P&T Committee Meeting Minutes
Commercial/Marketplace/GHP Kids
January 17, 2023

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Jeremy Bennett, MD
Amir Antonius, Pharm.D.	Holly Bones, Pharm.D.
Emily Antosh, Pharm.D.	Kim Castelnovo
Kristen Bender, Pharm.D.	Michael Evans, RPh
Alyssa Cilia, RPh	Rajneel Farley, Pharm.D.
Kimberly Clark, Pharm.D.	Jason Howay, Pharm.D.
Michael Dubartell, MD	Jamie Miller, RPh
Kelly Faust Pharm.D.	Jonas Pearson, RPh
Tricia Heitzman, Pharm.D.	William Seavey, Pharm.D.
Nichole Hossler, MD	Michael Shepherd, MD
Emily Hughes, Pharm.D.	Ariana Wendoloski, Pharm.D.
Keith Hunsicker, Pharm.D.	
Kelli Hunsicker, Pharm.D.	
Derek Hunt, Pharm.D.	
Kerry Ann Kilkenny, MD	
Philip Krebs, R.EEG T	
Briana LeBeau, Pharm.D.	
Ted Marines, Pharm.D.	
Lisa Mazonkey, RPh	
Tyreese McCrea, Pharm.D.	
Perry Meadows, MD	
Mark Mowery, Pharm.D.	
Austin Paisley, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Sartori, Pharm.D.	
Angela Scarantino	
Kristen Scheib, Pharm.D.	
Leslie Shumlas, Pharm.D.	
Aubrielle Smith Pharm.D.	
Kirsten Smith, Pharm.D.	
Michael Spishock, RPh	
Todd Sponenberg, Pharm.D.	
Jill Stone, Pharm.D.	
Robert Strony, MD MBA	
Luke Sullivan, DO	
Kevin Szczecina, RPh	
Amanda Taylor, MD	
Brandon Whiteash, Pharm.D.	
Margaret Whiteash, Pharm.D.	
Joseph Alario, DO (non-voting participant)	
Benjamin Andrick, Pharm.D. (non-voting participant)	
Birju Bhatt, MD (non-voting participant)	
Jeremy Garris (non-voting participant)	
Marianne Linko (non-voting participant)	
Dionardo Medina Encarnacion, MD (non-voting participant)	
Megan Sokol (pharmacy resident)	

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, January 17, 2023.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the October 2022 e-vote, November 15, 2022, and December 2022 e-vote minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

KRYSTEXXA (pegloticase)

Review: Krystexxa is indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. Gout refractory to conventional therapy occurs in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated. Krystexxa is not recommended for the treatment of asymptomatic hyperuricemia.

Krystexxa is supplied in single-dose vials containing 8 mg/ml of uricase protein. The recommended dosage is 8 mg every two weeks given only as an intravenous infusion, co-administered with weekly methotrexate 15 mg orally. Krystexxa monotherapy may be used in patients for whom methotrexate is contraindicated or not clinically appropriate. Methotrexate with folic acid or folinic acid supplementation should be initiated at least 4 weeks prior to initiating, and throughout treatment with Krystexxa. Discontinue oral urate-lowering agents before starting Krystexxa. Serum uric acid levels should be monitored before each infusion. Treatment should be discontinued if uric acid levels increase to above 6 mg/dL, particularly when two consecutive levels above 6 mg/dL are observed. Pre-medicate patients with antihistamines and corticosteroids due to reports of anaphylaxis and infusion reactions. The risk of infusion reactions, including anaphylaxis, is higher in patients who have lost therapeutic response.

Dr. Alfred Denio, rheumatologist at Geisinger Medical Center, was consulted regarding the appropriate use of Krystexxa in clinical practice. He indicated that target population would be adults (18 years old or older) with chronic symptomatic gout that have failed allopurinol and/or febuxostat. He stated that Krystexxa should be prescribed by rheumatology and administered in combination with methotrexate or mycophenolate to decrease infusion reactions and help prevent the development of auto-drug antibodies. All patients should be screened for glucose-6-phosphate dehydrogenase (G6PD) deficiency prior to starting therapy. Uric acid should be screened prior to each infusion and should be undetectable (lab reports less than 2.0mg/dL not less than 6, and any detectable uric acid level means patient is likely developing antibodies to drug and is at high risk for infusion reaction). Finally, Dr. Denio indicated that failure of xanthine oxidase inhibitors could be demonstrated by failure of nodules to resorb in a timely fashion.

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

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

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

Outcome: Krystexxa will be a medical benefit. Krystexxa will be added to the medical benefit cost share list when processed on the medical benefit. If processed at a specialty pharmacy, Krystexxa will process at the Specialty tier or the Brand Non-preferred tier for members with a three-tier benefit. The following prior authorization criteria will apply:

- Documentation of age greater than or equal to 18 years **AND**
- Prescribed by or in consultation with a rheumatologist **AND**
- Medical record documentation of a diagnosis of chronic, symptomatic gout **AND**
- Medical record documentation that Krystexxa is being given in combination with oral methotrexate (recommended dose 15 mg weekly) **OR** intolerance or contraindication to methotrexate **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two formulary xanthine oxidase inhibitors (examples: allopurinol and febuxostat) at the maximum medically appropriate dose **AND**
- Medical record documentation that high-risk patients (e.g., patients of African, Mediterranean [including Southern European and Middle Eastern], and Southern Asian ancestry) have been screened for glucose-6-phosphate dehydrogenase (G6PD) deficiency **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

GPI Level: GPI-12

QUANTITY LIMIT: 8 mg every 14 days

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 the following:

- Continued disease improvement or lack of disease progression **AND**
- Ongoing uric acid level monitoring prior to each infusion. The two most recent uric acid levels (from within the past 8 weeks) must be submitted. In individuals whose uric acid level is above 6mg/dL for two consecutive lab draws, therapy should be discontinued, and reauthorization will not be approved

The medication will no longer be covered if the patient experienced toxicity or worsening of disease.

Attention Reviewer: The risk of infusion reactions, including anaphylaxis, is higher in patients who have lost therapeutic response. Serum uric acid levels should be monitored prior to each infusion and treatment with Krystexxa should be discontinued if levels increase to above 6 mg/dL, particularly when two consecutive levels above 6 mg/dL are observed.

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

SOTYKTU (deucravacitinib)

Review: Sotyktu is an oral tyrosine kinase 2 (TYK2) inhibitor for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Sotyktu is not recommended for use in combination with other potent immunosuppressants (limitation of use). It is the second oral immunomodulator approved for the treatment of psoriasis after Otezla. Sotyktu binds the regulatory domain of TYK2 (a member of the Janus kinase [JAK] family) resulting in inhibition of activation of TYK2 and downstream activation of Signal Transducers and Activators of Transcription (STATs). The exact mechanism of therapeutic effectiveness in the treatment of adults with psoriasis is unknown.

The recommended dosage of Sotyktu is 6 mg orally taken once daily with or without food and is supplied in 6 mg tablets. Patients should be evaluated for active or latent tuberculosis (TB) infection prior to treatment with Sotyktu. Patients with positive TB results should be treated prior to initiation of Sotyktu.

The efficacy of Sotyktu was evaluated in two randomized, double-blind, placebo- and active-controlled clinical trials, PSO-1 and PSO-2 in 1,684 adult patients with moderate-to-severe plaque psoriasis who were eligible for systemic therapy or phototherapy. Patients included in the clinical trial had a body surface area (BSA) involvement of ≥ 10%, a Psoriasis Area and Severity Index (PASI) score ≥ 12, and a static Physician's Global Assessment (sPGA) ≥ 3 (moderate or severe). Patients were randomized to Sotyktu (6 mg orally once daily), placebo, or apremilast (30 mg twice daily).

The two co-primary endpoints in PSO-1 and -2 were Week 16 comparison to placebo for proportion of patients who achieved a sPGA score of 0 (clear) or 1 (almost clear) with at least a 2-grade improvement from baseline and the proportion of patients achieving at least a 75% improvement in PASI scores from baseline. Secondary endpoints included Week 16 comparison to placebo for the proportion of patients who achieved PASI 90, PASI 100, sPGA 0, scalp severity PGA (ssPGA) score of 0 or 1, and Psoriasis Symptoms and Signs Diary (PSSD) Symptom score of 0. Secondary endpoints comparing Sotyktu to apremilast were Week 16 and Week 24 assessments of the proportion of patients who achieved PASI 75, PASI 90, and sPGA 0/1 with at least 2-grade improvement and Week 16 assessment of the proportion of patients who achieved sPGA 0 and ssPGA 0/1 with at least 2-grade improvement.

Efficacy results of PSO-1 and -2 are shown in Tables 4 and 5. Maintenance and durability of response were also assessed. Results in PSO-1 showed that 82% of patients who achieved a PASI 75 response at Week 24 maintained the response to Week 52 and 74% of patients who achieved a PASI 90 response at Week 24 maintained the response at Week 52. In PSO-2, patients who were originally randomized to Sotyktu were re-randomized to continue treatment or switched to placebo. For patients who were re-randomized and had a sPGA score of 0/1 at week 24, 70% of patients continuing on Sotyktu maintained the response at Week 52 compared to 24% of patients who were re-randomized to placebo.

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

Clinical Discussion: Can you use a medication like a DMARD in combination with Sotyktu? Yes, it appears to only be other biologic medications that should not be used in combination. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: It was confirmed that Otezla does have rebates available similar to Humira and Cosentyx. Does the member need to fail medications in different classes, or is it acceptable to fail two in the same class? No requirements around what alternatives must come first. No additional comments or questions. The committee unanimously voted to accept the recommendations as amended. None were opposed.

Outcome: Sotyktu is a pharmacy benefit and will not be added to the Commercial, Exchange, or GHP Kids pharmacy formularies. The following prior authorization criteria will apply:

- Medical record documentation that Sotyktu is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation of an intolerance to, contraindication to or therapeutic failure on four (4) preferred formulary biologics for the treatment of psoriasis **AND**
- Medical record documentation that Sotyktu is not being used concurrently with a tumor necrosis factor TNF blocker or other biologic agent

GPI Level: GPI-12

AUTHORIZATION DURATION: Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of plaque psoriasis on Sotyktu therapy is required.

QUANTITY LIMIT: 1 tablet per day

RPH SIGNOFF REQUIRED: Yes

FORMULARY ALTERNATIVES: Enbrel, Humira, Otezla, Skyrizi, Tremfya, Cosentyx, Cimzia, Ilumya, Siliq

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

LYTGOBI (futibatinib)

Review: Cholangiocarcinomas are rare malignancies arising from the epithelial cells of the intrahepatic and extrahepatic bile ducts and have a poor prognosis with a median survival of 24 months. Surgery provides the only possibility for cure, but only a minority of patients present with early-stage disease and are considered candidates for resection.

Lytgobi (futibatinib) is a kinase inhibitor indicated for the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements. The FGFR pathway is involved in cell proliferation, migration, survival, and differentiation. By inhibiting FGFR, Lytgobi decreases proliferation and survival of malignant cells.

Lytgobi is the third FGFR2 inhibitor approved by the FDA for the treatment previously treated locally advanced or metastatic CCA harboring FGFR2 gene rearrangements and is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be dependent upon clinical benefit in a confirmatory trial(s).

Efficacy results determined in FOENIX-CCA2 Phase 2 Study showed an overall response rate of 42% with a median duration of response of 9.7 months. Commonly observed serious side effects included pyrexia, gastrointestinal hemorrhage, ascites, musculoskeletal pain, and bile duct obstruction. Less severe but most common side effects included nail toxicity, musculoskeletal pain, constipation, diarrhea, fatigue, dry mouth, alopecia, stomatitis, abdominal pain, dry skin, arthralgia, dysgeusia, dry eye, nausea, decreased appetite, urinary tract infection, palmar-plantar erythrodysesthesia syndrome, and vomiting.

The recommended dosage of Lytgobi is 20mg (five 4mg tablets) taken orally once daily until disease progression or unacceptable toxicity occurs. Dose reductions are recommended for various adverse reactions including Retinal Pigment Epithelial Detachment (RPED) and hyperphosphatemia. Discontinuation of Lytgobi may be necessary in some cases.
Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: Were there exclusion criteria such that people with vision in only one eye, or people with serious retinal disease, etc. were excluded from trials? Yes, patients with serious retinal disease were excluded from trials. There was no ongoing ophthalmologic monitoring. No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

Outcome: Lytgobi will be added to the Oral Oncology Brand Non-preferred tier ($0 copay) of the Commercial, Marketplace, and GHP Kids formulary. The following prior authorization criteria will apply for new starts only:

- Medical record documentation that prescription is written by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of unresectable locally advanced or metastatic cholangiocarcinoma **AND**
- Medical record documentation of confirmed fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as verified by molecular testing **AND**
- Medical record documentation of one prior line of therapy

QUANTITY LIMIT:

- Futibatinib 12mg daily dose (GPI 2153222800B720): 84 tablets per 28 days
- Futibatinib 16mg daily dose (GPI 2153222800B725): 112 tablets per 28 days
- Futibatinib 20mg daily dose (GPI 2153222800B730): 140 tablets per 28 days

MEDISPAN AUTHORIZATION LEVEL: GPI-12

REAUTHORIZATION CRITERIA: Lytgobi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90-day break in therapy.

RPH SIGNOFF REQUIRED: Yes

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

BYOOVIZ & CIMERLI (ranibizumab-nuna/ranibizumab-eqrn)

Review: Both Byooviz and Cimerli are vascular endothelial growth factor (VEGF) inhibitors with indications consistent with those presented in the Lucentis prescribing information.

- Byooviz is indicated for the treatment of patients with:
  - neovascular (wet) age-related macular degeneration (AMD)
  - macular edema following retinal vein occlusion (RVO)
  - myopic choroidal neovascularization (mCNV)
- Cimerli is indicated for the treatment of patients with:
  - neovascular (Wet) AMD
  - macular edema following RVO
  - diabetic macular edema (DME)
  - diabetic retinopathy (DR)
  - mCNV.

Byooviz (ranibizumab-nuna) and Cimerli (ranibizumab-eqrn) are VEGF inhibitors that bind to the receptor binding site of active forms of VEGF-A, including VEGF110. When ranibizumab binds VEGF-A, it prevents interaction of VEGF-A with its receptors (VEGF1 and VEGF2) and thereby reduces endothelial cell proliferation, vascular leakage and new blood vessel formation. VEGF-A is thought to contribute to the pathophysiology of neovascular AMD, mCNV, DR, DME and macular edema following RVO.

Byooviz and Cimerli are the first and second FDA-approved Lucentis biosimilars, respectively. Byooviz is a VEGF inhibitor that is highly similar to its reference product, Lucentis, with no clinically meaningful differences between it and Lucentis. Cimerli is a VEGF inhibitor that is an interchangeable product (IP) and is highly similar to its reference product, Lucentis, with no clinically meaningful differences between it and Lucentis. Cimerli is expected to produce the same clinical results as Lucentis in any given patient. The risk in terms of safety or diminished efficacy is no greater when switching between the two products as compared to continuing Lucentis and not switching between products.

No new clinical trials were included in the Byooviz or Cimerli prescribing information. The clinical trials in the Byooviz and Cimerli prescribing information are consistent with those presented in the Lucentis prescribing information for the approved indications.

No new safety information was included in the Byooviz or Cimerli prescribing information. The contraindications, warnings and precautions, adverse events and drug interactions are consistent with those presented in the Lucentis prescribing information.

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

Clinical Discussion: Are there any concerns with how the drug is supplied compared to Lucentis? Both are supplied in single use vials, while Lucentis is also supplied as a pre-filled syringe. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

Outcome: Byooviz and Cimerli are medical benefits that require prior authorization. Byooviz and Cimerli will be added to the medical benefit cost share list when processed on the medical benefit. If processed at a specialty pharmacy, Byooviz and Cimerli will process at the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. Because Byooviz and Cimerli have been proven to be highly similar to their reference product, it is recommended that the prior authorization and associated clinical criteria of their reference product, Lucentis, outlined by MBP 47.0, apply.

MBP 47.0 Lucentis (ranibizumab), Byooviz (ranibizumab-nuna), Cimerli (ranibizumab-eqrn)
Lucentis (ranibizumab), Byooviz (ranibizumab-nuna), and Cimerli (ranibizumab-eqrn) will be considered medically necessary for the commercial, exchange, CHIP, and Medicare lines of business when ALL of the following criteria are met:

- Medical record documentation of a diagnosis of neovascular age-related macular degeneration **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin)

OR

- Medical record documentation of a diagnosis of diabetic retinopathy with or without macular edema **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin)

OR

- Medical record documentation of a diagnosis of macular edema following retinal vein occlusion **OR** myopic choroidal neovascularization

NOTE: Indicators of intravitreal bevacizumab (Avastin) failure may include:

- Worse or unchanged intraretinal or subretinal fluid.
- Persistent subretinal or intraretinal fluid.
- Recurrent intraretinal or subretinal fluid at current interval or extended interval.
- New subretinal hemorrhage
- In the absence of subretinal fluid, intraretinal fluid, or subretinal hemorrhage a failure documented as evidence of growth of the neovascular membrane on clinical exam or multimodal imaging.
- Any ocular or systemic adverse event thought related to the use of intravitreal bevacizumab.

AUTHORIZATION DURATION: Approvals will be given for a lifetime duration.

QUANTITY LIMIT: 0.1mL (1mg) per 28 days (0.5mg per eye per 28 days)

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

ZORYVE (roflumilast)

Review: Zoryve is the first phosphodiesterase-4 (PDE4) inhibitor indicated for the topical treatment of plaque psoriasis in patients 12 years of age and older. Psoriasis is a chronic, immune-mediated skin condition that affects 7.5 million adults in the United States and causes thick plaques that may itch, burn, or sting. Of the five subtypes of psoriasis, plaque psoriasis is the most common subtype. Plaque psoriasis, also known as psoriasis vulgaris, affects 80-90% of all patients with psoriasis. Treatment for plaque psoriasis includes topical therapies, phototherapies, conventional oral agents, and/or targeted immunomodulators.

Roflumilast selectively inhibits PDE4, leading to the accumulation of cyclic AMP (cAMP). The precise mechanism by which roflumilast exerts its therapeutic effects in the treatment of plaque psoriasis is not well defined. Zoryve 0.3% is supplied as a 60g tube of cream that is applied once daily to affected areas, including intertriginous areas (e.g., axilla, groin).

The efficacy of Zoryve was evaluated in DERMIS-1 and DERMIS-2, two Phase 3, multicenter, randomized, double-blind, vehicle-controlled trials. Patients 2 years of age and older were included in the trial if they had a diagnosis of plaque psoriasis for 6 or more months (3 or more months for children). A total of 881 patients with mild to severe plaque psoriasis and body surface area (BSA) of 2%–20% were randomized 2:1 to receive Zoryve 0.3% cream or vehicle cream applied once daily for 8 weeks.

The primary efficacy endpoint was the proportion of subjects who achieved Investigator Global Assessment (IGA) treatment success at Week 8. IGA treatment success was defined as a score of “clear” (0) or “almost clear” (1), plus a 2- grade improvement from baseline. At baseline, 16% had IGA score of 2 (mild), 76% had IGA score of 3 (moderate), and 8% had IGA score of 4 (severe). Patients treated with Zoryve had a significantly higher rate of IGA success compared to vehicle cream (41.5% IGA success (Zoryve) vs 5.8% IGA success (vehicle) in DERMIS-1 and 36.7% IGA success (Zoryve) vs 7.1% IGA success (vehicle) in DERMIS-2).

There are no warnings or precautions for Zoryve. Zoryve is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C). The most common adverse reactions are diarrhea, headache, insomnia, nausea, application site pain, upper respiratory tract infections, and urinary tract infections.

Zoryve has not been studied in pregnant women. The safety and efficacy of Zoryve for the treatment of plaque psoriasis was established in pediatric patients ages 12 years and older. In regard to geriatric use, no differences in the safety or efficacy of Zoryve were observed in patients 65 years and older.

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

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

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

Outcome: Zoryve will be added to the Commercial/Exchange/CHIP formularies at the Specialty Tier or Brand Non-Preferred tier for members with a 3 Tier benefit. The following prior authorization criteria will be required:

- Medical record documentation that Zoryve is prescribed by or in consultation with a dermatologist or rheumatologist **AND**
- Medical record documentation of age greater than or equal to 12 years old **AND**
- Medical record documentation of a diagnosis of chronic plaque psoriasis **AND**
- Medical record documentation of BSA involvement less than or equal to 20% **AND**
- Medical record documentation of therapeutic failure, intolerance, or contraindication to at least one of the following:
    - A high- to ultrahigh-potency TCS used concurrently with a generic topical calcipotriene product **OR**
    - A generic calcipotriene/betamethasone combination product **OR**
    - A high- to ultrahigh-potency TCS used concurrently with generic tazarotene 0.1%

GPI Level: GPI-12

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent approvals will be for an additional 12 months and will require medical record documentation of the following.

- Medical record documentation of clinical improvement based on signs and symptoms of plaque psoriasis

QUANTITY LIMIT: 60g (1 tube) every 30 days

FORMULARY ALTERNATIVES: calcipotriene, calcipotriene-betamethasone, tazarotene, betamethasone, betamethasone-dipropionate, clobetasol, halobetasol

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

TERLIVAZ (terlipressin)

Review: Terlivaz is a vasopressin receptor agonist indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function. Patients with a serum creatinine > 5 mg/dL are unlikely to experience benefit. The American Association for the Study of Liver Diseases issued a guidance statement in 2021 recommending terlipressin in combination with albumin as first-line therapy. In settings where terlipressin is not available, norepinephrine should be given.

Terlipressin is a synthetic vasopressin analogue with twice the selectivity for vasopressin V1 receptors versus V2 receptors. Terlipressin acts as both a prodrug for lysine-vasopressin, as well as having pharmacologic activity on its own. Terlipressin is thought to increase renal blood flow by reducing portal hypertension and blood circulation in portal vessels and increasing effective arterial volume and mean arterial pressure.

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

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

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

Outcome: Terlivaz will be a medical benefit and will be added to the medical benefit cost share list. If processed at a specialty pharmacy, Terlivaz will process at the Specialty tier or the Brand Non-preferred tier for members with a three-tier benefit. The following prior authorization criteria will apply:

- Documentation of age greater than or equal to 18 years **AND**
- Prescribed by or in consultation with a hepatologist or nephrologist **AND**
- Medical record documentation of a diagnosis of hepatorenal syndrome causing a rapid reduction in kidney function **AND**
- Medical record documentation of a serum creatinine less than or equal to 5.0 mg/dL **AND**
- Medical record documentation that Terlivaz will be given in combination with intravenous albumin **OR** intolerance or contraindication to albumin **AND**
- Medical record documentation that the patient does NOT meet any of the following conditions:
    - Baseline oxygen saturation (SpO2) less than 90% **OR**
    - Volume overload **OR**
    - Acute-on-chronic liver failure (ACLF) Grade 3 **OR**
    - Ongoing coronary, peripheral, or mesenteric ischemia

AND

- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

AUTHORIZATION DURATION: Approval will be for up to 14 days of treatment and the authorization duration will be sufficient to cover the complete treatment course. Subsequent authorizations will be considered using the criteria outlined above.

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

ZERVIATE (cetirizine ophthalmic)

Review: Zerviate (cetirizine ophthalmic solution) 0.24% is indicated for the treatment of ocular itching associated with allergic conjunctivitis. The recommended dosage of Zerviate is to instill one drop into each affected eye twice daily (approximately 8 hours apart). Zerviate is a sterile, buffered, clear, colorless, aqueous ophthalmic solution, containing cetirizine 0.24%. Zerviate is supplied in a package of 30 single use vials (0.2ml each). Single use containers should be stored in the original foil pouch until ready to use, used immediately after opening, and can be used to dose both eyes. Single use container and remaining solution should be discarded after administration.

Allergic conjunctivitis occurs when airborne allergens affect the eye, leading to immunoglobulin E (IgE)-mediated local mast cell degranulation and allergic inflammation. Symptoms include ocular itching, redness, and watery discharge. Initial treatment consists of basic eye care and allergen avoidance. Basic eye care includes not rubbing the eyes, discontinuing the use of contact lenses, applying cool compresses, and generously using refrigerated artificial tears throughout the day. Topical (ocular) therapies can be used to reduce symptoms if initial treatment is not enough. Topical therapies include antihistamine/vasoconstrictor combination products, antihistamines with mast cell-stabilizing properties, mast cell stabilizers, and for refractory symptoms, topical glucocorticoids. When ocular symptoms are the main presenting problem, topical (ocular) therapies are preferred because they are faster acting, are less likely to cause systemic side effects, and are more effective for ocular symptoms than systemic antihistamines. Systemic therapy, such as oral antihistamines, is reserved for management of allergic conjunctivitis associated with nonocular symptoms.

For patients with frequent episodes (two or more days per month) and for those with seasonal allergic conjunctivitis, an antihistamine with mast-cell stabilizing properties is preferred and should be used first. Therapies in this class include olopatadine (Pataday), alcaftadine (Lastacaft), bepotastine (Bepreve), azelastine, epinastine, cetirizine (Zerviate), and ketotifen (Alaway, Zaditor). Dosing regimens are similar across all agents (majority are dosed twice daily). The onset of action is within minutes and therapy should be used for at least 2 weeks to determine efficacy since it takes time for the inflammation to go down and the symptoms to resolve. No agent is preferred or recommended over another.

The efficacy of Zerviate (cetirizine ophthalmic solution) 0.24% was established in three randomized, double-masked, placebo-controlled, conjunctival allergen challenge (CAC) clinical trials in patients with a history of allergic conjunctivitis. Onset and duration of action were evaluated in two of these trials in which patients were randomized to receive Zerviate or vehicle ophthalmic solutions. Patients were evaluated with an ocular itching severity score ranging from 0 (no itching) to 4 (incapacitating itch) at several time points after CAC administration. Table 1 (see below) displays data from the mean ocular itching severity scores after ocular administration of an antigen using the CAC model. A one-unit difference compared to vehicle is considered a clinically meaningful change in the ocular itching severity score. Patients treated with Zerviate demonstrated statistically and clinically significantly less ocular itching compared to vehicle at 15 minutes and 8 hours after treatment.

The most common adverse reactions associated with Zerviate use (1–7%) were ocular hyperemia, instillation site pain, and visual acuity reduced. There were no studies to determine the safety of using Zerviate in pregnant women and use should be limited to when potential benefit justifies the potential risk to the fetus. The safety and efficacy of Zerviate has been established in pediatric patients two years of age and older and use in these pediatric patients is supported by evidence from Zerviate studies in pediatric and adult patients. There was no overall difference in safety or efficacy between elderly and younger patients.

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

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

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

Outcome: Zerviate is a pharmacy benefit that will not be added to the Commercial/Exchange/CHIP formularies. It will be added to Policy 121.0 Alomide, Bepreve, Emadine, Lastacaft, and Pazeo and prior authorization criteria should remain the same:

- Medical record documentation of allergic conjunctivitis **AND**
- Medical record documentation of failure on, intolerance to or contraindication to azelastine eye drops, epinastine eye drops, olopatadine eye drops (generic Pataday or Patanol) **AND** OTC Zaditor

GPI LEVEL: GPI-12

FORMULARY ALTERNATIVES: azelastine eye drops (generic Optivar), epinastine (generic Elestat), olopatadine (generic Pataday or Patanol)

QUANTITY LIMIT: 60 units per 30 days

RPH SIGNOFF REQUIRED: No

Additional Recommendations: For Commercial/Exchange/Chip Policy 121.0, it is recommended to update the name to include Zerviate. Recommend name be changed to: Policy 121.0 Alomide, Bepreve, Emadine, Lastacaft, Pazeo and Zerviate

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

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

SEYSARA (sarecycline)

Review: The American Academy of Dermatology (AAD) guidelines recommend combination therapy with topical agents in the treatment of acne vulgaris for the majority of patients to target the different aspects of acne pathogenesis. In mild acne, the first-line treatment is topical benzoyl peroxide or a topical retinoid used as monotherapy. However, other first-line options for mild acne are combination topical therapies including benzoyl peroxide plus a retinoid, benzoyl peroxide plus a topical antibiotic, or a combination of all 3 agents. For moderate acne, the AAD recommends combination topical therapies or an oral antibiotic used in combination with topical agents as first-line options. For severe acne, the AAD recommends an oral antibiotic used in combination with topical agents or monotherapy with oral isotretinoin as first line options. With the use of systemic antibiotics, it is recommended to only continue therapy for the shortest duration possible due to the risk of bacterial resistance.

Seysara may be administered with or without food. It is important to counsel patients to take Seysara with enough water to avoid esophageal irritation and ulceration. Separate administration of antacids containing aluminum, calcium or magnesium, bismuth subsalicylate, and iron-containing preparations is recommended to avoid decreased absorption and serum concentration of Seysara.

During the clinical trials conducted for Seysara, Seysara was only compared to placebo and there are no additional head-to-head studies available that compare Seysara to other tetracyclines utilized for the treatment of acne vulgaris (like minocycline and doxycycline) to show advantage of one tetracycline over the other.

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

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

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

Outcome: Seysara is a pharmacy benefit and will not be added to the Commercial, Marketplace, or CHIP formulary. The following prior authorization criteria will apply:

- Medical record documentation a diagnosis of acne, acne vulgaris, or adult-onset acne **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

GPI LEVEL: GPI-12

QUANTITY LIMIT: 1 tablet per day

RPH SIGNOFF REQUIRED: No

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

ENTADFI (finasteride and tadalafil)

Review: Entadfi is indicated to initiate treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in men with enlarged prostate for up to 26 weeks. Entadfi is not recommended for more than 26 weeks because the incremental benefit of tadalafil decreases from 4 weeks to 26 weeks, and the incremental benefit beyond 26 weeks is unknown. Entadfi is available as one capsule (containing finasteride 5 mg and tadalafil 5 mg) and it is taken orally once daily at approximately the same time every day for up to 26 weeks.

The efficacy of Entadfi is based on a randomized, double-blind, parallel-designed study of 26 weeks duration. The trial included 696 men with BPH with an enlarged prostate (> 30cc). Men were randomized to either tadalafil 5 mg with finasteride 5 mg or placebo with finasteride 5 mg. Tadalafil and finasteride together demonstrated significant improvement in the signs and symptoms of BPH compared to finasteride alone, as measure by total symptom score (IPSS) at week 12. IPSS is a seven-question screening tool used to screen for diagnosis, track symptoms of BPH, the seven questions relate to urinary symptoms. Key secondary endpoints looked at the total IPSS score throughout the 26 weeks. The overall score remained decreased, however the magnitude of the treatment difference between placebo/finasteride and tadalafil/finasteride

decreased from Week 4 to Week 26. Therefore, the incremental benefit of Entadfi beyond 26 weeks is unknown.

Entadfi is contraindicated if used in combination with a nitrate, in patients with known hypersensitivities to any components of Entadfi, pregnancy, and if used in combination with a guanylate cyclase (GC) stimulator. The warnings and precautions in the labeling include the safety concerns of each of the individual products.

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

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

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

Outcome: Entadfi will not be added to the Commercial/Exchange/CHIP formularies. Prior authorization criteria will be as follows:

- Medical record documentation of a diagnosis of benign prostatic hyperplasia (BPH) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three therapy regimens for benign prostatic hyperplasia (BPH), one of which must be tadalafil in combination with finasteride **AND**
- Medical record documentation that the member did not exceed 26 weeks of therapy of finasteride in combination with tadalafil

GPI LEVEL: GPI-12

AUTHORIZATION DURATION: 26 weeks

RE-AUTHORIZATION CRITERIA: For requests exceeding 26 weeks durations, 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 beyond the FDA-approved treatment duration.

QUANTITY LIMIT: 1 capsule per day

RPH SIGNOFF REQUIRED: Yes

FORMULARY ALTERNATIVES: Finasteride, Tadalafil, Dutasteride, Alfuzosin, Tamsulosin

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

TECVAYLI (teclistamab-cqyv)

Review: Tecvayli is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who

have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. This indication was approved under the accelerated approval process, and continued approval may be contingent upon benefit in confirmatory trial(s). The dosing of Tecvayli is 2 step-up doses on day 1 and day 4, consisting of 0.06mg/kg and 0.3 mg/kg, respectively with patients being hospitalized for 48 hours after administration of the step up doses. The first treatment dose on Day 7 will consist of 1.5mg/kg. Treatment doses of 1.5mg/kg are given once weekly thereafter.

Tecvayli is the now fourth medication approved for only fifth-line use in relapsing or refractory multiple myeloma (RRMM). The other medications approved as only fifth-line treatment include Carvykti (ciltacabtagene autoleucel, CAR-T), Abecma (idecabtagene vicleucel, CAR-T) and Blenrep (belantamab mafodotin). On 11/22/2022, GSK announced they will be removing Blenrep from the US market after the confirmatory DREAMM-3 trial failed to show benefit compared to standard therapy (pomalyst-dexamethasone regimen) in delaying disease progression in patients with RRMM. Blenrep and Tecvayli are “off the shelf” products meaning they can be available to the patient right away, whereas Carvykti and Abecma are CAR-T products and can take more than 30 days to be produced. Routes of administration also differ, with Carvykti, Abecma and Blenrep being intravenous infusions and Tecvayli being a subcutaneous injection. Tecvayli also requires 6 days of hospitalization whereas Carvykti requires 10 days, Abecma requires 7 days and Blenrep requires 0 days of hospitalization. Lastly, each alternative is restricted under a REMS program but for varying reasons. Blenrep is restricted due to ocular toxicity while Abecma and Carvykti are restricted for CRS and neurologic toxicity.

The accelerated approval of Tecvayli was supported by a Phase 1/2 trial (NCT03145181 [Phase 1] and NCT04557098 [Phase 2]) called MajesTEC-1. MajesTEC-1 was a single arm, open-label, multicenter trial evaluating the safety, efficacy, tolerability, pharmacokinetics and antitumor activity of Tecvayli in 110 adults with RRMM who received at least three prior therapies. Prior therapies included a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. Exclusion criteria was patients who had stroke, seizure, allogenic stem cell transplantation within the past 6 months, ECOG performance score of 2 or more and known active CNS or meningeal involvement. The median number of prior lines of therapy was 5 (range 2 to 14), with 78% of patients having received at least 4 prior lines of therapy and 76% of patients being triple-class refractory (refractory to a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody). Patients received two step-up doses on days 1 and 4, followed thereafter by a once weekly treatment dose of 1.5mg/kg until disease progression or unacceptable toxicity.

Efficacy was established based on overall response rate (ORR) using the International Myeloma Working Group (IMWG) 2016 criteria. The ORR was 60%, with the median time to first response being 1.2 months (range 0.2 to 5.5 months) and the estimated duration of response (DOR) rate being 90.6% at 6 months (95% CI: 80.3%, 95.7%) and 66.5% at 9 months (95% CI: 38.8%, 83.9%). Other results are summarized in Table 3 above.

Black box warnings for Tecvayli include cytokine release syndrome (CRS) and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome (ICANS). Because of the black box warnings Tecvayli is only available through a Risk Evaluation and Mitigation Strategy (REMS) program called the Tecvayli REMS. No contraindications are listed on the package labeling. Warnings and precautions are significant for CRS, Neurologic toxicity including ICANS, hepatotoxicity, severe, life-threatening or fatal infections, neutropenia, hypersensitivity and other administration reactions. Serious adverse reactions occurred in 54%

of patients and included pneumonia (15%), CRS (8%), sepsis (6%), general physical health deterioration (6%), COVID-19 (6%), acute kidney injury (4.8%) and pyrexia (4.8%). Fatal adverse reactions occurred in 5% of patients, discontinuation due to adverse reactions occurred in 1.2% of patients, and dose interruptions due to adverse reactions occurred in 73% of patients. Common adverse reactions occurring in greater than or equal to 20% of patients included pyrexia, CRS, musculoskeletal pain, injection site reaction, fatigue, upper respiratory tract infection, nausea, headache, pneumonia, and diarrhea. Tecvayli suppresses the CYP450 enzyme causing increased exposure of CYP substrates, with the highest risk of interaction being expected in the step-up phase.

No overall differences in safety or efficacy were observed in patients aged 65 to 74 when compared to younger patients. The number of patients over 75 years was insufficient to determine if any differences exist. Of the patients treated, 48% were 65 years or older, and 15% were 75 years or older. The efficacy and safety of Tecvayli in pediatric patients has not been established.

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

Clinical Discussion: There is a lot of interest in this drug as there are really no other options for patients with Blenrep being removed from the market. The only other options at CAR-T therapies and they are no longer accepting additional sites. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

Outcome: Tecvayli is a medical benefit and will require prior authorization. Tecvayli will be added to the medical benefit cost share list when processed on the medical benefit. If processed at a specialty pharmacy, Tecvayli will process at the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. The following prior authorization criteria will apply:

- Medical record documentation that Tecvayli is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years old **AND**
- Medical record documentation of a diagnosis of relapsed or refractory multiple myeloma **AND**
- Medical record documentation of treatment with at least four (4) prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

GPI LEVEL: GPI-12

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 the member experiences unacceptable toxicity or worsening of disease.

RPH SIGNOFF REQUIRED: Yes

FORMULARY ALTERNATIVES: Revlimid*, Pomalyst*, bortezomib*, Kyprolis*, Ninlaro*, Darzalex*, Empliciti*, Farydak*, Sarclisa*, Xpovio* *Prior authorization required

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

RYALTRIS (olopatadine and mometasone)

Review: Allergic rhinitis is a very common condition affecting 10 to 30 percent of the population. Most patients require pharmacotherapy to address symptom control and improve quality of life. Many of these products have moved over the counter and people tend to self-treat. Treatment is usually based on the age of the patient and their treatment preference.

Treatment usually starts with minimally sedating antihistamines (loratadine, cetirizine, and fexofenadine). Cromolyn nasal spray is another good option, as it is not absorbed systemically and has no adverse effects.

Glucocorticoid nasal sprays (mometasone furoate, fluticasone furoate, and triamcinolone acetonide) are approved in children ≥ 2 years and up and are usually first line as well. They are very effective. Antihistamine nasal sprays are another good option, but intranasal azelastine is only approved in children ≥ 6 years of age (≥ 5 years of age for 0.1% solution according to official Rx labeling) and olopatadine ≥ 6 years of age and up.

Glucocorticoids are the most effective pharmacologic therapy and are recommended by guidelines as the best single therapy in the treatment of allergic rhinitis in patients with moderate-to-severe symptoms. If symptoms are not controlled, you can add an antihistamine nasal spray, add a minimally sedating oral antihistamine, add a minimally sedating oral antihistamine/decongestant combination, or use injection immunotherapy in some instances.

Saline nasal sprays or irrigations can be used alone for mild symptoms or just before the use of other topical medications.

Glucocorticoids are one of the first line agents because they are particularly effective in the treatment of nasal congestion. Second-generation glucocorticoids are preferred due to less systemic absorption and less side effects. These include fluticasone, mometasone, and ciclesonide. Many of these agents are available over the counter. They have an onset of action within 15 minutes to a few hours but may take several days or weeks in patients with severe, long-standing symptoms. A step-down approach is usually followed once symptoms are controlled.

Medications used in the treatment of allergic rhinitis include:

- Nasal sprays
- Nasal corticosteroids (OTC and Rx)
- Nasal antihistamines (OTC and Rx)
- Nasal anticholinergic - ipratropium bromide (Rx)
- Nasal cromolyn (OTC)

- Nasal saline (OTC)
- Oral antihistamines (OTC and Rx)
- Leukotriene pathway inhibitor - oral montelukast (Rx)
- Decongestants (OTC and Rx)
- Immunotherapy (Rx)
- Allergy shots (Rx)

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

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

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

Outcome: Ryaltris is a pharmacy benefit and will not be added to the Commercial/Exchange/ CHIP formularies. The following prior authorization criteria will apply:

- Medical record documentation of age ≥ 12 years old **AND**
- Medical record documentation of a diagnosis of allergic rhinitis **AND**
- Medical record documentation of therapeutic failure, intolerance to, or contraindication to intranasal olopatadine in combination with intranasal mometasone **AND** azelastine/fluticasone intranasal

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: 29g/30 days (0.96g per day)

FORMULARY ALTERNTATIVES: fluticasone propionate nasal spray, mometasone nasal spray, azelastine 0.1% nasal spray, azelastine 0.15% nasal spray, olopatadine nasal spray, azelastine/fluticasone nasal spray

RPH SIGNOFF REQUIRED: no

Additional Recommendations: Retire Policy 264.0 Commercial Drug Azelastine/Fluticasone Nasal Suspension (FDA approved age 6 and older)
Retire Policy 191.0 Commercial Drug. Olopatadine Nasal Spray

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

TADLIQ (tadalafil)

Review: Tadliq (tadalafil) is a phosphodiesterase-5 inhibitor indicated for the treatment of pulmonary arterial hypertension (PAH) to improve exercise ability. It is available as a 20mg/5mL (4mg/mL) suspension. The dosage is 40mg (10mL) once daily, with or without food. Studies establishing effectiveness included predominately patients with NYHA Functional Class II–III symptoms and etiologies of idiopathic or heritable PAH (61%) or PAH associated with

connective tissue diseases (23%). Phosphodiesterase-5 inhibitors are part of first-line therapy recommendations for PAH along with endothelin receptor antagonists.

Pulmonary arterial hypertension is a subclass (WHO group 1) of pulmonary hypertension which is characterized by elevated pulmonary arterial pressure (mean pulmonary artery pressure > 25mmHg at rest). The NYHA separates patients into classes 1-4 based on when patients experience symptoms relative to physical activity and whether those symptoms prevent them from physical activity.

No new clinical trials were conducted for the approval of Tadliq, but the previous ADCIRCA for Pulmonary Arterial Hypertension trial was used. A randomized, double-blind, 16-week placebo-controlled study was conducted in 405 patients with pulmonary arterial hypertension, defined as a resting mean pulmonary artery pressure (mPAP) ≥ 25mmHg, pulmonary capillary wedge pressure (PCWP) ≤ 15mmHg, and pulmonary vascular resistance (PVR) ≥ 3 Wood units via right heart catheterization. Allowed background therapy included bosentan (maintenance dosing up to 125 mg twice daily) and chronic anticoagulation. The use of prostacyclin or analogue, L–arginine, phosphodiesterase inhibitor, or other chronic PAH medications were not permitted.

Subjects were randomly assigned to 1 of 5 treatment groups (tadalafil 2.5, 10, 20, 40 mg, or placebo) in a 1:1:1:1:1 ratio. Subjects had to be at least 12 years of age and had a diagnosis of PAH that was idiopathic, heritable, related to connective tissue disease, anorexigen use, human immunodeficiency virus (HIV) infection, associated with an atrial-septal defect, or associated with surgical repair of a congenital systemic-to-pulmonary shunt of least 1 year in duration. Patients with a history of left-sided heart disease, severe renal insufficiency, or pulmonary hypertension related to conditions other than specified in the inclusion criteria were not eligible for enrollment. The mean baseline 6-minute walk distance (6-MWD) was 343 meters. Of the 405 subjects, 341 completed the study. The primary efficacy endpoint was the change from baseline at week 16 in 6-MWD. In the tadalafil 40 mg treatment group, the placebo-adjusted mean change increase in 6-MWD was 33 meters (95% C.I. 15-50 meters; p=0.0004). The improvement in 6-MWD was apparent at 8 weeks of treatment and then maintained at week 12 and week 16.

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

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

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

Outcome: Tadliq is a pharmacy benefit and will not be added to the Commercial, Exchange, or CHIP pharmacy formularies. The following prior authorization criteria will apply:

- Medical record documentation of a diagnosis of pulmonary arterial hypertension (PAH) **AND**
- Medical record documentation that prescription is written by a pulmonologist or cardiologist **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to sildenafil **AND** tadalafil tablets **OR**

- If the member has trouble swallowing, medical record documentation of therapeutic failure on, intolerance to, or contraindication to sildenafil oral liquid

GPI LEVEL: GPI-12

QUANTITY LIMIT: 10mL per day, 30-day supply per fill

FORMULARY ALTERNTATIVES: Sildenafil, Tadalafil tablets

RPH SIGNOFF REQUIRED: Yes

Additional Recommendations:

- Recommend for Commercial policy 209.0 to no longer require failure of sildenafil prior to approval of tadalafil due to the decreased cost of tadalafil tablets. Also, per the 2022 ESC guidelines, both phosphodiesterase-5 inhibitor (sildenafil, tadalafil) and endothelin receptor antagonists (ambrisentan. bosentan) are considered first line treatments and can be used in combination. Since tadalafil tablets are lower in cost than ambrisentan, do not require failure of ambrisentan before trial of tadalafil.
    - Update policy to read:
        - An exception for coverage of tadalafil 20mg (generic Adcirca) may be made for members who meet the following criteria:
            - Medical record documentation of a diagnosis of pulmonary arterial hypertension (PAH) **AND**
            - Medical record documentation that prescription is written by a pulmonologist or cardiologist **AND**
            - Medical record documentation that tadalafil will not be used concomitantly with organic nitrate therapy

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

IMJUDO (tremelimumab-actl)

Review: Imjudo is a cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) blocking antibody indicated in combination with Imfinzi (durvalumab) for the treatment of adult patients with unresectable hepatocellular carcinoma. It also is indicated in combination with Imfinzi and platinum-based chemotherapy for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.

Imjudo binds CTLA-4, a negative regulator of T-cell activity and blocks the CTLA-4 mediated inhibition of T-cell activation. In mouse tumor models, blocking CTLA-4 resulted in decreased tumor growth and increased proliferation of T-cells in tumors.

The recommended dosage of Imjudo for hepatocellular carcinoma is a single intravenous infusion administered on Day 1, Cycle 1, with Imfinzi followed by Imfinzi monotherapy every 4 weeks until disease progression or unacceptable toxicity. The dosage is based on body weight. For patients weighing 30 kg or more, a single dose of Imjudo 300 mg is administered while patients weighing less than 30 mg should receive an Imjudo dosed of 4 mg/kg.

The recommended dosage and schedule of Imjudo for the treatment of metastatic non-small cell lung cancer is based on patient's weight and tumor histology (Tables 4 and 5).

Table 4. Recommended Dosage Schedule for NSCLC[1]

	Week[1,2]																							
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Cycle:	1			2			3			4			5				6				7				8
IMJUDO[3,4]	X			X			X			X							X								
Durvalumab[1,3]	X			X			X			X			X				X				X				X
Chemotherapy	X			X			X			X			X[5]				X[5]				X[5]				X[5]

1 continue durvalumab until disease progression or intolerable toxicity.
2 dosing interval change from every 3 weeks to every 4 weeks starting at cycle 5.
3 intravenous infusion over 60 minutes.
4 if patients receive fewer than 4 cycles of platinum-based chemotherapy, the remaining cycles of IMJUDO (up to a total of 5) should be given after the platinum-based chemotherapy phase, in combination with durvalumab, every 4 weeks.
5 optional pemetrexed therapy from week 12 until disease progression or intolerable toxicity for patients with non-squamous disease who received treatment with pemetrexed and carboplatin/cisplatin.

Table 5. Recommended Regimen and Dosage for NSCLC[1]

Tumor Histology	Patient Weight	IMJUDO Dosage	Durvalumab[1] Dosage	Platinum-based Chemotherapy Regimen[1]
Non-Squamous	≥ 30 kg	75 mg	1,500 mg	• carboplatin & nab-paclitaxel OR • carboplatin or cisplatin & pemetrexed
	< 30 kg	1 mg/kg	20 mg/kg	
Squamous	≥ 30 kg	75 mg	1,500 mg	• carboplatin & nab-paclitaxel OR • carboplatin or cisplatin & gemcitabine
	< 30 kg	1 mg/kg	20 mg/kg	

[1] Refer to the Prescribing Information for dosing information.

No dosage adjustments are required for adverse reactions, but in general, Imjudo should be withheld for severe (Grade 3) immune-mediated adverse reactions and discontinued for life threatening (Grade 4) reactions.

Hepatocellular Carcinoma
The efficacy of Imjudo in unresectable hepatocellular carcinoma was evaluated in the HIMALAYA study, a randomized (1:1:1), open-label study in patients with confirmed uHCC who had not received prior systemic treatment. Patients were randomized to receive Imjudo + Imfinzi at the recommended dosage, Imfinzi 1500 mg every 4 weeks, or sorafenib 400 mg orally twice daily. Treatment regimens were continued until disease progression or unacceptable toxicity. Randomization was stratified by macrovascular invasion, etiology of liver disease, and ECOG performance status. Patients with Hep B or Hep C coinfection, GI bleed within 12 months, ascites within 6 months, hepatic encephalopathy within 12 months, and active or prior autoimmune or inflammatory disorders were excluded from the study.

The major efficacy outcome was overall survival (OS) between the Imjudo + Imfinzi arm and the

sorafenib arm. Additional outcomes assessed were progression-free survival (PFS), objective response rate (ORR), and duration of response according to RECIST v1.1. Efficacy Results are shown in Table 6.

Table 6. Efficacy Results for HIMALAYA Study[1]

Endpoint	IMJUDO and Durvalumab (N=393)	Sorafenib (N=389)
OS		
Number of deaths (%)	262 (66.7)	293 (75.3)
Median OS (months) (95% CI)	16.4 (14.2, 19.6)	13.8 (12.3, 16.1)
HR (95% CI) [1]	0.78 (0.66, 0.92)	
p-value[2,3]	0.0035	
PFS		
Number of events (%)	335 (85.2)	327 (84.1)
Median PFS (months) (95% CI)	3.8 (3.7, 5.3)	4.1 (3.7, 5.5)
HR (95% CI)[1]	0.90 (0.77, 1.05)	
ORR		
ORR % (95% CI)[4,5]	20.1 (16.3, 24.4)	5.1 (3.2, 7.8)
Complete Response n (%)	12 (3.1)	0
Partial Response n (%)	67 (17.0)	20 (5.1)
DoR		
Median DoR (months) (95% CI)	22.3 (13.7, NR)	18.4 (6.5, 26.0)
% with duration ≥ 6 months	82.3	78.9
% with duration ≥ 12 months	65.8	63.2

1 HR (IMJUDO and durvalumab vs. sorafenib) based on the stratified Cox proportional hazard model. 2 Based on a stratified log-rank test. 3 Based on a Lan-DeMets alpha spending function with O'Brien Fleming type boundary and the actual number of events observed, the boundary for declaring statistical significance for IMJUDO and durvalumab vs. sorafenib was 0.0398 (Lan and DeMets 1983). 4 Confirmed complete response or partial response. 5 Based on Clopper-Pearson method. CI=Confidence Interval, HR=Hazard Ratio, NR=Not Reached

Metastatic Non-Small Cell Lung Cancer

The efficacy of Imjudo in metastatic NSCLC was evaluated in the POSEIDON trial, a randomized, active controlled, open-label trial in patients with previously untreated metastatic NSCLC with no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations. Patients were randomized 1:1:1 to receive Imjudo + Imfinzi + platinum based chemotherapy (Investigator's choice), Imfinzi + platinum based chemotherapy, or platinum based chemotherapy alone. Patients received one of the following platinum based chemotherapy regimens:

- Non-squamous NSCLC
  - Pemetrexed 500 mg/m^2 with carboplatin AUC 5-6 or cisplatin 75 mg/m^2 every 3 weeks for 4 cycles
- Squamous NSCLC
  - Gemcitabine 1,000 or 1,250 mg/m^2 on Days 1 and 8 with cisplatin 75 mg/m^2 or carboplatin AUC 5-6 on Day 1 every 3 weeks for 4 cycles
- Non-squamous and Squamous NSCLC
  - Nab-paclitaxel 100 mg/m^2 on Days 1, 8, and 15 with carboplatin AUC 5-6 on Day 1 every 3 weeks for 4 cycles

Imjudo was given up to a maximum of 5 doses while Imfinzi was continued until disease progression or unacceptable toxicity. Patients with active and/or untreated brain metastases, history of active primary immunodeficiency, autoimmune disorders, and systemic immunosuppressants within 14 days of first dose of treatment were excluded. Randomization was stratified by tumor cells PD-L1 expression, disease stage, and histology.

The major efficacy outcome measures were progression-free survival (PFS) and overall survival (OS) of Imjudo + Imfinzi + platinum based chemotherapy compared to platinum-based chemotherapy alone. Additional efficacy outcome measures were overall response rate (ORR) and duration of response (DoR). Efficacy results are shown in Table 7.

Table 7. Efficacy Results for POSEIDON study[1]

	IMJUDO with durvalumab and platinum-based chemotherapy (n=338)	**Platinum-based chemotherapy (n=337)**
OS[1]		
Number of deaths (%)	251 (74)	285 (85)
Median OS (months) (95% CI)	14.0 (11.7, 16.1)	11.7 (10.5, 13.1)
HR (95% CI)	0.77 (0.65, 0.92)	
p-value[2]	0.00304	
PFS[1]		
Number of events (%)	238 (70)	258 (77)
Median PFS (months) (95% CI)	6.2 (5.0, 6.5)	4.8 (4.6, 5.8)
HR (95% CI)	0.72 (0.60, 0.86)	
p-value[2]	0.00031	
ORR % (95% CI)[3]	39 (34, 44)	24 (20, 29)
Median DoR (months) (95% CI)	9.5 (7.2, NR)	5.1 (4.4, 6.0)

Imjudo has warnings and precautions for severe and fatal immune-mediated adverse reactions which can occur in any organ system or tissue and occur at any time after starting Imjudo in combination with Imfinzi. Immune-mediated reactions which occurred in clinical trials included pneumonitis, colitis, hepatitis, endocrinopathies, nephritis with renal dysfunction, dermatological reactions, and pancreatitis. Other warnings and precautions include infusion related reactions and embryo-fetal toxicity. In the pooled safety population from the HIMALAYA and POSEIDON trials, the most common adverse reactions were nausea, decreased appetite, and fatigue. The most common Grade 3 or higher laboratory abnormalities were neutropenia, leukopenia, lymphocytopenia, anemia, hyponatremia, increased lipase, and thrombocytopenia.

During the HIMALAYA trial, serious adverse reactions occurred in 41% of patients and included hemorrhage, diarrhea, sepsis, pneumonia, rash, vomiting, acute kidney injury, and anemia.

Fatal adverse reactions occurred in 8% of patients and included intracranial hemorrhage, cardiac arrest, pneumonitis, hepatic failure, and immune mediated hepatitis. Imjudo was permanently discontinued by 14% of patients due to adverse reactions.

During the Poseidon trial, serious adverse reactions occurred in 44% and included pneumonia, anemia, diarrhea, thrombocytopenia, pyrexia, and febrile neutropenia. Fatal adverse reactions occurred in 4.2% of patients and included sepsis, pneumonitis, acute kidney injury, febrile neutropenia, COPD, dyspnea, sudden death, ischemic stroke, and one patient with hepatitis, nephritis, myocarditis and pancreatitis. Imjudo was permanently discontinued due to an adverse reaction in 17% of patients.

The safety and efficacy of Imjudo has not been established in pediatric patients. Of the 393 patients with uHCC treated with Imjudo, 50% of patients were 65 years or older and 13% of patients were 75 years or older. No overall differences in safety and efficacy have been observed between older and younger patients. Of the 330 patients with metastatic NSCLC treated with Imjudo, 43% were 65 years or older and 11% were 75 years or older. No overall differences in safety or effectiveness were observed between older and younger patients.

NCCN recommends Imjudo as first-line therapy options (non-preferred) with Imfinzi and platinum based chemotherapy for eligible patients with metastatic NSCLC, regardless of histology or PD-L1 levels, and negative for actionable driver mutations. The category assignment is dependent on histology, chemotherapy, and PD-L1 levels. Imjudo recommendations are Category 1 for patients with PD-L1 ≥ 1-49% and non-squamous cell histology, Category 2A for PD-L1 ≥ 1-49% and squamous cell histology, and Category 2B for all others.

NCCN recommends Imjudo as a preferred first-line treatment option with Imfinzi for patients with uHCC with unresectable disease and not transplant candidates, liver-confined disease that is inoperable, or metastatic disease or extensive liver tumor burden (Category 1).

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

Clinical Discussion: Dr. Yarczower asked about severe adverse reactions, including death as a result of the drug and if we should get some input from oncology for this medication. Kimberly Reichard, Pharm.D., responded that it's preferred by NCCN but we can still reach out to oncology for additional comments. The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

Outcome: Imjudo will be a medical benefit and will require a prior authorization. It will be added to the medical benefit cost share list. If processed at a specialty pharmacy, Imjudo will process at the Specialty tier or Brand Non-Preferred tier for members with a three tier benefit. The following prior authorization criteria will apply:

uHCC

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Imjudo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of unresectable hepatocellular carcinoma (uHCC) **AND**

- Medical record documentation that Imjudo will be used in combination with durvalumab (Imfinzi)

Metastatic NSCLC

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Imjudo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations **AND**
- Medical record documentation that Imjudo will be used in combination with durvalumab (Imfinzi) and platinum-based chemotherapy

MEDISPAN AUTHORIZATION LEVEL: GPI-12

AUTHORIZATION DURATION: For the treatment of unresectable HCC, approval will be given for a one time dose of Imjudo (not to exceed 300 mg) for a duration of 1 month. Authorization of Imjudo for the treatment of unresectable HCC should not exceed the FDA-approved treatment of one dose. 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 the treatment of metastatic NSCLC, the approval of Imjudo will be for 6 months. Authorization of Imjudo for the treatment of metastatic NSCLC should not exceed the FDA-approved treatment duration of 16 weeks. 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

RPH SIGNOFF REQUIRED: Yes

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

FAST FACTS

IMFINZI (durvalumab)

Clinical Summary: Imfinzi is now indicated in combination with tremelimumab-actl (Imjudo) for the treatment of adult patients with unresectable hepatocellular carcinoma and in combination with tremelimumab-actl (Imjudo) and platinum-based chemotherapy for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations. Imfinzi has one additional new indication for treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC) in combination with gemcitabine and cisplatin.

The approval of Imfinzi for uHCC is supported by efficacy results of the HIMALAYA trial which is discussed in detail in the January new drug review for Imjudo. The approval of Imfinzi for metastatic NSCLC is supported by efficacy results of the POSEIDON trial which is discussed in detail in the January new drug review for Imjudo. The approval of Imfinzi in combination with gemcitabine and cisplatin in patients with locally advanced or metastatic BTC is supported by results of TOPAZ-1, a randomized, double-blind, placebo-controlled trial that enrolled 685 patients with histologically confirmed locally advanced unresectable or metastatic BTC who have not previously received systemic therapy. Patients with ampullary carcinoma, autoimmune or inflammatory disorders, HIV or other active infections, and current or prior immunosuppressive use within 14 days of the start of Imfinzi were excluded. Treatment was continued until disease progression or unacceptable toxicity. The major efficacy outcome was overall survival (OS). Additional outcome measures were progression-free survival (PFS), objective response rate (ORR) and duration of response (DoR). At the pre-specified interim analysis, the trial demonstrated a statistically significant improvement in OS and PFS in patients randomized to Imfinzi + gemcitabine + cisplatin versus gemcitabine + cisplatin.

The most common adverse reactions that occurred when Imfinzi was used in combination with Imjudo and platinum based chemotherapy were nausea, fatigue, musculoskeletal pain, decreased appetite, rash, and diarrhea. The most common adverse reactions that occurred when Imfinzi was used in combination with Imjudo was rash, diarrhea, fatigue, pruritis, musculoskeletal pain, and abdominal pain. The most common adverse reactions when Imfinzi was used in combination with gemcitabine and cisplatin were fatigue, nausea, constipation, decreased appetite, abdominal pain, rash, and pyrexia.

Current formulary status: Medical Benefit, when processed at a Specialty Pharmacy, Specialty Brand NP tier, requires a PA

Recommendation: No changes are recommended to the formulary placement of Imfinzi. The following changes to the authorization duration and additional prior authorization criteria are recommended to incorporate the new indications for Imfinzi into Medical Benefit Policy 156.0. It is also recommended that the Authorization Duration for Stage III NSCLC be updated to one approval of 12 months based on NCCN guidance which does not recommend routine surveillance MRI for Imfinzi for Non-small cell lung cancer:

1. **Stage III Non-Small Cell Lung Cancer (NSCLC)**
   - 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 unresectable Stage III Non-Small Cell Lung Cancer (NSCLC) **AND**
- Medical record documentation that patient has received and has not progressed following a minimum of two cycles of concurrent platinum-based chemotherapy **AND** radiation therapy

AUTHORIZATION DURATION (Stage III NSCLC): One approval for 12 **months** or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Imfinzi for the treatment of non-small cell lung 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

2. Metastatic Non-Small Cell Lung Cancer (NSCLC)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of metastatic non-small cell lung cancer (NSCLC) AND
- Medical record documentation no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations AND
- Medical record documentation that Imfinzi will be used in combination with tremelimumab-actl (Imjudo) and platinum-based chemotherapy

AUTHORIZATION DURATION (Metastatic NSCLC): 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.

3. Extensive-Stage Small Cell Lung Cancer (ES-SCLC)

- 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 extensive-stage small cell lung cancer (ES-SCLC)* **AND**
- Medical record documentation that Imfinzi will be used as first-line treatment **AND**
- Medical record documentation that Imfinzi will be used in combination with etoposide and either carboplatin or cisplatin

*Note: The National Comprehensive Cancer Network (NCCN) Guidelines defines small cell lung cancer as consisting of two stages:
Limited Stage: Stage I-III (T any, N any, M0) that can be safely treated with definitive radiation doses. Excludes T3-4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan.

Extensive Stage: Stage IV (T any, N any, M1a/b), or T3-4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan

AUTHORIZATION DURATION (ES-SCLC): 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.

4. **Unresectable Hepatocellular Carcinoma (uHCC)**
   - Medical record documentation of age greater than or equal to 18 years AND
   - Medical record documentation that Imjudo is prescribed by a hematologist or oncologist AND
   - Medical record documentation of unresectable hepatocellular carcinoma (uHCC) AND
   - Medical record documentation that Imfinzi will be used in combination with tremelimumab-actl (Imjudo)

AUTHORIZATION DURATION (uHCC): 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.

5. **Biliary Tract Cancer (BTC)**
   - Medical record documentation of age greater than or equal to 18 years AND
   - Medical record documentation that Imjudo is prescribed by a hematologist or oncologist AND
   - Medical record documentation of locally advanced or metastatic biliary tract cancer (BTC) AND
   - Medical record documentation that Imfinzi will be used in combination with gemcitabine and cisplatin

AUTHORIZATION DURATION (BTC): 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: Keith Hunsicker, Pharm.D., asked if we could make the approval for Stage III NSCLC only one 12 month approval instead of two 6 month approvals and if providers are doing follow-up PET scans. Benjamin Andrick, Pharm.D., stated that oncologists do tend to treat through to finish the series and will follow up on the PET scan comment prior to responding if one single 12 month authorization would be appropriate. Benjamin Andrick was able to confirm that routine PET/CT scans are not recommended in NCCN guidelines for that use. Keith Hunsicker, Pharm.D., then proposed that the authorization duration for Stage III NSCLC be updated to one single 12 month approval. Dr. Bret Yarczower asked if there was a range of months for overall survival rates and if there were a lot of people who got a longer benefit or

majority were clumped around the median. Kim Reichard, Pharm.D., responded that she would need to look into further.

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

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

UPDATES

MIGRAINE PREVENTION CLASS REVIEW UPDATE

Background: The Migraine Prevention Class review presented for the December 2022 e-vote erroneously made a recommendation to move Aimovig and Emgality to the non-preferred brand tier. This recommendation was included prior to receiving the most recent rebating information, where Aimovig, Emgality, and Nurtec ODT are all preferred migraine prevention agents. Since all 3 agents will be preferred, there should not have been a recommendation to move Aimovig and Emgality to the non-preferred brand tier.

Recommendation: Aimovig and Emgality should remain in their current position on the brand preferred tier for the Commercial, Exchange, and CHIP formularies.

Discussion: No comments or questions.

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

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

MEDICAL BENEFIT POLICY UPDATES

BACKGROUND:

Policies retired upon annual review:

- MBP 92.0 Off-Label Drug Use for Oncologic Indications [Content of this policy now addressed by MBP 33.0 (Medical Benefit Pharmaceutical Administrative Policy]
- MBP 111.0 Marqibo (vincristine sulfate liposome injection) [Marqibo voluntarily withdrawn from market by manufacturer as of 5/2/22 [published on federal register on 4/26/22]

Policies updated at the direction of DHS during PARP submission process:

MBP 33.0 Medical Benefit Pharmaceutical Administrative Policy

DESCRIPTION:

This policy explains how coverage decisions are determined for GHP members who have medical drug benefits, including Commercial, Affordable Care Act (ACA), GHP Kids, Self-Insured plans, Medicare and Medicaid, unless a specific limitation, exception, or exclusion exists. Coverage exceptions include decisions about the medical necessity of a specific drug, decisions about drugs exceeding quantity limits, and decisions whether a member has satisfied prior authorization requirements, or site of care requirements. The policy is utilized when a drug specific policy does not exist or the existing drug specific policy does not address the requested indication or process.

A. Coverage Determination Procedure ~~(Medicaid (GHP Family))~~

1. For the Medicaid (GHP Family) line of business: Requests should be directed to the Department of Pharmacy Services. The procedure set forth by Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization will be adhered to with the following exceptions:

i. If a Member's prescription for a medication is not filled when a prescription is presented to the pharmacist due to a Prior Authorization requirement, GHP will instruct the pharmacist to dispense either a fifteen (15) day supply if the prescription qualifies as an ongoing medication for a GHP Family member, or a five (5) day supply for a new medication by contacting the Plan directly to dispense a 5-day supply for a new medication or to dispense a 15-day supply for ongoing therapy. When a pharmacist determines that taking the prescribed medication may jeopardize the health or safety of the member this 15-day and 5-day rule will not apply. GHP Family will allow one emergency fill per medication per 180 days. ~~Coverage Determination Procedure (non-Medicaid (GHP Family) lines of business~~

2. For non-Medicaid (GHP Family) lines of business, a request may be initiated for an exception in accordance with the following:
    i. Requests should be directed to the Department of Pharmacy Services
    ii. Information needed for a determination include, but is not limited to, the following:
        1. Caller's name and telephone number;
        2. Member's medical record number and insurance identification number;
        3. Prescribing and providing healthcare provider's name and telephone number;
        4. The product and exception requested;
        5. Clinical rationale including medical records, laboratory data, past treatment history and other documentation, as determined by the Plan to be relevant.
    iii. Requests for exception will be reviewed as follows:
        1. A Certified Pharmacy Technician (CPhT) or License Practical Nurse (LPN), under the supervision of a Health Plan Pharmacist, will perform an initial review of medical record documentation and treatment history to recommend approval or denial of requests where there are explicit utilization management criteria and no clinical judgement is required, utilizing drug specific MBP.
            a. If the request for exception is approved, no further action will be required on the part of the Health Plan Pharmacist or the Licensed Physician (dependent upon the exception requested).
            b. If the CPhT or LPN recommends denial upon initial review, the requests will be forwarded to a Health Plan Pharmacist for review.
        2. For all requests where clinical judgement is required, explicit utilization management criteria do not exist, or those which a CPhT or LPN recommends denial (or approval, dependent upon the determination requested), a Health Plan Pharmacist will perform an initial review of medical record documentation and treatment history to recommend approval or denial, utilizing drug specific MBP if applicable as well as the compendia references listed below. The request will be approved if, in the professional judgment of the pharmacist reviewer, the services are medically necessary to meet the medical needs of the member of the request.
            a. If the request for exception is approved, no further action will be required on the part of the Licensed Physician.
            b. If the Health Plan Pharmacist recommends denial upon initial review, the request will be forwarded to a Licensed Physician for review.

3. A Licensed Physician shall make the final decision in all instances where a Health Plan Pharmacist recommends denial. The request will be approved if, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member of the request.

iv. Documentation of the determination of coverage and the notifications will take place within GHP coverage determination decision making or customer service documentation tool(s).

B. Off-Label Requests

1. Off-label drug use for a medical drug is considered to be medically necessary when **all** of the following criteria are met:
   i. The drug has been approved by the FDA for at least one indication; **AND**
   ii. The drug is being prescribed to treat a condition not listed in the product labeling, but for which treatment is medically necessary; **AND**
   iii. Conventional therapies have been tried and failed, are contraindicated, or do not exist; **AND**
   iv. The proposed drug use is supported by any one or more of the following:
      - The National Comprehensive Cancer Network Practice Guidelines™ in Oncology category 1, 2A, or 2B recommendation; **OR**
      - The National Comprehensive Cancer Network Drug & Biologics Compendium™ category of Evidence and consensus 1, 2A, or 2B; **OR**
      - The American Hospital Formulary Service – Drug Information; **OR**
      - Thompson Micromedex DrugDex Compendium (DrugDex®) class I, IIa, or IIb indication; or
      - Elsevier Gold Standard's Clinical Pharmacology Compendium (Clinical Pharmacology®)
      - Indication is listed in Lexi-Drugs as "Use: Off-Label" and rated as "Evidence Level A"
2. If a medical policy exists for a specific drug and addresses the requested off-label indication, reference should be made to that document for information regarding the medical necessity of that drug for the requested indication. When a clinical trial is open for accrual that provides the drug under consideration for the indication requested, and when the insured individual meets the eligibility requirements of that trial, providers are encouraged to consider that option.

C. Quantity Limit Exceptions

1. A quantity limit exception may be made for members who meet the following criteria:
   i. Medical record documentation that requested dose cannot be achieved by using a formulary alternative (e.g. use of one 90mg syringe in place of two 45mg syringes) **AND**
   ii. Medical record documentation that prescribed dosage does not exceed those approved by the Food and Drug Administration (FDA) or accepted standards of care **AND**
   iii. If request is for dose that exceeds Food and Drug Administration (FDA) approved labeling, 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 **AND**
   iv. Medical record documentation that current quantity limit has been ineffective in management of member's condition or is likely to be ineffective or adversely affect the patient's compliance based on clinical evidence & the known physical and mental characteristics of the member

~~D. Claims Editing Process~~

~~1. A claim edit is developed to ensure the drug is:~~

~~i. Used for industry accepted indications – both on- and off-label.~~

~~ii. Dosed appropriately based on the specific diagnosis.~~

~~iii. Administered at a frequency that is appropriate for the diagnosis.~~

~~iv. Given in accordance with any lifetime maximum units, visits and/or administrations.~~

~~v. Administered to the appropriate age group.~~

~~vi. Administered by an appropriate route.~~

~~vii. Given in conjunction with appropriate laboratory studies and/or monitoring.~~

~~viii. Not given in conjunction with other drugs that might cause adverse drug interactions.~~

~~ix. Reported with an appropriate amount if billed as drug wastage.~~

~~x. Reported with the appropriate National Drug Code (NDC).~~

~~2. A review for the medical necessity of a claim not having met requirements set forth by a claim edit shall have the use supported by one or more of the following:~~

~~i. Manufacturer's prescribing information~~

~~ii. Elsevier Gold Standard's Clinical Pharmacology~~

~~iii. Thomson MICROMEDEX® (DRUGDEX®, DrugPoints®)~~

~~iv. American Hospital Formulary System (AHFS) DI~~

~~v. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium~~

E. Site of Care (Excluding Medicaid and Medicare lines of business)

Medical benefit policy (MBP) 181.0 provides a policy of coverage regarding the use of hospital-based outpatient facilities as a site of care for drugs that require administration via intravenous infusion or injection for participating lines of business. See MBP 181.0 for information regarding the medical necessity of site of care.

MBP 166.0 Adcetris (brentuximab vedotin)

AUTHORIZATION DURATION:

Indication	Initial Authorization	Subsequent Authorizations
Previously Untreated Stage III or IV cHL	Initial approval will be limited to 12 doses (6 months) or less if the reviewing provider feels it is medically appropriate.	Subsequent approval for treatment past the initial 12 doses will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.
cHL Consolidation	Initial approval will be limited to 6 months or less if the reviewing provider feels it is medically appropriate.	Subsequent approval will be for one additional 6-month authorization to allow for a total of 16 cycles of treatment. Subsequent approval for treatment past 16 cycles will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.
Relapsed pcALCL or CD30-expressing MF		
Previously Untreated sALCL or Other CD30-expressing PTCLs	Initial approval will be limited to 8 doses (6 months) or less if the reviewing provider feels it is medically appropriate.	Subsequent approval for treatment past the initial 8 doses will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.
Relapsed cHL	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. Adcetris will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.
Relapsed sALCL ~~**Relapsed pcALCL or CD30-expressing MF**~~		

MBP 220.0 Scenesse (afamelanotide)

- Prescription ~~written by a dermatologist~~ prescribed by, or in consultation with, a hematologist, dermatologist, gastroenterologist, or other specialist with expertise in the diagnosis and management of EPP **AND**
- Medical record documentation of the member being ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of erythropoietic protoporphyria (EPP) as confirmed by elevated total erythrocyte protoporphyrin* **AND**
- Medical record documentation of one of the following:
  - Erythrocyte fractionation showing a greater percentage of metal-free protoporphyrin compared to zinc protoporphyrin** **OR**
  - Gene sequencing showing an FECH or ALAS2 mutation

AND

- Medical record documentation of a history of phototoxic reaction (e.g. pain, stinging, redness, swelling) AND
- Medical record documentation that sun and light protection measures will be maintained during treatment with Scenesse.

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

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

QUARTERLY CASE AUDIT

The Quarterly Case Audit for 3rd quarter 2022 was held on December 1st, 2022. There were no formulary changes proposed at this meeting. We will continue to look for opportunities to create more drug specific policies at future quarterly case audit meetings.

Discussion: No comments or questions.

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

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

QUARTERLY CASE AUDIT

Commercial/Exchange/TPAs (COMM, D6)

Drug Use Evaluations (DUEs)

- Overutilization of albuterol and levalbuterol
  - This is our 2022 3rd quarter Geisinger Health Plan DUE for Commercial, Exchange, Medicaid, Chip

- For this report, we identified members who had greater than a 180-day cumulative day supply of Albuterol and/or levalbuterol (based on pharmacy claims from 1/1/2022-12/23/22) with a diagnosis of Asthma (based on medical claims from 4/1/2021 through 12/23/22)
    - See below for the number of members identified:
        - For COMM: **61**
        - For D6: **66**
    - Letters were sent to the MI attributed PCP of each member with their medication fill history of both their controller and rescue inhalers to help providers identify members that may be overutilizing their rescue inhalers and to identify potential compliance concerns with their controller inhaler.
    - We will be re-running this data in June 2023 to analyze effectiveness of the letter

- Use of Opioids at High Dosage
    - This is our 2022 2nd quarter Geisinger Health Plan DUE for Commercial, Exchange, TPA, Medicaid, Medicare
    - From this report, we identified members 18 years and older with 15+ opioid covered days and had an MME of 90 or greater per day based on claims from 1/1/2022 through 7/27/2022
        - See below for the number of members that were identified with an MME of 90 or greater per day:
            - For COMM: **13**
            - For D6: **19**
            - For TP45: **2**
            - For TPE0: **1**
            - For SASN: **1**
            - For TG48/TG51: **18**
        - Letters were sent to the MI attributed PCP of each member with the respective medication fill history for providers to evaluate their patients current pain regimen and ensure lowest effective doses are utilized.
        - Letters were mailed out on 9/15/2023
        - We will be re-running this data in January 2023 to analyze effectiveness of the letter.
- Asthma Medication Ratio
    - This is our 2022 1st quarter Geisinger Health Plan DUE for Commercial, Exchange, Medicaid, CHIP
    - From this report, we used proactive HEDIS data and identified members aged 5-64 with an AMR<0.5. Pharmacy claims from the prior 6 months (9/2021-3/2022) were pulled into the report.
        - See below for the number of members that were identified with an AMR<0.5
            - For **COMM:** 6
            - For **D6: 6**
        - Letters were sent to the MI attributed PCP of each member with the respective medication fill history to encourage conversation around the importance of controller medications.
    - Letters were mailed out on 4/20/2022
    - Adam K. re-ran this data on 8/29/2022 to analyze the effectiveness of the letter. Of the 12 members initially identified, 9 members were still active. Of those members, **4 members** showed an AMR increase compared to 4/2022.
- Use of Opioids from Multiple Providers (UOP) DUE

- This is our 2021 3rd quarter Geisinger Health Plan DUE for Medicare, Medicaid, Commercial
- From this report, we identified members 18 years of age and older with a total day supply of all opioid claims to be 15 day or greater based on claims from 1/1/2021 through 9/27/2021:
  - See below for the number of **members** who were identified who were seeing 4 or more providers from different offices for their opioid prescriptions
    - For COMM: **15**
    - For D6: 5
  - See below for the number of **members** who were identified who were seeing 4 or more providers within the same office for their opioid prescriptions
    - For COMM: **0**
    - For D6: **0**
  - We sent letters to the member's MI attributed PCP with the respective medication fill history to encourage medication evaluation of the opioid medications
- Mitch Kocen completed the mail merge via Quadient on 10/14/2021 and the print shop sent out the letters on 10/18/2021
- Adam K. re-ran this data on 3/10/2022 to analyze the effectiveness of the letter. Of the 20 members initially addressed, 13 members were still active. Of those members, **all 13 members** showed a decrease in the number of prescribers they were seeing compared to 10/2021

- <u>Statin Use in Persons with Diabetes DUE</u>
  - This is our 2021 2nd quarter Geisinger Health Plan DUE for all LOBs
  - From this report, we identified **1,564 members** age 40 to 75 with at least 2 distinct fills of any diabetic medication(s) without a statin claim. We sent an educational letter to providers to encourage prescribing of a statin to members, if medically appropriate.
  - The Print Shop completed the mail merge and sent out letters to the member's providers on 8/2/2021.
  - Adam K. re-ran this data on 11/19/2021 to analyze the effectiveness of the letter. Of the **1564 members** initially addressed, **1430** are still active. Of those members, **128** now have a claim for a statin medication. This equates to about **9%** of the targeted members.
  - See below for the number of letters sent:
    - For COMM: **613**
    - For D6: **372**
    - For TP23: **4**
    - For TP33: **2**
    - For TPI0: **4**
    - For TPI2: **4**
    - For TPL0: **0**
    - For TPM2: **2**

In Progress

- For Exchange: HEDIS PQA Adherence Reports for the following measures:
  - Renin Angiotensin System Antagonists (PDC-RASA)
  - Diabetes All Class (PDC-DR)
  - Statins (PDC-STA)
- For Exchange: HEDIS PQA Long term Opioid use report
  - Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Ongoing

- TNF and Oral Oncology Agent Report
    - We get this report monthly for the Commercial/Exchange, TPA, and CHIP LOBs from Adam Kelchner.
    - This report was generated in response to removing the renewal prior authorization requirement for these agents.
    - This report identifies members who are on a TNF or Oral Oncology agent and may not have been seen by their applicable specialist in the last 15 months.
    - We research these members and reach out to the offices/members as necessary to ensure the member has been seen within the last 15 months, an appointment has been scheduled or will be scheduled with the member to ensure the member continues to be able to receive their medication.
- Cystic Fibrosis Adherence Report
    - We get this report monthly for all LOBs from Adam Kelchner. The report identifies patients who have a specific diagnosis of Cystic Fibrosis & outpatient/office visits within the past 2 years. Further the report calls out medication fill history for specific CF medications and the corresponding PDC.
        - For those members who are seen by a GHS provider we send their information to the CF coordinators to discuss their medication adherence
        - We send letters to non-GHS providers with the CF medication fill history for those members with a PDC less than 80%
        - And for all members we send a letter discussing the importance of medication adherence
        - In 2022, please see below for the number of **members** an adherence letter was sent to:
            - Letters are only sent to members every 6 months
                - For COMM: 6
                - For D6: 7
                - For TG48: **16**
                - For WF89: **5**
        - Please see below for the number of letters sent to non-GHS pulmonologists
            - For D6: **1**
        - Please see below for the number of members referred to the CF coordinators:
            - For COMM: **24**
            - For D6: **25**
            - For TG48: **48**
            - For WF89: **12**
- Duplicate Anticoagulant Report
    - We get this report **weekly** for **all LOBs** flagging members filling duplicate anticoagulant medications. We personally reach out to the providers/members of the flagged members to confirm proper medication therapy.
    - For 2022:
        - For COMM (Commercial): **7 members** reviewed and **2 interventions** made
        - For D6 (Exchange): **9 members** reviewed and **0 interventions** made
        - For TG48/GH51: **5 members** reviewed and **0 interventions** made
        - For TP23: **1 member** reviewed and **0 interventions** made
        - For TP45: **0 members** reviewed and **0 interventions** made
        - For TP56: **0 members** reviewed and **0 interventions** made

        - For EMYD: **0 members** reviewed and **0 interventions** made
        - For MT38: **0 members** reviewed and **0 interventions** made
        - For TP74: **0 members** reviewed and **0 interventions** made
        - For SASN: 0 **member** reviewed and **0 interventions** made
        - For SASF: 0 **member** reviewed and **0 interventions** made
- Duplicate Specialty Therapy
    - We run an in-house retrospective report **quarterly** for **all LOBs** with help from Adam Kelchner and Aubrielle Smith. These members are identified and written up and sent to a medical director if follow up is needed.
        - For Commercial/Exchange/TPA in 2022, we reviewed all 2022 data and **0 members** were referred to Dr. Yarczower for additional follow-up.
- Duplicate Buprenorphine Therapy
    - We get this report **quarterly** with help from Adam Kelchner. The report works to identify members who have at least a 7 day overlap period of generic Buprenorphine and generic Buprenorphine/naloxone products. Members identified as being on both products are being forwarded to Dr. Meadows and Dr. Hossler for further outreach.
        - For Commercial/Exchange, TPAs in 2022, we have reviewed **0 members** and **0 members** were referred to Dr. Meadows
- Suboxone with an Opioid Report
    - We get this report **weekly** for **all LOBs** from Adam Kelchner and we are writing up each new member that flags on the report. These members are being discussed at our weekly meeting with Dr. Meadows and Dr. Hossler. Both medical directors look into whether it is appropriate to end the opioid authorizations still in place or if further intervention is required.
    - For Commercial/Exchange/TPA in 2022, see below for the new members reviewed and those referred to the MDs:
        - For COMM: we have reviewed **1 new member** and **0 members** were referred to MDs
        - For D6: we have reviewed **6 new members** and **3 members** were referred to MDs
        - For EMYD: we have reviewed **0 new members** and **0 members** were referred to MDs
        - For TG48: we have reviewed **2 new members** and **0 members** was referred to MDs
        - For SASE: we have reviewed **0 new members** and **0 members** was referred to MDs
        - For SASN: we have reviewed **1 new member** and **1 member** was referred to MDs
        - For TPI2: we have reviewed **1 new member** and **1 member** was referred to MDs
- Ending Opioid Authorizations
    - We are working on identifying members who have active opioid authorizations in place but have since started Buprenorphine therapy. The letter is sent to the members notifying them the opioid authorization has been ended due to the start of buprenorphine therapy.
    - For Commercial/Exchange/TPA in 2022, see below for the number of letters we sent to members notifying them that we are ending their opioid authorization(s):
        - For D6: **1**
        - For COMM: **0**

        - For TG48/TG51: **1**
        - For SASN: **1**
- Opioid Overutilization Report
    - We get this report **monthly** from PerformRx and we write up each member that flags on the report. We have been monitoring the members that are continuously showing up on the report by any change in their MED. For those members we deem appropriate we will send a letter to their PCP.
    - For Commercial/Exchange/TPA in 2022, see below for the number of reviewed cases.
        - For COMM: we have reviewed **1 member** and sent **1 case** to MDs for review
        - For EMYD: we have reviewed **1 member** and sent **0 cases** to MDs for review
        - For TG48: we have reviewed **0 member** and sent **0 cases** to MDs for review
- FWA Reports
    - We get this report **weekly** for **all LOBs** from Jeremy Baker. We prepare this report by determining which claims need to be verified, and our GHP technician makes calls to pharmacies to correct/verify claims.
    - We review claims for anti-hypertensives, statins, 1-day supply, and inhalers
        - For COMM in 2022, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $3,452.11**
        - For D6 in 2022, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $1,935.88**
        - For TPJ0 in 2022, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $29.99**
        - For TPH2 in 2022, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $430.83**
        - For TPE0 in 2022, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $17.19**
        - For TPN2 in 2022, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $156.32**
        - For EMYD in 2022, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $2,588.34**
        - For TG48, TG51 in 2022, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $4,680.43**
        - For SASE in 2022, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $169.57**
        - For SASN in 2022, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $820.91**
        - For SASK in 2022, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $7.81**
        - For TP23 in 2022, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $31.78**
        - For TP45 in 2022, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $190.87**
- Duplicate Antipsychotics
    - We get this report **quarterly**, and we send letters to the PCPs to address potential duplicate therapy issues.
        - We have sent the following provider letters in 2022
            - For COMM: **7**

        - FOR D6: **11**
        - FOR TG48, TG51: **8**
        - For TP45: **1**
        - For TP56: **0**
        - For EMYD: **0**
        - For MT38: **0**
        - For TP74: **0**
        - For SASN: **0**
        - For SASF: **0**
- Severity Report
    - We get this report **monthly** for **all LOBs** on members who have filled a medication that has a level one interaction with another medication they have a claim for
        - For Commercial/Exchange/TPA in 2022 see below for the number of members identified and had sent letters to their MI attributed PCP:
            - For COMM: **94**
            - For D6: **87**
            - For EMYD: **0**
            - For SASF: **1**
            - For SASN: **9**
            - For SASE: **2**
            - For TG48: **88**
            - ForTG51: **7**
            - For TPB3: **0**
            - For TPE0: **1**
            - For TPH2: **1**
            - For TPM2: **1**
            - For TP23: **0**
            - For TP45: **3**
            - For TP46: **1**
            - For TP50: **3**
            - For TP56: **2**
            - For TP88: **0**
            - For TPU1: **2**
            - For TPA6: **0**
            - For WF89: **3**
- Tobacco Cessation Program
    - We get this report **monthly** to identify members on prolonged tobacco cessation treatment. We send a letter and resource pamphlet to provide additional behavioral health support through Geisinger Health and Wellness.
    - For Commercial/Exchange/TPA in 2022, we sent letters to the below number of members:
        - For COMM: **6**
        - For D6: **12**
        - For EMYD: **9**
        - For SASN: **2**
        - For SASE: **2**
        - For TG48, TG51: **11**
        - For TPB3: **0**
        - For TP23: **1**
        - For TP33: **2**

        - For TP45: **0**
        - For TP46: **1**
        - For TP50: **2**
        - For TP56: **0**
        - For TP64: **1**
        - For TP88: **0**
        - For TPA6: **0**
        - For TPT2: **1**
        - For WF89: **1**
- STENT Adherence Report
    - We get this report **monthly** to identify members on an antiplatelet medication and then flag for betablocker and statin medication claims.
    - In 2022, we have sent letters encouraging adherence to the below number of members:
        - **Members for Antiplatelet:**
            - COMM: **102**
            - D6: **84**
            - EMYD: **9**
            - SASN: **10**
            - TG48, TG51: **16**
            - TP41: **0**
            - TP23: **0**
            - TP33: **1**
            - TP45: **3**
            - TP46: **3**
            - TP50: **1**
            - TP56: **0**
            - TP64: **1**
            - TP74: **1**
            - PM71: **1**
            - TP88: **0**
            - TPA6: **0**
            - WF89: **3**
            - TPD2: **0**
            - SASE: **3**
            - SASF: **1**
            - SASK: **1**
            - TPB3: **1**
            - TPF2: **0**
            - TPI0: **0**
            - TPL0: **0**
            - TPM2: **0**
            - **P**M70: **1**
            - PM71: **1**
        - **Members for Beta-Blocker:**
            - COMM: **107**
            - D6: **124**
            - EMYD: **13**
            - SASN: **11**
            - TG48, TG51: **43**
            - TP23: **3**
            - TP45: **2**
            - TP46: **1**
            - TP50: **0**
            - TP56: **1**
            - TP88: **0**
            - TPA6: **0**
            - WF89: **2**
            - TPI0: **4**
            - SASK: **0**
            - TPB3: **2**
            - TPR1: **1**
            - TPT2: **1**
            - TPU1: **3**
            - SASE: **2**
        - **Members for Statin:**
            - COMM: **136**
            - D6: **124**
            - EMYD: **13**
            - SASN: **15**
            - SASF: **1**
            - TG48, TG51: **57**
            - TP23:**2**
            - TP45: **3**
            - TP46: **2**
            - TP56: **0**
            - PM71: **0**
            - SASK: **0**
            - SAQ2: **1**
            - TPI0: **0**
            - TPM2: **0**
            - TPR1: **0**
            - TP88: **1**
            - TPA6: **0**

        - TPU1: **1**
        - WF89: **2**
        - TP50: **1**
        - TP64: **2**
        - PM70: **0**
        - TP74: **1**
        - SASE: **3**
        - TPB3: **5**
        - TPH2: **1**
        - TPT2: **1**
        - TP41: **1**
    - *member may flag for more than one measure and are included in the count for each measure
  - In 2022, we have attempted telephonic outreach to the below number of members non-adherent in all 3 measures and reached the below members to encourage adherence.
    - COMM:
      - Attempted:**6**
      - Reached: **2**
    - D6:
      - Attempted: **4**
      - Reached:**2**
    - SASN:
      - Attempted: **1**
      - Reached: **0**

- **HEDIS Initiatives: *Using proactive HEDIS data***
- Asthma Medication Ratio (AMR)
  - Jesse Barsh runs this report **monthly,** and we send letters to the flagged members who have a ratio of controller to total asthma medications of < 0.5.
    - For Commercial/Exchange in 2022, see below for the number of letters sent to members:
      - COMM: **13**
      - D6: **12**
- Asthma Medication Ratio (AMR) Member Calls
  - Adam Kelchner runs this report **weekly** based off of proactive HEDIS reporting. The RPHs call Commercial/Exchange members who have had a controller or reliever medication filled in the past 3 months AND are past due for their controller medication.
  - For Commercial/Exchange in 2022, see below for the number of members we have outreached to and the number of members that have been reached:
    - COMM:
      - Outreached to: **48**
      - Reached: **22**
    - D6:
      - Outreached to: **43**
      - Reached: **21**
- Antidepressant Medication Management (AMM)
  - Jesse Barsh runs this report **monthly,** and we send letters to the flagged members who appear non-adherent to their antidepressant medications.
    - For Commercial/Exchange in 2022, see below for the number of letters sent to members:
      - Effective Acute Phase:
        - COMM: **0**
        - D6: **2**

        - Effective Continuation Phase:
            - COMM: **61**
            - D6: **49**
- Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
    - Jesse Barsh runs this report **monthly,** and we send letters to the flagged members who appear non-adherent to their antipsychotic medications.
        - For Commercial/Exchange in 2022, see below for the number of letters sent to members:
            - COMM: **1**
            - D6: **2**
- Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - We get this report **monthly** to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For Commercial/Exchange in 2022, see below for the number of letters sent to **providers** to encourage statin therapy initiation**:**
            - COMM: **23**
            - D6: **18**
        - For Commercial/Exchange in 2022, see below for the number of letters sent to **members** to promote statin adherence:
            - COMM: **27**
            - D6: **11**
- Statin Therapy for Patients with Diabetes (SPD)
    - We get this report **monthly** to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For Commercial/Exchange in 2022, see below for the number of letters sent to **providers** to encourage statin therapy initiation**:**
            - COMM: **149**
            - D6: **76**
        - For Commercial/Exchange in 2022, see below for the number of letters sent to **members** to promote statin adherence:
            - COMM: **28**
            - D6: **11**
- Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
    - We get this report **monthly** to identify members with a diagnosis of AMI who received beta-blocker treatment for 6 months after discharge and who are non-adherent to beta-blocker therapy
        - For Commercial/Exchange in 2022, see below for the number of letters sent to **members:**
            - COMM: **1**
            - D6: **0**
- Use of Opioids from Multiple Providers (UOP)
    - We get this report quarterly to identify members 18 years of age and older with a total day supply of all opioid claims to be 15 days or greater
        - See below for the number of members that were identified who were seeing 4 or more providers from different offices for their opioid prescriptions
            - **COMM: 13**
            - **D6: 6**

        - See below for the number of members that were identified who were seeing 4 or more providers within the same office for their opioid prescriptions
            - **COMM: 2**
            - **D6: 1**
        - We sent letters to the MI attributed PCP of each member with the respective medication fill history to encourage medication evaluation of the opioid medications

- **HEDIS PQA Initiatives:**
- HEDIS PQA- INR Report
    - We get this report **weekly** for the Exchange population from Adam Kelchner
    - This report looks at the percentage of members 18 years of age and older who had at least one 56-day interval of warfarin therapy and who received at least one international normalized ratio (INR) monitoring test during each 56-day interval with active warfarin therapy.
        - For Exchange in 2022, we have performed telephonic outreach to providers for **5 members** that had not had an INR level drawn.

Fliers/Letters

- Commercial/Exchange DUR/FWA Program internal Fliers
    - Last updated 11/2022 next update 6/2023
- Current Provider Letters
        - Cystic Fibrosis Adherence Letter
        - TNF/Oral Oncology Letter
        - Congestive Heart Failure DUE
        - Coronary Artery Disease DUE
        - Statin Use in Persons with Diabetes DUE
        - Opioid Overutilization
        - Duplicate Antipsychotic medication
        - Severity Report
        - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
        - HEDIS: Statin Therapy for Patients with Diabetes (SPD)
        - HEDIS: Asthma Medication Ratio (AMR)
        - HEDIS: Use of Opioids from multiple providers (UOP)
        - HEDIS: Use of Opioids at High Dosage (HDO)
- Current Member Letters
        - Cystic Fibrosis Adherence Letter
        - TNF/Oral Oncology Letter
        - Ending Opioid Authorizations
        - Tobacco Cessation Letter
        - STENT Adherence Report
        - HEDIS: Asthma Medication Ratio (AMR)
        - HEDIS: Antidepressant Medication Management (AMM)
        - HEDIS: Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
        - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
        - HEDIS: Statin Therapy for Patients with Diabetes (SPD)
        - HEDIS: Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)

CHIP (CHBQ)

- All of our Medicaid adherence/DUR reports include logic to identify the CHIP population

Drug Use Evaluations (DUEs)

- Overutilization of albuterol and levalbuterol
  - This is our 2022 3rd quarter Geisinger Health Plan DUE for Commercial, Exchange, Medicaid, Chip
  - For this report, we identified members who had greater than a 180-day cumulative day supply of Albuterol and/or levalbuterol (based on pharmacy claims from 1/1/2022-12/23/22) with a diagnosis of Asthma (based on medical claims from 4/1/2021 through 12/23/22)
    - **5 members** were identified with overutilization of their inhalers
    - Letters were sent to the MI attributed PCP of each member with their medication fill history of both their controller and rescue inhalers to help providers identify members that may be overutilizing their rescue inhalers and to identify potential compliance concerns with their controller inhaler.
    - We will be re-running this data in June 2023 to analyze effectiveness of the letter
- Asthma Medication Ratio
  - This is our 2022 1st quarter Geisinger Health Plan DUE for Commercial, Exchange, Medicaid, CHIP
  - From this report, we used proactive HEDIS data and identified members aged 5-64 with an AMR<0.5. Pharmacy claims from the prior 6 months (9/2021-3/2022) were pulled into the report.
    - **0 members** were identified with an AMR<0.5
    - Letters were sent to the MI attributed PCP of each member with the respective medication fill history to encourage conversation around the importance of controller medications.
- Statin Use in Persons with Diabetes DUE
  - This is our 2021 2nd quarter Geisinger Health Plan DUE for all LOBs
  - From this report, we identified **0 members** age 40 to 75 with at least 2 distinct fills of any diabetic medication(s) without a statin claim. We sent an educational letter to providers to encourage prescribing of a statin to members, if medically appropriate.

Ongoing

- Cystic Fibrosis Adherence Report
  - We get this report **monthly** for **all LOBs** from Adam Kelchner. The report identifies patients who have a specific diagnosis of Cystic Fibrosis & outpatient/office visits within the past 2 years. Further the report calls out medication fill history for specific CF medications and the corresponding PDC.
    - For those members who are seen by a GHS provider we send their information to the CF coordinators to discuss their medication adherence with the member
    - We send letters to non-GHS providers with the CF medication fill history for those members with a PDC less than 80%
    - And for all members we send a letter discussing the importance of medication adherence
    - For CHBQ in 2022, we sent **0 members** an adherence letter
      - Letters are only sent to members every 6 months

        - There were **0 members** who saw a non-GHS pulmonologist and a letter was sent to that pulmonologist
        - There were **0 members** who saw GHS pulmonologists and were sent to the CF coordinators for follow up
- Duplicate Anticoagulant Report
    - We get this report **weekly** for **all LOBs** flagging members filling duplicate anticoagulant medications. We personally reach out to the providers/members of the flagged members to confirm proper medication therapy.
        - For CHBQ in 2022, we have reviewed **0 members** and have made interventions for **0 members**
- Duplicate Specialty Therapy
    - We run an in-house retrospective report **quarterly** for **all LOBs** with help from Adam Kelchner and Aubrielle Smith. These members are identified and written up and sent to a medical director if follow up is needed.
        - For CHBQ in 2022, we reviewed all 2022 data and **0 members** were referred to Dr. Yarczower for additional follow-up.
- Duplicate Buprenorphine Therapy
    - We get this report **quarterly** with help from Adam Kelchner. The report works to identify members who have at least a 7 day overlap period of generic Buprenorphine and generic Buprenorphine/naloxone products. Members identified as being on both products are being forwarded to Dr. Meadows and Dr. Hossler for further outreach.
        - For CHBQ in 2022, we have reviewed **0 members** and **0 members** were referred to MDs
- Suboxone with an Opioid Report
    - We get this report **weekly** for **all LOBs** from Adam Kelchner and we are writing up each member that flags on the report. These members are being discussed at our weekly meeting with Dr. Meadows and Dr. Hossler. Both MDs look into whether it is appropriate to end the opioid authorizations still in place or if further intervention is required.
        - For CHBQ in 2022, we have reviewed **0 new members**, and **0 members** were referred to MDs
- Ending Opioid Authorizations
    - We are working on identifying members who have active opioid authorizations in place but have since started Buprenorphine therapy. The letter is sent to the members notifying them the opioid authorization has been ended due to the start of buprenorphine therapy.
        - For CHBQ in 2022, we sent **0 members** a letter notifying them of the end of their opioid authorization(s).
- Severity Report
    - This is a **monthly** report for **all LOBs** on members who have filled a medication that has a level one interaction with another medication they have a claim for
        - For CHBQ in 2022, letters have been sent to MI attributed providers of **1 CHIP member**
- FWA Reports
    - We get this report **weekly** for **all LOBs** from Jeremy Baker. We prepare this report by determining which claims need to be verified, and our GHP technician makes calls to pharmacies to correct/verify claims.
    - We review claims for anti-hypertensives, statins, 1-day supply, and inhalers

        - For CHBQ in 2022, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $1,119.61**
- Tobacco Cessation Program
    - We get this report **monthly** to identify members on prolonged tobacco cessation treatment. We send a letter and resource pamphlet to provide additional behavioral health support through Geisinger Health and Wellness.
        - For CHBQ in 2022, we have not sent any letters
- STENT Adherence Report
    - We get this report **monthly** to identify members on an antiplatelet medication and then flag for betablocker and statin medication claims.
    - For CHBQ in 2022, we have sent letters encouraging adherence to:
        - Members for Antiplatelet:
            - CHBQ: **0**
        - Members for Beta-blocker:
            - CHBQ: **0**
        - Members for Statin:
            - CHBQ: **0**
        - *member may flag for more than one measure and are included in the count for each measure
- Antipsychotic with Opioid Report
    - We get this report **quarterly** to identify **CHIP** members with an overlap of 8 or more days between an opioid and antipsychotic medication.
    - We send a letter with claims data to both the opioid prescriber and the antipsychotic prescriber to encourage collaboration in medication management.
        - For CHBQ in 2022, we sent **0 letters** to **opioid prescribers** and **0 letters** to **antipsychotic prescribers**
- Duplicate Antipsychotics
    - We get this report **quarterly**, and we send letters to the PCPs to address potential duplicate therapy issues.
        - For CHBQ in 2022, we have sent letters to **1 provider**

HEDIS Initiatives: *Using proactive HEDIS data*

- Asthma Medication Ratio (AMR)
    - Jesse Barsh runs this proactive HEDIS report **monthly,** and we send letters to the flagged members who have a ratio of controller to total asthma medications of < 0.5.
        - For CHBQ in 2022, we sent **6 letters** to members
- Asthma Medication Ratio (AMR) Member Calls
    - Adam Kelchner runs this report **weekly** based off of proactive HEDIS reporting. we send CHIP members who have had a controller or reliever medication filled in the past 3 months AND are past due for their controller medication to the Respiratory Therapists for direct telephonic outreach.
        - For CHBQ in 2022, we have referred **16 members** to the Respiratory Therapists for outreach.
- Antidepressant Medication Management (AMM)
    - Jesse Barsh runs this proactive HEDIS report **monthly,** and we send letters to the flagged members who appear non-adherent to their antidepressant medications.
        - For CHBQ in 2022, we sent **0 letters** to members in the **Effective Acute Phase**, and **3 letters** to members in the **Effective Continuation Phase**

- Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
    - Jesse Barsh runs this report **monthly,** and we send letters to the flagged members who appear non-adherent to their antipsychotic medications.
        - For CHBQ in 2022, we have sent **0 letters** to members
- Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - This is a **monthly** report to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For CHBQ in 2022, we have sent **0 letters** to providers
        - For CHBQ in 2022, we have sent **0 letters** to members
- Statin Therapy for Patients with Diabetes (SPD)
    - This is a **monthly** report to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For CHBQ in 2022, we have sent **0 letters** to providers
        - For CHBQ in 2022, we have sent **0 letters** to members
- Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
    - This is a **monthly** report to identify members with a diagnosis of AMI who received beta-blocker treatment for 6 months after discharge and who are non-adherent to beta-blocker therapy
        - For CHBQ in 2022, we have sent **0 letters** to members

Fliers/Letters

- Chip DUR/FWA Program internal Fliers
    - Last updated 11/2022 next update 6/2023
- Current Provider Letters
        - Cystic Fibrosis Adherence Letter
        - TNF/Oral Oncology Letter
        - Duplicate Antipsychotic medication
        - Severity Report
        - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
        - HEDIS: Statin Therapy for Patients with Diabetes (SPD)
        - HEDIS: Asthma Medication Ratio (AMR)
- Current Member Letters
        - Cystic Fibrosis Adherence Letter
        - TNF/Oral Oncology Letter
        - Ending Opioid Authorizations
        - Tobacco Cessation Letter
        - STENT Adherence Report
        - HEDIS: Asthma Medication Ratio (AMR)
        - HEDIS: Antidepressant Medication Management (AMM)
        - HEDIS: Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
        - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
        - HEDIS: Statin Therapy for Patients with Diabetes (SPD)

Discussion: No comments or questions.

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

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

2023 FORMULARIES FOR APPROVAL

Background: The following formularies were submitted to the committee for approval:

- AON Exchange Formulary
- Commercial 4 Tier Formulary
- Commercial Traditional Formulary
- Commercial Triple Choice Formulary
- GHP Kids Formulary
- Marketplace Formulary
- Northern Light Employee Formulary

Discussion: No comments or questions.

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

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

Meeting adjourned at 3:44 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on March 21st, 2023 at 1:00 p.m.

Meeting will be held virtually via phone/Microsoft Teams.