular disease OR
    - Greater than or equal to 70 mg/dL in adult patients with established cardiovascular disease

AND

- Medical record documentation of Evkeeza to be used in adjunct with maximum tolerated statin dose AND low density lipoprotein (LDL) apheresis AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one formulary proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor.

AUTHORIZATION DURATION: Initial authorization will be for a period of six (6) months. 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 that current medical necessity criteria are met and that therapy has been effective.

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

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Lupkynis (voclosporin)

Review: Lupkynis is a calcineurin-inhibitor immunosuppressant indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis (LN). Safety and efficacy of Lupkynis have not been established in combination with cyclophosphamide.

Both the American College of Rheumatology (ACR) and the Kidney Disease Improving Global Outcome (KDIGO) practice guidelines recommend the following or Class III and IV LN: mycophenolate mofetil (MMF) at a dose of 2 to 3 grams total daily (preferred) or cyclophosphamide for 6 months with glucocorticoids as induction therapy, followed by maintenance therapy with azathioprine, MMF, or a calcineurin inhibitor (CNI), and a low-dose steroid. The average length of immunosuppression in LN can be ≥3 years with up to 60% of patients never reaching full remission with current therapies. Lupkynis is the first oral treatment for lupus nephritis (LN). It is the second medication approved for LN, following Benlysta in December 2020. Lupkynis and Benlysta will likely be added to induction therapy and continued into maintenance therapy, pending results of longer-term extension studies.

Lupkynis is supplied as 7.9 mg capsules. Four individual 3 x 5 blister strips are assembled into a cardboard wallet. Lupkynis is available in a wallet containing 60 capsules or a carton containing 3 wallets (180 capsules). The recommended starting dose of Lupkynis is 23.7 mg twice daily. Lupkynis should be used in combination with mycophenolate mofetil (MMF) and corticosteroids. Prior to starting Lupkynis therapy, eGFR should be checked, Lupkynis is not recommended in patients with a baseline eGFR ≤ 45 mL/min/1.73 m2 unless the benefit exceeds the risk. If the patient does not experience therapeutic benefit by 24 weeks, consider discontinuation of Lupkynis. The safety and efficacy have not been established beyond one year.

The safety and efficacy of Lupkynis were investigated in Study 1, a 52-week, randomized, double-blind, placebo-controlled trial in patients (n=357) with a diagnosis of systemic lupus erythematosus and with International Society of Nephrology/Renal Pathology Society (ISN/RPS) biopsy-proven active Class III or IV LN (alone or in combination with Class V LN) or Class V LN. A total of 357 patients with LN were randomized in a 1:1 ratio to receive either Lupkynis 23.7 mg twice daily or placebo. Patients in both arms received background treatment with MMF and corticosteroids. Patients with baseline eGFR ≤45 mL/min/1.73 m2 were not enrolled in this study. The primary efficacy endpoint was the proportion of patients achieving complete renal response at Week 52, defined as the following: UPCR of ≤ 0.5 mg/mg and eGFR ≥ 60 mL/min/1.73 m2 or no confirmed decrease from baseline in eGFR of > 20% or no-treatment- or disease-related eGFR-associated event (defined as blood creatinine increased, creatinine renal clearance decreased, glomerular filtration rate decreased, serum creatinine increased, renal impairment, renal failure, or renal failure acute) at time of assessment. In order to be considered a responder, the patient must not have received more than 10 mg prednisone for ≥ 3 consecutive days or for ≥ 7 days in total during Weeks 44 through 52. A statistically significant higher proportion of patients in the Lupkynis arm (40.8%) achieved complete renal response at Week 52 compared to placebo (22.5%). A higher proportion of patients in the Lupkynis arm than the placebo arm achieved complete renal response at Week 24. Time to UPCR of ≤ 0.5 mg/mg was shorter in the Lupkynis arm than the placebo arm. Results were consistent regardless of baseline patient characteristics, suggesting a similar treatment response regardless of race and ethnicity. A phase 3 continuation study is ongoing to assess long-term safety and efficacy for an additional 24 months, following the 52-week period. Results are expected in August 2021.

Lupkynis has a boxed warning for increased risk for developing serious infections and malignancies with Lupkynis or other immunosuppressants that may lead to hospitalization or death. Lupkynis is contraindicated in patients concomitantly using strong CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, clarithromycin). Lupkynis, like other calcineurin-inhibitors, may cause acute and/or chronic nephrotoxicity. Lupkynis may also cause hypertension, neurotoxicity, hyperkalemia, QTc prolongation. The most common adverse reactions (≥3%) were glomerular filtration rate decreased, hypertension, diarrhea, headache, anemia, cough, urinary tract infection, abdominal pain upper, dyspepsia, alopecia, renal impairment, abdominal pain, mouth ulceration, fatigue, tremor, acute kidney injury, and decreased appetite. The safety and efficacy of Lupkynis in pediatric patients has not been established.

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

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

Outcome: Lupkynis will be a pharmacy benefit. It is recommended to not add Lupkynis to the GHP Family formulary. Lupkynis will require a prior authorization with the following criteria:

- Medical record documentation of a diagnosis of active lupus nephritis, Class III, IV, V alone or in combination, confirmed by a kidney biopsy AND
- Medical record documentation of age greater than or equal to 18 AND
- Prescription written by or in consultation with a rheumatologist or nephrologist AND

- Medical record documentation that Lupkynis will be prescribed in combination with a background immunosuppressive therapy regimen (e.g. mycophenolate mofetil (MMF) and corticosteroids) AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Benlysta* **AND**
- Medical record documentation that Lupkynis is prescribed with a dose of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Authorization Duration: Initial approval will be for 6 months. Subsequent approvals will be for 12 months. Re-authorization will require the following:

- Medical record documentation of a positive clinical response to Lupkynis (e.g. improvement/stabilization in UPCR, eGFR, renal-related events) AND
- Medical record documentation that Lupkynis will be prescribed in combination with a background immunosuppressive therapy regimen (e.g. mycophenolate mofetil (MMF) and corticosteroids) AND
- Medical record documentation that Lupkynis is prescribed with a dose of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

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

Rybrevant (amivantamab-vmjw)

Review: Rybrevant is a human immunoglobulin G1-based bispecific antibody that binds the extracellular domains of EGF and MET receptors. It is the first bispecific antibody approved for the treatment of non-small cell lung cancer (NSCLC) which targets EGFR exon 20 insertion mutations. Prior to the approval of Rybrevant, patients with exon 20 insertion mutations had no targeted therapies or clear subsequent treatment options following progression on platinum-based chemotherapy.

The efficacy of Rybrevant was evaluated in one cohort of the CHRYSALIS trial, an open-label, multicohort trial in patients with locally advanced or metastatic NSCLC with EGFR exon 20 insert mutations whose disease had progressed on or after platinum-based chemotherapy. Patients received Rybrevant 1050 mg (for patient baseline body weight < 80 kg) or 1400 (for patient baseline body weight ≥ 80 kg) once weekly for 4 weeks, then every 2 weeks thereafter until disease progression or unacceptable toxicity. The major efficacy outcome evaluating overall response rate according to RECIST v1.1 evaluated by Blinded Independent Central Review (BICR) demonstrated a 40% response rate, with a majority of patients having a partial response. The median duration of response was 11.1 months, with 63% of patients having a response lasting at least 6 months.

There are no black box warnings for Rybrevant. Rybrevant carries warnings for infusion related reactions (IRR) which occurred in 66% of patients treated with Rybrevant, most commonly with the initial infusion on Week 1, Day 1. Other warnings and precautions include interstitial lung disease (ILD)/pneumonitis, dermatologic adverse reactions, ocular toxicity, and embryo fetal toxicity. During the CHRYSALIS trial, the most common adverse reactions were rash, IRR, paronychia, musculoskeletal pain, dyspnea, nausea, fatigue, edema, stomatitis, cough, constipation, and vomiting.

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

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

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

- Medical record documentation that Rybrevant 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 with locally advanced or metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of epidermal growth factor receptor (EGFR) exon 20 insertion mutations as determined by an FDA approved test* **AND**
- Medical record documentation of disease progression on or following prior treatment with a platinum-based chemotherapy.

OR

- Medical record documentation of use for a medically accepted indication.

Authorization Duration (All LOB): 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.

***NOTE:** The FDA approved test for Rybrevant to detect the presences of EGFR exon 20 insertion mutations is the Guardant360® CDx.

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

FAST FACTS

Nplate

Updated Indication: Nplate is now indicated to increase survival in adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [HS-ARS])..

Recommendation: There are no changes to the current formulary placement of Nplate. It is recommended that the following criteria and auth duration be added to Medical Benefit Policy to incorporate the new indication.

HS-ARS

- Medical record documentation of Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS) AND
- Medical record documentation of suspected or confirmed acute exposure to myelosuppressive doses of radiation (estimated as radiation levels greater than 2 gray [Gy]).

Authorization Duration for HS-ARS: One-time authorization for one administration of Nplate

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.

Rapivib

Updated Indication: Rapivab is an influenza virus neuraminidase inhibitor now indicated for the treatment of acute uncomplicated influenza in patients 6 months and older who have been symptomatic for no more than two days.

Recommendation: no changes recommended

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:

- in combination with trastuzumab and fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic HER2 positive gastric or gastroesophageal junction adenocarcinoma. Previously Keytruda was indicated for third-line treatment of PD-L1 positive recurrent or metastatic gastric or GEJ adenocarcinoma.
- for the treatment of patients with locally advanced cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation. Previously Keytruda was indicated for recurrent and metastatic disease.

Recommendation: Make the following updates to the policy:

Gastric Cancer

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of a diagnosis of recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma **AND**
    - Medical record documentation that tumors express PD-L1 (combined positive score [CPS] greater than or equal to 1) as determined by an FDA-approved test **AND**
    - Medical record documentation of disease progression on or after two or more prior lines of therapy (including fluoropyrimidine- and platinum-containing chemotherapy)* **AND**
    - If patient has HER2-positive disease, medical record documentation of disease progression on or after HER2/neu-targeted therapy (including but not limited to trastuzumab (Herceptin))*

OR

- Medical record documentation of a diagnosis of locally advanced unresectable or metastatic HER-2 positive gastric or gastroesophageal junction adenocarcinoma **AND**
- Medical record documentation that Keytruda will be used as first-line treatment **AND**
- Medical record documentation that Keytruda will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy

*Note to reviewer: Current recommendations intend Keytruda to be used as third-line treatment (i.e. patient is to have 2 prior lines of therapy, one of which must include HER2/neu-targeted therapy if the patient has HER-2 positive disease)

Cutaneous Squamous Cell Carcinoma (cSCC)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of recurrent or metastatic cutaneous squamous cell carcinoma **OR** locally advanced cutaneous squamous cell carcinoma **AND**
- Medical record documentation that the patient's disease is not curable by surgery **AND**
- Medical record documentation that the patient's disease is not curable by radiation.

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.

Benlysta

Updated Indication: Benlysta is now indicated in adult patients with active lupus nephritis (LN) who are receiving standard therapy.

Recommendation: There are no changes to the current formulary status. However, it is recommended to add a section to the Benlysta SC and Benlysta vial policies for Lupus Nephritis. It is also recommended to update the note in the SC policy to the following: "Note: Benlysta has not been studied in combination with other biologics. Use of Benlysta is not recommended in these situations". It is also recommended to update the limitation from the vial policy to the following: "Limitation: Benlysta has not been studied in combination with other biologics. Use of Benlysta is not recommended in these situations."

- Medical record documentation of a diagnosis of active lupus nephritis, Class III, IV, V alone or in combination, confirmed by a kidney biopsy AND
- Medical record documentation of age greater than or equal to 18 AND
- Prescription written by or in consultation with a rheumatologist or nephrologist AND
- Medical record documentation that Benlysta will be prescribed in combination with standard therapy (e.g. mycophenolate mofetil (MMF), corticosteroids, cyclophosphamide, azathioprine)

Authorization Duration: Initial approval will be for 12 months. Subsequent approvals will be for 12 months. Re-authorization will require the following:

- Medical record documentation of a positive clinical response to Benlysta (e.g. improvement/stabilization in UPCR, eGFR, renal-related events) AND
- Medical record documentation that Benlysta will be prescribed in combination with standard therapy (e.g. mycophenolate mofetil (MMF), corticosteroids, cyclophosphamide, azathioprine)

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.

Yervoy

Updated Indication: Yervoy is now indicated in combination with nivolumab (Opdivo) for the treatment of adult patients with unresectable or metastatic melanoma

Recommendation: Update the policy to:
Melanoma

- Prescription written by a hematologist/oncologist AND
- Medical record documentation of unresectable or metastatic melanoma AND
- One of the following:
    - Medical record documentation of use in combination with nivolumab for first line therapy OR
    - Medical record documentation of use as a single agent or in combination with nivolumab as second-line or subsequent therapy for disease progression if not previously used **OR**
    - Medical record documentation of use as a single-agent reinduction therapy in select patients who experienced no significant systemic toxicity during prior ipilimumab therapy and who relapse after initial clinical response or progress after stable disease >3 months

OR

- Prescription written by a hematologist/oncologist AND
- Medical record documentation of use as a single agent for adjuvant therapy:
    - For Stage IIIA with metastases > 1 mm, or Stage IIIB or Stage IIIC cutaneous melanoma with nodal metastases following a complete lymph node dissection or resection **OR**
    - Following complete lymph node dissection and/or complete resection of nodal recurrence

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.

Trodelvy

Updated Indication: Trodelvy is now indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.

Recommendation: Update the policy to:
Melanoma
Breast Cancer

- Medical record documentation that Trodelvy is written by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of unresectable locally advanced or metastatic triple-negative breast cancer* **AND**
- Medical record documentation of trial of at least two previous lines of systemic therapy, of which at least one was for metastatic disease

***Note:** Triple negative breast cancer lacks expression of estrogen receptor (ER-negative), progesterone receptor (PR-negative) and human epidermal growth factor receptor 2 (HER2-negative).

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.

Updates

GHP Family

Recommendation: Approve the following:

Policy 1252.0F Controlled Substances – Buprenorphine

The HealthChoices contract prohibits PH-MCOs from imposing additional prior authorization requirements for drugs and products included on the Statewide PDL. As a result, Policy 1252.0F has been retired and only the PDL policies will be applied.

Policy 1362.0F Remodulin SQ

During DHS' annual policy review, the criteria for Remodulin SQ was updated to match that of MBP 62.0 Remodulin IV:

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

- Prescription is written by a pulmonologist or cardiologist **AND**
- Medical record documentation that Remodulin SQ is being administered subcutaneously **AND**
- Medical record documentation of a diagnosis of class 4 pulmonary arterial hypertension **OR**
- Medical record documentation of a diagnosis of class 2 or 3 pulmonary arterial hypertension with therapeutic failure on, intolerance to or contraindication to one (1) preferred agent which is approved or medically accepted for the beneficiary's diagnosis or indication, from any of the following classes of medications
    - Endothelin Receptor Antagonist
    - Phosphodiesterase-5 Enzyme Inhibitor
    - Prostacyclin

OR

- Medical record documentation that the individual require transition from Flolan, to reduce the rate of clinical deterioration. The risks and benefits of each drug should be carefully considered prior to transition

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.

Santyl

Recommendation: update the re-authorization criteria to the following:
Authorization Duration: Initial approval will be for 3 months. Subsequent approval will be for 3 months. Reauthorization will require the following:

- Medical record documentation that the member has been evaluated by a burn, a wound care specialist, or other specialist with experience in the management of severe wounds AND
- Medical record documentation of the wound length and width AND
- Medical record documentation of anticipated duration of therapy AND
- Medical record documentation that the prescribed dose is medically necessary based on the size and intended duration of therapy*

*Note: Please calculate the dose on the manufacturer's website to confirm it is within a medically appropriate range- https://santyl.com/hcp/dosing

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.

April 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 June 18, 2021 to June 25, 2021. Responses were received from 24 members (out of 39) and all voted to approve.

The following was approved for GHP Family:

Drug	Recommendation
Abecma	Medical drug requiring prior authorization: • Medical record documentation that Abecma is prescribed by a hematologist/oncologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of relapsed or refractory multiple myeloma **AND** • Medical record documentation of at least four prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody **AND** • Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy **Authorization duration:** One-time authorization for one administration of Abecma
Klisyri	Non-formulary pharmacy benefit: • Medical record documentation that the prescription is written by a dermatologist AND • Medical record documentation of actinic keratosis of the face or scalp **AND** • Medical record documentation that Klisyri is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature AND

	• Medical record documentation of greater than or equal to 4 lesions within a contiguous 25 cm2 area AND • Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical fluorouracil AND imiquimod. **Other recommendations:** A policy will be created for diclofenac 3% gel with the following criteria: • Medical record documentation of actinic keratosis **AND** • Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical fluorouracil AND imiquimod
Zokinvy	Pharmacy drug added to the Brand Tier requiring prior authorization: • Medical record documentation of a confirmed diagnosis through genetic testing of one of the following: o Hutchinson-Gilford Progeria Syndrome o Processing-deficient progeroid laminopathy with either: ▪ Heterozygous *LMNA* mutation with progerin-like protein accumulation ▪ Homozygous or compound heterozygous *ZMPSTE24* mutations AND • Medical record documentation of age greater than or equal to 12 months AND • Medical record documentation of body surface area of at least 0.39m^2 AND • Medical record documentation that the requested dose is appropriate based on the patient's body surface area AND • Medical record documentation that all potential drug interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact) <u>Authorization Duration:</u> 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 the following: • Medical record documentation that the requested dose is appropriate based on the patient's body surface area AND • Medical record documentation that all potential drug interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact)
Carbaglu	Create prior authorization policy for NF medication: <u>N-acetylglutamate synthase (NAGS) deficiency</u> • Medical record documentation that Carbaglu is prescribed by a metabolic disorder specialist **AND** • Medical record documentation of a diagnosis of hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS) **AND**

	• Medical record documentation that Carbaglu is prescribed with a dose of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **Authorization duration:** 6 months <u>Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA)</u> • Medical record documentation that Carbaglu is prescribed by a metabolic disorder specialist **AND** • Medical record documentation of a diagnosis of propionic acidemia (PA) or methylmalonic acidemia (MMA**) AND** • Medical record documentation of plasma ammonia level greater than or equal to 50 micromol/L **AND** • Medical record documentation that Carbaglu is being prescribed as adjunctive treatment to standard of care (including but not limited to intravenous glucose, insulin, L-carnitine, protein restriction, and dialysis) **AND** • Medical record documentation that Carbaglu is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **Authorization duration**: 7 days
Opdivo	Make the following update/addition to the medical benefit policy: <u>Adjuvant Treatment of Resected Esophageal or Gastroesophageal Junction Cancer</u> • Prescription written by a hematologist/oncologist **AND** • Medical record documentation of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease **AND** • Medical record documentation that patient has received neoadjuvant chemoradiotherapy • Medical record documentation Opdivo is being used in the adjuvant setting **AND** • Medical record documentation Opdivo is being used as a single agent **(*Note: The FDA-approved treatment duration for use of Opdivo in the adjuvant setting for <u>resected esophageal or gastroesophageal junction cancer</u> is for up to 1 year, see specific reauthorization criteria below.)* <u>Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma</u> • Prescription written by a hematologist/oncologist **AND** • Medical record documentation of advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma **AND** • Medical record documentation that Opdivo will be used in combination with fluoropyrimidine- and platinum-based chemotherapy.

	AUTHORIZATION DURATION: ****For adjuvant treatment of metastatic melanoma *(completely resected melanoma*) and adjuvant treatment of resected esophageal or gastroesophageal junction cancer:** 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 and adjuvant treatment of resected esophageal or gastroesophageal junction cancer 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, 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, 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.
Trodelvy	Make the following addition to the medical benefit policy: **Urothelial Cancer** • Medical record documentation that Trodelvy is written by a hematologist/oncologist **AND** • Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation of diagnosis of locally advanced or metastatic urothelial cancer **AND** • Medical record documentation of progression on platinum-containing chemotherapy **AND** • Medical record documentation of progression on a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PDL1) inhibitor
Yescarta	Make the following addition to the medical benefit policy: **Follicular Lymphoma** • Prescription written by a hematologist/oncologist **AND** • Medical record documentation that patient is 18 years of age or older **AND** • Medical record documentation of a diagnosis of relapsed or refractory follicular lymphoma (FL) **AND** • Medical record documentation of a therapeutic failure on two or more previous lines of therapy **AND** • Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

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

Meeting adjourned at 4:42 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on Tuesday, September 21, 2021 at 1:00 via Microsoft Teams.