P&T Committee Meeting Minutes
Commercial, Marketplace, GHP Kids
January 19, 2021

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

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, January 18, 2021.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the October 22, 2020 (Commercial/Marketplace/GHP Kids only), November 17, 2020, and December 22, 2020 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

ONGENTYS (opicapone)

Review: Ongentys is a catechol-O-methyltransferase (COMT) inhibitor indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes. Ongentys is the third reversible and selective catechol-O-methyltransferase (COMT) inhibitor approved for the adjunctive treatment of Parkinson's disease (PD) in patients who experience "off" episodes as their carbidopa/levodopa wears off. Ongentys has a slow complex dissociation rate constant and long duration of action allowing it to be dosed once daily, compared to entacapone which is administered with each carbidopa/levodopa dose and tolcapone which is administered three times daily. Ongentys also lacks the hepatotoxicity risks seen with tolcapone.

The efficacy of Ongentys as adjunctive treatment for patients with Parkinson's disease experiencing "off" episodes was evaluated in two double-blind, randomized, parallel-group studies, BIPARK-1 and BIPARK-2.

BIPARK 1 included 600 patients aged 30-83 years with Parkinson's disease treated with levodopa, who had end-of-dose motor fluctuations and a mean "off" period of at least 1.5 hours. Patients were randomized to receive one of three doses of Ongentys [5 mg (n=122), 25 mg (n=119), or 50 mg (n=116) once daily, placebo (n=121), or the active-comparator entacapone 200 mg with each levodopa dose (n=122) for 14 to 15 weeks. The primary endpoint evaluating change from baseline to end of study treatment in absolute time in the "off" state assessed by daily patient diaries showed the largest improvement in the group treated with Ongentys 50 mg group (-116.8 minutes). Ongentys 50 mg was found to be superior to placebo and non-inferior to entacapone. Ongentys 50 mg also had a greater proportion of patients with at least a on hour reduction in "off" time, larger reductions in the "off" state time and significant increases in percentage of time in the "on" state without troublesome dyskinesia.

BIPARK-2 was a randomized, double-blind, placebo-controlled trial which evaluated the efficacy and safety of Ongentys 25 mg and 50 mg compared to placebo as adjunct treatment to levodopa therapy, followed by a 1-year open-label phase during which all patients received Ongentys. Results from this trial supported BIPARK-1 with the largest mean change in "off" time with Ongentys 50 mg (-118.8 minutes). The secondary endpoint evaluating the proportion of patients with at least 1-hour reduction in "off" time was significantly higher for both Ongentys 25 and 50 mg compared to placebo. Other diary-reported secondary efficacy findings supported those of the primary analysis. Scale based secondary endpoints showed some improvements across all treatment groups, with no significant differences among them.

There are no black box warnings for Ongentys. It has warnings and precautions consistent with other COMT inhibitors including somnolence, hypotension and syncope, dyskinesia, hallucinations and psychosis, and impulse control and compulsive disorders. The most common adverse reaction which led to discontinuation of Ongentys was dyskinesia (3%). The most common adverse events in patients treated with Ongentys were dyskinesia, constipation, increased blood creatine kinase, hypotension/syncope, and decreased weight.

During BIPARK 1, which included entacapone as an active comparator, the rates of dyskinesia reported with higher with Ongentys 50 mg. This is consistent with the more potent inhibition of COMT shown with Ongentys which results in a greater increase in levodopa bioavailability. Most dyskinesias were deemed non-troublesome by the patients. There were no differences in the incidence of serious treatment-emergent adverse events between the Ongentys and entacapone treatment groups.

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: Dr. Yarczower asked if we know what the consequences are of someone interrupting or not taking Ongentys as recommended? Kim R. commented that there's no information available. No other comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Ongentys is a pharmacy benefit and will be added to the brand non-preferred tier of the Commercial, Marketplace, and GHP Kids formularies. The following step therapy criteria will apply:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of entacapone, carbidopa/levodopa/entacapone, or tolcapone within the previous 180 days. If this electronic step is met, the claim with automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to entacapone, carbidopa/levodopa/entacapone, or tolcapone

Other Recommendations: Tolcapone has a risk of hepatoxicity that is not seen with entacapone and Ongentys. It is also dosed more frequently per day and has a considerably higher cost. Because of this, it is recommended that the step therapy for tolcapone be updated to include Ongentys as follows:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of Ongentys **AND** either entacapone or carbidopa/levodopa/entacapone within the previous 180 days. If this electronic step is met, the claim with automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to Ongentys **AND** either entacapone or carbidopa/levodopa/entacapone.

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

KYNMOBI (apomorphine)

Review: Kynmobi is a non-ergoline dopamine agonist indicated for the acute intermittent treatment of "off" episodes in patients with Parkinson's disease. This sublingual formulation of apomorphine is the third medication approved for on demand treatment of "off" episodes of Parkinson's disease, joining Apokyn, a subcutaneous formulation of apomorphine, and Inbrija, an inhaled formulation of levodopa. Kynmobi provides an easier administration method for apomorphine compared to Apokyn, but still must be initiated within a healthcare setting and patients must be pretreated with an anti-emetic prior to initiation.

FDA approval of Kynmobi is supported by the results of bioavailability studies between Kynmobi, Apokyn, and Apo-go (a subcutaneous apomorphine injection marketed outside of the United States) as well as the results of one randomized, double-blind, placebo-controlled, parallel-group study (Study 1).

Study 1 included 109 patients with a diagnosis of Parkinson's disease who were responsive to levodopa but had at least 2 hours of "off" time per day. After an open-label titration period, patients were randomized 1:1 to receive their tolerated dose of Kynmobi up to five times per day (once per "off" period) or placebo for a 12-week double blind maintenance phase. The Kynmobi treatment group showed a least-square mean improvement of -11.1 points compared to -3.5 points for the placebo group for the primary endpoint of mean change from pre-dose to 30 minutes post-dose in the MDS-UPDRS part 3 score (motor examination) at the 12-week visit of the maintenance phase. Thirty-five percent of patients in the Kynmobi group achieved a full "on" response within 30 minutes compared to 16% of patients receiving placebo (p=0.043). Other benefits were observed in exploratory endpoints evaluating Clinical Global Impression of Improvement (CGI-I) at week 12, the frequency of patients achieving a full "on" response according to home-dosing diaries, and the time to medication effect.

There are no black box warnings and the side effect profile is similar to Apokyn but Kynmobi carries an additional warning for oral mucosal irritation due to the route of administration. Unlike Apokyn, Kynmobi was not associated with clinically significant worsening of dyskinesia, orthostatic hypotension, impulse control disorders, hallucinations, or unwanted sleep episodes. The most common adverse reactions were nausea, oral/pharyngeal soft tissue swelling, oral/pharyngeal soft tissue pain and paresthesia, dizziness, and somnolence. The most common adverse reactions leading to discontinuation during the maintenance phase were oral/pharyngeal soft tissue swelling, oral mucosal erythema, and nausea/vomiting. Roughly one-third of patients discontinued treatment during Study 1, most commonly due to oral/pharyngeal soft tissue swelling, oral mucosal erythema, and nausea/vomiting.

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: Kynmobi is a pharmacy benefit and will be added to the specialty tier, or the brand non-preferred tier for members with a three-tier benefit of the Commercial, Marketplace, and GHP Kids formularies. No prior authorization will be required, but the following quantity limit will apply:

QUANTITY LIMIT: 5 films per day

Other Recommendations: Currently, there are no clinical trials comparing the efficacy of Apokyn and Kynmobi and treatment guidelines do not recommend one product over another. While the warnings and precautions are similar for Apokyn and Kynmobi, Kynmobi was not associated with clinically significant worsening of dyskinesia, orthostatic hypotension, impulse control disorders, hallucinations, or unwanted sleep episodes. It also has an advantage with ease of administration and cost. It is recommended that step therapy criteria be added to Apokyn as follows:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of Kynmobi within the previous 180 days. If this electronic step is met, the claim with automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to Kynmobi

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

BAFIERTAM (monomethyl fumarate)

Review: Bafiertam, monomethyl fumarate, is the active metabolite of both dimethyl fumarate (Tecfidera) and diroximel fumarate (Vumerity). It was formulated to produce bioequivalent plasma levels to Tecfidera while bypassing the need for conversion in the gastrointestinal tract. Although the exact mechanism by which monomethyl fumarate exerts its therapeutic effect in multiple sclerosis is unknown, it has demonstrated both neuroprotective and anti-inflammatory properties which may delay disease progression.

There are no clinical trials evaluating the efficacy of Bafiertam. Instead, the FDA approval of Bafiertam is based on bioavailability studies in healthy volunteers which compared oral dimethyl fumarate delayed release capsules to Bafiertam delayed-release capsules and prior findings of efficacy in two clinical studies of dimethyl fumarate.
There are no black box warnings for Bafiertam and the warnings and precautions are based on previous clinical trials of dimethyl fumarate. Warnings and precautions include risk of anaphylaxis and angioedema, progressive multifocal leukoencephalopathy (PML), herpes zoster and opportunistic infections, lymphopenia, liver injury, and flushing. In bioavailability studies in 178 healthy subjects who received singles doses of Bafiertam, the adverse reaction profile was consistent with the known profile of dimethyl fumarate

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: Keith provided background information regarding availability of generic Tecfidera and the reasons why we previously did not require failure for Vumerity. The generic is now widely available allowing for the addition of the PA. No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed

Outcome: Bafiertam is a pharmacy benefit and will be added to the specialty tier or the brand preferred tier for members with a three-tier benefit on the Commercial, Marketplace, and GHP Kids formularies. The following step therapy and quantity limit will apply:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of dimethyl fumarate within the previous 180 days. If this electronic step is met, the claim with automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to dimethyl fumarate

QUANTITY LIMIT: 4 capsules per day

Other Recommendations: Vumerity or diroximel fumarate, like Tecfidera, is a prodrug to the active metabolite monomethyl fumarate. Approval of Vumerity was based on bioavailability studies and a study evaluating gastrointestinal adverse reactions compared to Tecfidera, which is now available generically

(dimethyl fumarate). Because it is unclear if Vumerity offers an advantage in efficacy and will most likely be reserved for patients unable to tolerate dimethyl fumarate, it is recommended that step therapy be added to Vumerity as follows:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of dimethyl fumarate within the previous 180 days. If this electronic step is met, the claim with automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to dimethyl fumarate

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

ENSPRYNG (satralizumab-mwge)

Review: Enspryng is an interleukin-6 (IL-6) receptor antagonist indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. is the third agent approved by the FDA for anti-AQP4 antibody patients with NMOSD and the first option approved for self-administration.

The efficacy of Enspryng was evaluated in two randomized, placebo-controlled clinical trials in adult patients with NMOSD with (Study 2) and without (Study 1) concurrent immunosuppressive therapy.

Study 1 included adult patients with AQP4-IgG seropositive or seronegative NMOSD who had experienced at least one NMOSD attack or relapse in the past 12 months. Patients were randomized 2:1 to receive Enspryng 120 mg or placebo during the double-blind treatment period at weeks 0, 2, and 4 then every 4 weeks thereafter. Concomitant use of immunosuppressants was not allowed during Study 1.

In the anti-AQP4 antibody positive patients, there was a 74% risk reduction, with 83% of patients remaining relapse free at 48 weeks and 77% of patients relapse free at 96 weeks compared to 55% and 41% of placebo treated patients (Table 2). There was no evidence of benefit in the anti-AQP4 antibody negative patients. Secondary endpoints assessments showed that VAS pain score changes from baseline did not differ significantly between treatment groups and FACIT fatigue scores showed no improvement or worsening in fatigue in either group.

Study 2 included adolescent and adult patients with AQP4-IgG seropositive or seronegative NMOSD who had experienced at least two NMOSD attacks or relapses in the past 2 years and at least 1 in the previous 12 months. Patients were randomized 1:1 to receive Enspryng 120 mg (n=41) or placebo (n=42) administered at weeks 0, 2, and 4 and every 4 weeks thereafter, added to a stable immunosuppressant regimen. Although Study 2 did enroll adolescent patients, FDA approve is based on results from the adult population and the safety and efficacy in pediatric patients has not been established.

In the anti-AQP4 antibody positive subgroup, there was a 78% risk reduction, with a protocol defined relapse in 3 out of 27 patients receiving Enspryng compared to 12 out of 28 patients receiving placebo. The secondary endpoint assessing VAS at week 24 showed no significant differences between treatment groups. Due to the hierarchical analysis, subsequent end points were presented as point estimates and confidence intervals only.

There are no black box warnings for Enspryng, and other warnings and precautions include risk of infection, elevations in livers enzymes, and decreased neutrophil counts. Injection site reactions have also been reported. During clinical trials, the most common adverse reactions were nasopharyngitis, headache, upper respiratory tract infection, gastritis, rash, arthralgia, extremity pain, fatigue, and nausea.

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: Dr. Yarczower asked if interleukin-6 levels in CSF were compared between patients who were anti-AQP4 negative vs. positive. Does it correlate at all to who may benefit from treatment with Enspryng? Kim R. said that IL-6 levels may be higher in relapse, but no comparative information in differences between anti-AQP4 positive vs. negative patients.

Dr. Yarczower – Is there still a PA on rituximab? Keith – Yes, for certain indications, including NMOSD. Dr. Yarczower would like to look at the possibility of removing the PA for NMOSD and other indications.

We are still awaiting specialist feedback on this product.

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

Outcome: Enspryng is a pharmacy benefit and will be added to the specialty tier or brand non-preferred tier for members with a three-tier benefit for Commercial, Marketplace, and GHP Kids members. The following prior authorization criteria will apply:

- Medical record documentation that Enspryng is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) **AND**
- Medical record documentation that member is anti-aquaporin-4 (AQP4) antibody positive **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to rituximab or rituximab biosimilar

QUANTITY LIMIT:

Initial – One-time, one-week authorization	**Remainder/Subsequent**
Quantity limit: 3 mL per 28 days Max quantity supply: 3 Min day supply: 28 Max day supply: 28	Quantity limit: 1 mL per 28 days Max quantity supply: 1 Min day supply: 28 Max day supply: 28

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Other Recommendations: Current guidelines do not recommend one treatment option approved for NMOSD over another and Enspryng offers an advantage over Uplizna and Soliris in the ease of administration since it is the only option approved for self-administration. For these clinical reasons and due to the cost differences between Enspryng and the other treatment options, it is recommended that the following prior authorization criteria be added to the medical benefit policy for Uplizna:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Enspryng

Additionally, the following changes are recommended to the medical benefit for Soliris:

Medical Benefit Policy 54.0 Soliris

4. Neuromyelitis Optica Spectrum Disorder (NMOSD)

- Prescribed by or in consultation with a neurologist
- Medical record documentation that member is 18 years or older **AND**
- Medical record documentation of diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) **AND**
- Medical record documentation that member is anti-Aquaporin-4 (AQP4) antibody positive **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to ~~Rituxan~~ rituximab or rituximab biosimilar **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Enspryng

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

VILTEPSO (viltolarsen)

Review: Viltepso is an antisense oligonucleotide designed to bind exon 53 resulting in the exclusion of this exon during mRNA processing allowing for production of a truncated dystrophin protein. It joins Exondys 51 and Vyondys 53 as the third exon-skipping agent approved for the treatment of DMD. Like Vyondys 53, it is specifically approved for mutations amenable to exon 53 skipping (about 8% of DMD patients) It appears that Viltepso generally led to greater increases in dystrophin expression compared to placebo versus Vyondys 53 compared to placebo; however, statistical significance is unable to be determined as these products have not been compared in head-to-head trials, and clinical significance is unable to be determined due to lack of head-to-head trials and the lack of an association of therapeutic benefit and dystrophin levels.

The accelerated approve of Viltepso is based on results of a phase 2, multicenter, 2-period, dose finding study in ambulatory male patients age 4-10 with Duchenne muscular dystrophy patients with a confirmed mutation of the DMD gene that is amenable to exon 53 skipping and who had been stable on a corticosteroid regimen for at least 3 months.

During the initial period (the first four weeks) of the study, patients in both cohorts were randomized 3:1 (double blind) to Viltepso or placebo. At week 5, the second period began, and all participants received Viltepso according to their cohort dose (40 mg/mL or 80 mg/mL) for a 20-week open label treatment period. The primary outcome assessed at week 25, showed patients treated with Viltepso 80 mg/kg once weekly had a mean dystrophin levels increase from 0.6% (SD 0.8) of normal at baseline to 5.9% (SD 4.5) and a mean change of 5.3% of normal values (p=0.01) assessed by validated Western blot. As assessed

by mass spectrometry, mean dystrophin levels increased from 0.6% (SD 0.2) to 4.2% (SD 3.7) of normal by Week 25 (nominal p=0.03, not adjusted for multiple comparisons).

There are no black box warnings for Viltepso. It does include warnings for kidney toxicity based on observations in animal studies. Although not observed during clinical trials with Viltepso, kidney toxicity, including potentially fatal glomerulonephritis, has been observed after administration of some antisense oligonucleotides. The most common adverse reactions (incidence ≥ 15% in Viltepso treated patients) were upper respiratory tract infection, injection site reaction, cough, and pyrexia.

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 commented that Exondys does nothing for cardiac manifestations of DMD. Does this medication improve cardiomyopathy? Kim R. clarified that glucocorticoids can delay the onset, but this medication does not have any impact. They did not evaluate CV outcomes with this medication.

Dr. Yarczower recommended sharing the criteria with Dr. Maguire from pediatric neurology.

Keith asked that FDA be defined within the criteria.

No other 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: Viltepso is a medical benefit and will not be added to the Commercial, Marketplace, and GHP Kids formularies. When Viltepso is processed at a specialty pharmacy, it will be processed on 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 of interdisciplinary team involvement including, at a minimum, neurology, cardiology, pulmonology, and a genetic specialist (e.g. geneticist, genetic counselor, etc.) **AND**
- Medical record documentation of Duchenne's Muscular Dystrophy (DMD) confirmed by genetic testing **AND**
- Medical record documentation that the member has a confirmed mutation of the DMD gene that is amenable to exon 53 skipping confirmed by a genetic counselor **AND**
- Medical record documentation of a baseline evaluation, including a standardized assessment of motor function by a neurologist with experience treating Duchenne muscular dystrophy **AND**
- Medical record documentation that Viltepso is being given concurrently with oral corticosteroids **AND**
- Medical record documentation that the patient is ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility) as proven by documentation of a 6-Minute Walk Test Distance (6MWT) within the past 3 months of initiation of Viltepso **AND**
- Medical record documentation that patient does not have a symptomatic cardiac abnormality **AND**
- Medical record documentation that patient will receive a dose consistent with the FDA approved labeling (maximum dose of 80 mg/kg infused once weekly)

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 the following:

- Medical record documentation that the member continues to benefit from treatment with viltolarsen **AND**
- Medical record documentation of an annual evaluation, including an assessment of motor function ability, by a neurologist with experience treating Duchenne muscular dystrophy **AND**
- Medical record documentation that Viltepso continues to be given concurrently with oral corticosteroids **AND**
- Medical record documentation that patient does not have a symptomatic cardiac abnormality **AND**
- Medical record documentation that the patient will continue to receive a dose consistent with the FDA approved labeling (maximum dose of 80 mg/kg infused once weekly) **AND**
- Medical record documentation that the patient remains ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility) as proven by documentation of a follow-up 6-Minute Walk Test Distance (6MWT) within the past 6 months

Note: Exon Deletions* on the Duchenne Muscular Dystrophy Gene Theoretically Amenable to Exon 53 Skipping

3-52	4-52	5-52	6-52	9-52					
10-52	11-52	13-52	14-52	15-52	16-52	17-52	19-52		
21-52	23-52	24-52	25-52	26-52	27-52	28-52	29-52		
30-52	31-52	32-52	33-52	34-52	35-52	36-52	37-52	38-52	39-52
40-52	41-52	42-52	43-52	45-52	47-52	48-52	49-52		
50-52	52	54-58	54-61	54-63	54-64	54-66	54-76	54-77	

*The first number represents the first exon deleted. The last number is the last exon deleted. The dash (-) represents all exons in between the first and last exon deleted.

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

FAST FACTS

XEOMIN (incobotulinumtoxin A)

Updated Indication: Xeomin is now indicated for the treatment of pediatric patients ages 2 to 17 years with upper limb spasticity, excluding spasticity caused by cerebral palsy.

Previously, Xeomin was only indicated for treatment of adult patients with upper limb spasticity.

Xeomin is also now indicated for the treatment of chronic sialorrhea in patients 2 years of age and older.

Previously, Xeomin was only indicated for the treatment of adult patients with chronic sialorrhea.

Current formulary Medical benefit requiring prior authorization

Recommendation: No changes are recommended to the formulary placement of Xeomin at this time. It is recommended that MBP 11.0 be updated to account for the updated labeling changes.

31. Upper Limb Spasticity

Botulinum toxin A for the treatment of upper limb spasticity is considered medically necessary when the following criteria are met:

- Patient is at least 2 years of age **AND**
- Medical record documentation that Botox or Xeomin is being used for the treatment of upper limb spasticity **AND**
- ~~For Botox, documentation that the patient is at least 2 years of age **OR**~~
- ~~For Xeomin, documentation that the patient is at least 18 years of age~~

Geisinger Health Plan approved FDA labeled indications for Botulinum Toxin Type A (**Xeomin** only) are:

1. Sialorrhea

- Documentation that patient is at least ~~18~~ 2 years of age **AND**
- For adults ages 18 years or older: Medical record documentation of a diagnosis of chronic sialorrhea resulting from Parkinson's disease, atypical parkinsonism, stroke, or traumatic brain injury **OR**
- For pediatric patients ages 2 to 17 years: Medical record documentation of a diagnosis of chronic sialorrhea resulting from cerebral palsy, other genetic or congenital disorders, or traumatic brain injury

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.

SELZENTRY (maraviroc)

Updated Indication: Selzentry is indicated in combination with other antiretroviral agents for the treatment of only CCR5-tropic human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 2 kg.

Limitations of Use: Not recommended in patients with dual/mixed- or CXCR4-tropic HIV-1.

Previously, this was indicated in pediatric patients 2 years and older weighing at least 10 kg.

Current formulary status: Brand Preferred Tier

Quantity Limits:
Selzentry 20 mg/mL solution: 60 mL per day
Selzentry 25 mg tablets: 8 tablets per day
Selzentry 150 mg tablets: 2 tablets per day

Recommendation: Because Selzentry is available without a prior authorization and the updated dosing recommendations would be covered under the current quantity limits, no changes are recommended at this time.

Discussion: No comments or questions.

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

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

STELARA (ustekinumab)

Updated Indication: Stelara is now indicated for the treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. Previously this indication included patients 12 years and older.

Current formulary status: Medical or pharmacy benefit on the Specialty tier/Brand Non-Preferred tier for patients with 3 tier benefit, requiring prior authorization

Recommendation: No changes are recommended to the formulary placement, authorization duration, or quantity limits for Stelara based on the new indication. It is recommended to update the age criteria as follows:

Commercial Policy 318.0 Stelara

Pediatric Plaque Psoriasis

- Medical record documentation that Stelara is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to ~~12 years~~ 6 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease affecting crucial body areas such as hands, feet, face or genitals **AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two topical corticosteroids **AND**
- Medical record documentation that the prescribed dosing is appropriate for patient's weight **AND**
- Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

Medical Benefit Policy 75.0 Stelara

1. **Pediatric Plaque Psoriasis**
   - Prescription must be written by a dermatologist **AND**
   - Member must be at least ~~12 years of age~~ 6 years of age **AND**
   - Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by ≥5% of body surface area involved or disease affecting crucial body areas such as hands, feet, face, or genitals **AND**
   - Medical record documentation of intolerance to, contraindication to, or therapeutic failure on at least two topical corticosteroids **AND**
   - Medical record documentation that the prescribed dose is appropriate for the patient's weight

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.

VIMPAT (lacosamide)

Updated Indication: Vimpat is now indicated as adjunctive treatment for the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older.

Previously it was indicated for the treatment of partial-onset seizures in patients 4 years of age and older.

Current formulary status: Brand Non-Preferred tier requiring a prior authorization

Recommendation: There are no changes recommended to the formulary placement of Vimpat. It is recommended that the following prior authorization criteria be added to the Commercial and Part D policies for Vimpat to incorporate the new indication:

- Medical record documentation of one of the following:
  - Documentation of a diagnosis of partial-onset seizures **OR**
  - Documentation of a diagnosis of primary generalized tonic-clonic seizures **AND** documentation that Vimpat will be used as adjunctive treatment

AND

- Medical record documentation of age greater than or equal to 4 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

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.

SUPREP (sodium sulfate/potassium sulfate/magnesium sulfate)

Updated Indication: Suprep Bowel Prep Kit is now indicated for cleansing of the colon as preparation for colonoscopy in adult and pediatric patients 12 years of age and older.

Current formulary status: Brand Non-Preferred tier

Recommendation: No changes are needed to the formulary placement of Suprep. Suprep is available without an age restriction for Commercial, Marketplace, and GHP Kids members. When the new formulation for the pediatric dose containing two 4.5-ounce doses is available it is recommended to add it to the Brand Non-preferred tier of the Commercial, Marketplace, and GHP Kids formularies to match the adult dose of Suprep.

Discussion: No comments or questions.

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

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

UPDATES

DUPIXENT (dupilumab)

Background: As part of the creation of the Geisinger Health System ProvenCare Pathway for atopic dermatitis, the Geisinger department of dermatology, led by Dr. Howard Pride, reviewed the current Dupixent (dupilumab) drug utilization policies and provided feedback to GHP (summarized below).

- Treatment with topical corticosteroids is an appropriate first-line drug treatment in most patients, including the pediatric population. The American Academy of Dermatology guidelines of care for the management of atopic dermatitis provide strong recommendations for the use of topical steroids in both adults and children. Children between the ages of 2 and 15 years are not excluded from the use of topical corticosteroids in clinical practice.
- The current commercial/exchange/CHIP policy appears to attempt to "escalate" a patient's treatment by stepping through topical steroids, followed by topical calcineurin inhibitors, followed by crisaborole. It was explained that the "relative potencies" of topical calcineurin inhibitors and crisaborole are "lower" than topical corticosteroids, and that one would not expect a patient to respond better topical calcineurin inhibitors or crisaborole if not responding to topical steroids. Instead, topical calcineurin inhibitors and crisaborole are used as steroid sparing agents in patients responding well to topical steroids but needing a break. Generally, tacrolimus ointment or pimecrolimus cream are chosen over crisaborole for steroid sparing therapy as crisaborole seems to be less effective than the calcineurin inhibitors and has more application site pain.
- Light therapy is an appropriate therapy to trial prior to dupilumab in many patients although some patients may not be good candidates for light therapy based on past medical history. In general, patients should be considered for light therapy prior to prescribing dupilumab, especially considering the cost difference between the therapies.
- Clinicians prefer utilizing dupilumab over oral systemic treatments (methotrexate, cyclosporine, mycophenolate) as dupilumab maintains a better efficacy and safety profile than the aforementioned products. While some patients may be appropriate for a product such as methotrexate, limited patients are eligible, and the standard of care points towards dupilumab after topical treatments are failed.

Based on the above bulleted feedback, it was recommended by Geisinger Dermatology for GHP to remove the age exclusion from topical corticosteroids and alter the policy so that patients do not have to step through topical corticosteroids AND topical calcineurin inhibitors AND crisaborole.

Current Formulary Status/Prior Authorization Criteria: Pharmacy benefit on the specialty tier (brand non-preferred tier for members with a 3-tier benefit) requiring prior authorization.

Recommendation: No changes are recommended to the tiering of Dupixent at this time. It is recommended that the following policy changes are made based on the clinical discussion above. No changes are recommended to the existing authorization duration or quantity limits or to other indications for Dupixent at this time.

<u>Atopic Dermatitis</u>

- Medical record documentation that Dupixent is prescribed by or in consultation with an allergist, dermatologist, or immunologist **AND**
- Medical record documentation of one of the following:
    - If request is for Dupixent pre-filled pen: documentation of age greater than or equal to 12 years **OR**

- If request if for Dupixent pre-filled syringe: documentation of age greater than or equal to 6 years **AND**

- Medical record documentation of a diagnosis of moderate to severe atopic dermatitis **AND**
- ~~Medical record documentation of contraindication to, intolerance to, or therapeutic failure* on an adequate trial of at least one medium potency** topical corticosteroid unless deemed inadvisable due to potential risks such as (a) use on sensitive skin areas (face, axillae, or groin) or (b) member is between 2 and 15 years of age **AND**~~
- ~~Medical record documentation of contraindication to, intolerance to, or therapeutic failure on tacrolimus ointment **AND**~~
    - Medical record documentation of one of the following:
    - A therapeutic failure* on an adequate trial of at least one medium (or higher) potency** topical corticosteroid **OR**
    - For patients with an intolerance or contraindciation to topical corticosteroids or for patients in whom topical corticosteroids are inadvisable (use on sensitive skin areas, age between 2 and 15 years): A contraindication to, intolerance to, or therapeutic failure on a topical calcineurin inhibitor (e.g. tacrolimus ointment, pimecrolimus cream)

AND

- ~~Medical record documentation of contraindication to, intolerance to, or therapeutic failure on Eucrisa* **AND**~~
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on an adequate trial of phototherapy (UVA/UVB treatment)

***NOTE:** Therapeutic failure is defined as an inability to achieve and maintain remission of low to mild disease activity.

Discussion: Dr. Yarczower asked when Dupixent will be going generic. Keith said that there is no generic availability anticipated in the near future. 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.

JANUARY 2021 P&T DUR/ADHERENCE UPDATE

Drug Use Evaluations (DUEs)

- Statin Use in Persons with Diabetes DUE
    - This is the 2020 4th quarter MedImpact DUE for Commercial/Exchange and GHP Family
    - From this report, we identified members whose medication history was suggestive of the presence of diabetes and who were not receiving a statin drug during the previous three-month period.
    - The Print Shop completed the mail merge and sent out letters to the member's providers on 12/3/2020.
    - See below for letters sent:
        - For GHS01: **98**
        - For GHS25: **9**
        - For GT045: **33**
        - For GHS05: **87**
        - For GHS90: **95**
        - For GT046: **26**

        - For GT062: **26**
        - For GT400: **99**
        - For GT095: **87**
        - For GT900: **60**
    - We will re-run the data on this population in March 2021 to determine the effectiveness of the letter.

- Asthma DUE
    - This is the 2020 3rd quarter MedImpact DUE for all LOBs
    - From this report, we identified members who received 4 or more prescriptions for an asthma medication over a 12-month period but did not receive an asthma controller medication in that same 12-month period.
    - The Print Shop completed the mail merge and sent out letters to the member's providers on 8/26/2020.
    - Adam K. re-ran this data on 12/11/2020 to analyze the effectiveness of the letter. Of the original 412 members that we sent letters, 372 are still active. Of those 372 members, 30 now have a claim for a controller medication. This equates to about 8.1% of the targeted members.
    - See below for letters sent:
        - For GHS01: **98**
        - For GHS25: **4**
        - For GT023: **2**
        - For GT045: **5**
        - For GT056: **3**
        - For GT070: **1**
        - For GT095: **22**
        - For GT140: **2**
        - For GT291: **1**
        - For GT400: **96**
        - For GHS05: **62**
        - For GHS90: **99**
        - For GT036: **1**
        - For GT046: **6**
        - For GT062: **1**
        - For GT089: **2**
        - For GT106**: 1**
        - For GT210: **1**
        - For GT310: **3**
        - For GT902: **2**

- Congestive Heart Failure DUE
    - This is the 2020 2nd quarter MedImpact DUE for Commercial/Exchange and GHP Family
    - From this report, we identified members who have a presumed diagnosis of heart failure taking metoprolol succinate, carvedilol, or bisoprolol, and who were not taking an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin II receptor blocker (ARB) drug therapy in a 3-month timeframe
    - The Print Shop completed the mail merge and sent out letters to the member's providers on 6/30/2020.
    - Adam K. re-ran this data on 10/21/2020 to analyze the effectiveness of the letter. Of the original 559 members that we sent letters, 503 are still active. Of those 503 members, 28 now have a claim for an ACEI or ARB. This equates to about 5.6% of the targeted members.
    - See below for letters sent:
        - For GHS01: **89**
        - For GHS25: **6**
        - For GT038: **51 -Life Geisinger**
        - For GT062: **13**
        - For GT400: **92**
        - For GHS05: **84**
        - For GHS90: **81**
        - For GT046: **23**
        - For GT095: **87**
        - For GT900: **33**

- Coronary Artery Disease DUE
    - This is the 2020 1st quarter MedImpact DUE for all LOBs
    - From this report, we identified members age 40-75 years who are not on a statin drug therapy in a 3-month timeframe and who have at least one of the following cardiovascular disease (CVD) risk factors: diabetes, hypertension, or smoking.
    - Brandy P. is completed the mail merge and sent out letters to the member's providers on 2/21/2020.
    - See below for letters sent:
        - For GHS01: **91**
        - For GHS25: **36**
        - For GT023: **54**
        - For GT036: **12**
        - For GT041: **15**
        - For GT046: **100**
        - For GT062: **100**
        - For GT065: **100**
        - For GT088**: 18**
        - For GT095: **100**
        - For GT107: **14**
        - For GT140: **31**
        - For GT210: **22**
        - For GT260: **30**
        - For GT400: **100**
        - For GHS05: **87**
        - For GHS90: **100**
        - For GT033: **32**
        - For GT038: **14**
        - For GT045: **100**
        - For GT056: **43**
        - For GT064: **14**
        - For GT070: **27**
        - For GT089: **74**
        - For GT106**: 23**
        - For GT108: **14**
        - For GT180: **13**
        - For GT230: **65**
        - For GT310: **28**
        - For GT900: **100**
    - Adam K. was able to re-run the data on this population on 8/5/2020 and of the original 1,296 members that we sent letters to 1,195 are still active. Of those 1,195 members, 128 now have a claim for a statin. This equates to 11% of the members.

In Progress

- Working internally to create new quarterly DUEs

Ongoing

- DUR Duplicate Anticoagulant Report
    - We get this report **weekly** for **all LOBs** flagging members filling duplicate anticoagulant medications. We personally reach out to the providers/pharmacy/patient of the flagged members to confirm proper medication therapy.
    - For 2020:
        - For GHS01: **3 members** reviewed and **0 interventions** made
        - For GHS02: **3 members** reviewed and **0 interventions** made
        - For GHS05: **3 members** reviewed and **1 intervention** made
        - For GHS90: **10 members** reviewed and **2 interventions** made
        - For GT045: **2 members** reviewed and **0 interventions** made
        - For GT062: **1 member** reviewed and **0 interventions** made
        - For GT065: **8 members** reviewed and **1 intervention** made
        - For GT095: **1 member** reviewed and **0 interventions** made
        - For GT400: **10 members** reviewed and **0 interventions** made
        - For GT900: **1 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 Prater. These members are identified and written up and sent to a medical director if follow up is needed.
    - For Commercial/Exchange 2020, we have reviewed the Q1, Q2, and Q3 reports and have discussed the following patients with Dr. Yarczower for intervention:
        - GHS01: **1**
        - GHS90: **2**
        - GT095: **4**
        - GT400: **1**

- Suboxone with an Opioid Report
    - We are getting this report **weekly** for **all LOBs** from Adam Kelchner. These members are being forwarded to Dr. Meadows, and he is looking into whether it is appropriate to end the opioid authorizations still in place
    - For Commercial/Exchange and TPAs in 2020, see below for the new members reviewed and those referred to Dr. Meadows:
        - For GHS01: we reviewed **3 new members** and **0 members** were referred to Dr. Meadows
        - For GHS05: we reviewed **2 new members** and **1 member** was referred to Dr. Meadows
        - For GHS25: we reviewed **1 new members** and **0 members** were referred to Dr. Meadows
        - For GHS90: we reviewed **6 new members** and **3 members** were referred to Dr. Meadows
        - For GT023: we reviewed **1 new member** and **0 members** were referred to Dr. Meadows
        - For GT062: we reviewed **1 new member** and **0 members** were referred to Dr. Meadows
        - For GT210: we reviewed **1 new member** and **1 member** was referred to Dr. Meadows
        - For GT400: we reviewed **5 new members** and **1 member** was referred to Dr. Meadows
        - For GT902: we reviewed **1 new member** and **0 members** were referred to Dr. Meadows

- 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 and TPAs in 2020, see below for the number of letters we have sent to members notifying them that we are ending their opioid authorization(s):
        - For GHS05: **1**
        - For GHS90: **2**
        - For GT400: **1**

- Opioid Overutilization Report
    - We are getting this report **monthly** from MedImpact and we are writing 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 and TPAs in 2020, see below for the number of reviewed cases.
        - For GHS90: **2 patients** were reviewed, and **1 case** was sent to Dr Meadows for further review

- FWA Reports
    - We are getting this report **weekly** for **all LOBs** from Marie Strausser. We prepare this report by determining which claims need to be verified, and the Wilkes pharmacy students/GHP technicians have been making the calls to pharmacies.
    - We review claims for anti-hypertensives, statins, 1-day supply, and inhalers
        - For GHS01 in 2020, we reviewed **63 cases** and **corrected 34 claims**, resulting in a **cost savings of $1,304.24**
        - For GHS02 in 2020, we have reviewed **10 cases** and **corrected 1 claim**, resulting in a **cost savings of $0**
        - For GHS05 in 2020, we reviewed **45 cases** and **corrected 34 claims**, resulting in a **cost savings of $1,807.16**
        - For GHS25 in 2020, we reviewed **2 cases** and **corrected 1 claim**, resulting in a **cost savings of $0**
        - For GHS90 in 2020, we reviewed **92 cases** and **corrected 60 claims**, resulting in a **cost savings of $1,682.78**
        - For GT038 in 2020, we reviewed **20 cases** and **corrected 7 claims,** resulting in a **cost savings of $507.63**
        - For GT045 in 2020, we reviewed **4 cases** and **corrected 3 claims**, resulting in a **cost savings of $31.05**
        - For GT046 in 2020, we reviewed **6 cases** and **corrected 2 claims**, resulting in a **cost savings of $3.00**
        - For GT056 in 2020, we reviewed **2 cases** and **corrected 2 claims**, resulting in a **cost savings of $321.13**
        - For GT062 in 2020, we reviewed **14 cases** and **corrected 4 claims**, resulting in a **cost savings of $21.49**
        - For GT065 in 2020, we reviewed **49 cases** and **corrected 38 claims**, resulting in a **cost savings of $2,256.13**
        - For GT070 in 2020, we reviewed **1 case** and **corrected 1 claim**, resulting in a **cost savings of $0.40**
        - For GT089 in 2020, we reviewed **1 case** and **corrected 1 claim**, resulting in a **cost savings of $48.23**
        - For GT095 in 2020, we reviewed **39 cases** and **corrected 14 claims**, resulting in a **cost savings of $1,336.54**
        - For GT180 in 2020, we reviewed **2 cases** and **corrected 2 claims**, resulting in a **cost savings of $1.90**
        - For GT400 in 2020, we reviewed **53 cases** and **corrected 27 claims**, resulting in a **cost savings of $4,173.24**

        - For GT900 in 2020, we reviewed **10 cases** and **corrected 6 claims**, resulting in a **cost savings of $449.28**

- 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 Commercial/Exchange in 2020, we have sent letters to providers on the below members:
        - For GHS01: **10**
        - For GHS05: **8**
        - For GHS90: **12**
        - For GT038: **3**
        - For GT062: **2**
        - For GT065: **7**
        - For GT095: **7**
        - For GT400: **9**
        - For GT900: **1**
    - *We are working on a revision to this report that will result in a substantial increase of the interactions identified/outreached on*

- Enbrel Overutilization for Treating Plaque Psoriasis
    - A **monthly** report was created to determine members who have been overutilizing Enbrel twice weekly dosing as outlined by the FDA approved dose.
        - We put in place QLs for Enbrel, so we should not be seeing these cases moving forward for new starts or for re-authorization
            - For 2020, we did not identify any members
            - For 2021, we will discontinue this report since quantity limits are coded and pulled into authorizations and authorizations are audited daily

- Tobacco Cessation Program
    - We are getting 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 in 2020, we sent letters to the below members:
        - For GHS01: **7**
        - For GHS05: **3**
        - For GHS90: **8**
        - For GT045: **1**
        - For GT046: **1**
        - For GT062: **1**
        - For GT065: **14**
        - For GT095: **1**
        - For GT230: **1**
        - For GT310: **1**
        - For GT400: **4**

- STENT Adherence Report

- This is a **monthly** report to identify members on an antiplatelet medication and then flag for betablocker and statin medication claims.
- In 2020, we sent letters encouraging adherence to the below members:
  - **Members for Antiplatelet:**
    - GHS01:**78**
    - GHS05: **52**
    - GHS25: **2**
    - GHS90:**142**
    - GT291: **1**
    - GT023: **1**
    - GT036: **1**
    - GT038: **22**
    - GT039: **1**
    - GT041: **1**
    - GT045: **3**
    - GT056: **1**
    - GT062: **9**
    - GT065: **17**
    - GT089: **4**
    - GT095: **16**
    - GT180: **2**
    - GT230: **2**
    - GT400: **33**
    - GT900: **5**
  - **Members for Beta-Blocker:**
    - GHS01:**64**
    - GHS05: **44**
    - GHS25: **2**
    - GHS90: **120**
    - GT023: **1**
    - GT036: **1**
    - GT038: **15**
    - GT039: **1**
    - GT041: **1**
    - GT045: **2**
    - GT056: **2**
    - GT062: **17**
    - GT065: **17**
    - GT089: **2**
    - GT095: **21**
    - GT106: **1**
    - GT108: **1**
    - GT230: **2**
    - GT311: **1**
    - GT400: **36**
    - GT900: **8**
  - **Members for Statin:**
    - GHS01: **93**
    - GHS05: **60**
    - GHS25: **2**
    - GHS90: **130**
    - GT023: **1**
    - GT036: **1**
    - GT038: **17**
    - GT039: **1**
    - GT045: **4**
    - GT056: **1**
    - GT062: **22**
    - GT065: **21**
    - GT089: **5**
    - GT095: **37**
    - GT107: 1
    - GT108: 2
    - GT230: **2**
    - GT291: 1
    - GT400: **48**
    - GT900: **7**

        - *member may flag for more than one measure and are included in the count for each measure
    - We are also attempting telephonic outreach to members who are non-adherent in all 3 measures to encourage adherence.

HEDIS Initiatives:

- Asthma Medication Ratio (AMR)
    - Kayla Stanishefski 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 Commercial/Exchange in 2020, see below for letters sent to members:
            - GHS01: **14**
            - GHS90: **6**
- Antidepressant Medication Management (AMM)
    - Kayla Stanishefski runs this proactive HEDIS report **monthly,** and we send letters to the flagged members who appear non-adherent to their antidepressant medications.
        - For Commercial/Exchange in 2020, see below for letters sent to members:
            - Effective Acute Phase:
                - GHS01: **6**
                - GHS90: **1**
            - Effective Continuation Phase:
                - GHS01: **100**
                - GHS90: **86**
- Medication Management for People with Asthma (MMA)
    - Kayla Stanishefski runs this proactive HEDIS report **monthly,** and we send letters to the flagged members who appear non-adherent to their asthma controller medications**.**
        - For Commercial/Exchange in 2020, see below for letters sent to members:
            - GHS01: **52**
            - GHS05: **3**
            - GHS90: **40**
- Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
    - Kayla Stanishefski runs this report **monthly,** and we send letters to the flagged members who appear non-adherent to their antipsychotic medications.
    - HEDIS Specifications: The percentage of members 19-64 years of age during the measurement year with schizophrenia or schizoaffective disorder who were dispensed and remained on an antipsychotic medication for at least 80% of their treatment period.
        - For Commercial/Exchange in 2020: **0 letters** were sent 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 Commercial/Exchange in 2020, see below for letters sent to **providers** to encourage statin therapy initiation**:**
            - GHS01: **40**
            - GHS02: **1**
            - GHS05: **1**
            - GHS90: **21**
        - For Commercial/Exchange in 2020, see below for letters sent to **members** to promote statin adherence:

        - GHS01: **25**
        - GHS90: **10**
- 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 Commercial/Exchange in 2020, see below for letters sent to **providers** to encourage statin therapy initiation**:**
            - GHS01: **481**
            - GHS05: **2**
            - GHS90: **208**
        - For Commercial/Exchange in 2020, see below for letters sent to **members** to promote statin adherence:
            - GHS01: **88**
            - GHS05: **17**
            - GHS25: **1**
            - GHS90: **42**
            - GT023: **1**
            - GT036: **1**
            - GT038: **1**
            - GT039: **1**
            - GT045: **1**
            - GT046: **2**
            - GT062: **7**
            - GT065: **2**
            - GT089: **1**
            - GT095: **12**
            - GT230: **1**
            - GT400: **21**

- 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 Commercial/Exchange in 2020, **0 letters** were sent to members.

Completed

- Commercial/Exchange DUR/FWA Program Fliers
    - Last updated 08/2020 next update 02/2021
- Current Provider Letters
        - Congestive Heart Failure DUE
        - Coronary Artery Disease DUE
        - Statin Use in Persons with Diabetes DUE
        - Asthma Med Ratio DUE
        - Opioid Overutilization
        - Severity Report
        - Duplicate Anticoagulant Report
        - Statin Therapy for Patients with Cardiovascular Disease (SPC)
        - Statin Therapy for Patients with Diabetes (SPD)

- Current Member Letters
    - Ending Opioid Authorizations
    - Adherence to Antipsychotics (SAA)
    - Antidepressant Medication Management (AMM)
    - Asthma Medication Ratio (AMR)
    - Medication Management for People with Asthma (MMA)
    - Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - Statin Therapy for Patients with Diabetes (SPD)
    - Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
    - STENT Adherence Report

Discussion: Has there been any change on the number of DUR reviews that we're completing as a result of the pandemic? Only thing that stands out is the Gold population with members either afraid to go to the pharmacy or stock piling medications. No other 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

Discussion: Our most recent Quarterly Case Audit was held on December 4th for 3rd quarter 2020. There were no recommendations at this time. We will continue to look for opportunities to create more drug specific policies at future quarterly case audit meetings. No other 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 2:59 pm.

Voting responses were received from 21 of 35 members. The vote was unanimously approved.

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on Tuesday, March 16, 2021 at 1:00 HCN3A & 3B Conference room

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