P&T Committee Meeting Minutes
Medicaid
January 19, 2021

Present (via Skype):	**Absent:**
Bret Yarczower, MD, MBA – Chair Megan Ammon, Pharm.D. Kristen Bender, Pharm.D. Dean Christian, MD Alyssa Cilia, RPh Kimberly Clark, Pharm.D. Rajneel Farley, 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)	Holly Bones, Pharm.D. Kim Castelnovo Michael Evans, RPh Tricia Heitzman, Pharm.D. Nichole Hossler, MD Jonas Pearson, RPh William Seavey, Pharm.D.

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, January 19, 2021

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the November 17, 2020 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

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 Discussion: The committee unanimously voted to accept the recommendations.

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

Outcome: Enspryng should be added to the Brand tier for GHP Family members. The following additional criteria should 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

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 Discussion: The committee unanimously voted to accept the recommendations.

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

Outcome: Viltepso is a medical benefit that will be managed by GHP and should not be added to the GHP Family formulary. 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 unless intolerant or contraindicated **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 Food and Drug Administration (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 unless intolerant or contraindicated **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 Food and Drug Administration (FDA) approved labeling (maximum dose of 80 mg/kg infused once weekly)

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

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.

Recommendation: No changes are needed to the formulary placement of Suprep. The current policy for Suprep does not include prior authorization criteria based on age and no changes are needed to the current prior authorization criteria. When the new formulation for the pediatric dose containing two 4.5 ounce doses is available it is recommended that it be Non-Formulary to match the adult dose of Suprep.

Outcome: The committee unanimously voted to accept the recommendations.

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

UPDATE

January 2021 P&T DUR/Adherence Update

Recommendation: The January 2021 DUR/Adherence update was presented to the committee for review.

Outcome: No questions or comments

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

2021 GHP Family Supplemental Formulary

Recommendation: The 2021 GHP Family Supplemental Formulary was presented to the Committee for review and approval.

Outcome: The committee unanimously voted to accept the recommendations.

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

December Electronic Vote

Due to the volume of full drug reviews, fast facts, and updates that must reviewed by the P&T Committee an additional electronic vote was held from December 22, 2020 to December 31, 2020. Responses were received from 19 members (out of 35) and all voted to approve.

The following was approved for GHP Family:

Drug	Recommendation
Evrysdi	• Medical record documentation that Evrysdi is prescribed by a neurologist or pediatric neurologist AND • Medical record documentation of age of 2 months or older AND • Medical record documentation of a confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following: o Homozygous exon 7 gene deletion OR o Homozygous exon 7 conversion mutation OR o Compound heterozygous exon 7 mutation OR • Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies AND • Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Zolgensma)* • Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g. Spinraza) *Note: Requests for members that show decline in clinical status following treatment with Zolgensma will be reviewed on a case by case basis. **AUTHORIZATION DURATION:** Evrysdi will be approved for an initial authorization duration of 12 months. Subsequent authorizations will be determined medically necessary and should be approved for an authorization duration of 12 months when the following criteria are met: • Medical record documentation that member is compliant with the prescribed risdiplam regimen AND • Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Zolgensma)* AND • Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g. Spinraza) *Note: Requests for members that show decline in clinical status following treatment with Zolgensma will be reviewed on a case by case basis. **Other Recommendations:** Although safety of treatment with Evrysdi in patients with previously treated SMA was evaluated in the JEWELFISH, efficacy in previously treated SMA was not evaluated. The safety and efficacy of concomitant use of Evrysdi in combination with Spinraza was not evaluated. It is recommended to make the following changes to the prior authorization criteria in the Zolgensma and Spinraza policies. Zolgensma Medical Benefit Policy 199.0 • Medical record documentation of a confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following: o Homozygous exon 7 gene deletion OR o Homozygous exon 7 conversion mutation OR o Compound heterozygous exon 7 mutation OR o Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies AND • Prescription is being prescribed by a neurologist or pediatric neurologist AND

	• Medical record documentation that the patient will be less than 2 years of age at the time of dosing AND • Medical record documentation that patient does not have anti-AAV9 antibody titers >1:50 as determined by ELISA (within two weeks of the anticipated infusion date) AND • Medical record documentation that patient is not permanent ventilator-dependent AND • Medical record documentation that patient has not received a prior dose of Zolgensma AND • Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g. Spinraza, Evrysdi) with Zolgensma (Note: Any current authorizations for SMN modifying therapy will be terminated upon Zolgensma approval) <u>Spinraza Medical Benefit Policy 151.0</u> • Prescription is being prescribed by a neurologist or pediatric neurologist AND • Medical record documentation of a confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following: • Homozygous exon 7 gene deletion OR • Homozygous exon 7 conversion mutation OR • Compound heterozygous exon 7 mutation OR • Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies. AND • Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Zolgensma)* AND • Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g. Evrysdi) *Note: Requests for members that show decline in clinical status following treatment with Zolgensma will be reviewed on a case by case basis. **AUTHORIZATION DURATION:** If determined to be medically necessary, Spinraza should be approved for an initial authorization duration of 12 months. Subsequent authorizations of Spinraza will be determined medically necessary and should be approved for an authorization duration of 12 months when the following criteria are met: 16 • Medical record documentation that member is compliant with prescribed nusinersen regimen. AND • Medical record documentation that the patient has not received prior treatment with gene therapy (Zolgensma)* AND • Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g. Evrysdi) *Note: Requests for members that show decline in clinical status following treatment with Zolgensma will be reviewed on a case by case basis.
Veklury	Veklury will be a medical benefit for GHP Family members. Veklury will not require a prior authorization.
Keytruda	There are no updates recommended to the authorization duration or the formulary placement for Keytruda. It is recommended to make the following changes to the Medical Benefit Policy 199.0 to incorporate the change in the indication for Classical Hodgkin Lymphoma.

	Classical Hodgkin Lymphoma • Prescription written by a hematologist/oncologist AND • Medical record documentation of Classical Hodgkin Lymphoma AND • One of the following: a. Medical record documentation of a diagnosis of refractory Classical Hodgkin Lymphoma OR b. Medical record documentation of age greater than or equal to 18 years AND relapse following one (1) or more prior lines of therapy OR c. Medical record documentation of age less than 18 years AND relapse following two (2) or more prior lines of therapy It is recommended that the following criteria be added to Medical Benefit Policy 199.0 to incorporate the new indication in Triple Negative Breast Cancer. **Triple Negative Breast Cancer** • Prescription written by a hematologist/oncologist AND • Medical record documentation of age greater than or equal to 18 years AND • Medical record documentation of locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) AND • Medical record documentation that tumors express PD-L1 [Combined Positive Score (CPS) greater than or equal to 10] as determined by an FDA approved test AND • Medical record documentation that Keytruda will be given in combination with chemotherapy (paclitaxel, paclitaxel protein-bound, or gemcitabine and carboplatin).
Crysvita	Based on the availability of the Kainos assay as well as feedback from Dr. Evan Norfolk and the nephrology department at Geisinger Medical Center, the following changes are recommended to Medical Benefit Policy 182.0 to allow for other testing for FGF23 levels. **FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO)** • Medical record documentation that the patient is at least 2 years of age or older AND • Medical record documentation that Crysvita is being prescribed by, or in consultation with, an endocrinologist, nephrologist, geneticist, or oncologist AND • Medical record documentation of a diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors AND • Medical record documentation of ~~a serum level of FGF23 greater than or equal to 100 pg/mL determined by Kainos assay~~ an elevated serum level of FGF23 AND • Medical record documentation that tumors cannot be curatively resected or localized AND • Medical record documentation that the patient is not concurrently using vitamin D analogs or phosphate supplements.
Preventive Vaccine Update	In order to facilitate the administration of these vaccinations, it is recommended that the following formulary changes are approved to expand access at in-network pharmacies: MENVEO MENA COMPONENT (19 to 55 years), MENVEO MENCYW-135 COMPONENT (19 to 55 years), VARIVAX VACCINE (19 to 999 years

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

Meeting adjourned at 2:58 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on Tuesday, March 16, 2021 at 1:00 via Microsoft Teams.