WY P&T Committee Meeting Minutes
Thursday, August 13, 2020
Cheyenne, WY
10 a.m – 1 p.m.

Members present: Alissa Aylward, Melinda Carroll, Hoo Fang Choo, Joseph Horam, Paul Johnson, Scott Johnston, Kristen Lovas, Robert Monger, Chris Mosier, Garry Needham, Scot Schmidt, Patrick Yost

Ex-officio: Cori Cooper, Melissa Hunter, James Bush

Guests: Donna Artery, Melissa Eames, Sandra Deaver, Amy Stockton (CHC), Matt Robison (CHC), Cory Moss (CHC), Adam Kopp (Zogenix), Aimee Weems (Acorda), Anne Stratton (Children's Hospital Colorado), Beatriz Reyes (UW), William O'Neill (Sunovion), Chris DeSimone (Akcea Therapeutics), Coleen Fong (Gilead), Dana Koehn (Sanofi Genzyme), Deb Guay (Genentech), Erin Hohman (Janssen), Jane Stephen (Amgen), Jason Smith (Gilead), Jeanne Vander Zanden (Biocodex), Jenna Gianninoto (Abbvie), Jennifer Lauper (BMS), Jody Legg (Alkermes), Keri Smith (Viiv), Kim Walter (Janssen), Leslie Zanetti (Sarepta), Mike Donabedian (Sarepta), Rhonda Clark (Indivior), Ronald Abraham (Sunovion), Roy Lindfield (Sunovion), Shannon Payne (Aimmune), Sibin Stephen (Zogenix), Terra Stone (Viiv), Tracy Copelan (Sarepta), Warren Quon (Ascendis), Joe Ferroli (Takeda), Gary Okano (BMS), Todd Ness (Abbvie)

Dr. Monger called the meeting to order at 10:00 a.m.

Introductions were made. Aimee introduced Meghan Monahan. Meghan is the new DUR Project Assistant.

Approval of Minutes

The minutes of the May 14, 2020 meeting were approved.

Department of Health

A. Pharmacy Program Manager Report: The Department of Health continues to work remotely. A 9% budget cut has been requested. There is no official word on what is being cut. They are hoping not to have layoffs, however, many employees will have one furlough day per month. We recently attended the SSDC conference remotely. We have received all of the offers for 2021 and are reviewing them to determine what changes will be made to the PDL.

B. Medical Director Report: Due to COVID, there has been a large increase in use of Telehealth services. 1500 members have been served through telehealth, with claims increasing from $5,000 pre-COVID to $4 million. Other payers including Medicare also contributed to the increase in claims.

C. DUR Manager Report: None

Old Business:

A. None.

New Business

A. PA Criteria

1. Review existing criteria

i. The current Daliresp criteria includes a requirement for concurrent therapy with Spiriva. As this is no longer a part of guidelines or the label, this will be removed. There was a motion, second and all were in favor.

2. New Drugs

i. Palforzia is indicated for mitigation of allergic reactions associated with peanut exposure. Shannon Payne (Aimmune) provided public comment. Dr. Johnson asked how long the desensitization lasted without maintenance therapy. At this time, it is a lifetime therapy. Long-term studies are being conducted with 6 – 12 month drug holidays. If a patient goes two weeks without maintenance, initiation should be started again. It was noted that patients should have an epipen on hand with this medication. There was a motion to limit to indication. Aimee will bring it back in six months with any data on late refills and epipen utilization. The motion was seconded and all were in favor.

ii. Dayvigo is indicated for treatment of insomnia in adults. There was no public comment. The Committee determined that there was not sufficient data to show a difference in safety and efficacy compared to other agents in the class. There was a motion, second and all were in favor. Dayvigo will be referred to the Department of Health for cost analysis.

iii. Zeposia is a new drug for the treatment of relapsing forms of multiple sclerosis. Gary Okano (BMS) provided public comment. It is a once daily, oral medication. There is comparative evidence with Avonex and indirect comparisons with Gilenya. The Committee felt that there was not sufficient safety and efficacy data to make it a preferred agent. There was a motion, second, and all were in favor.

iv. Oriahnn is approved for heavy bleeding associated with uterine fibroids. It is a combination of elagolix (Orilissa) with estradiol/norethindrone add-back therapy. Jenna Gianninoto (Abbvie) provided public comment. The add-back therapy decreases hot flush symptoms and risk of osteoporosis. There is a two-year limit on utilization due to the risk of osteoporosis. There was a motion to limit to indication with a two year limitation on duration of use. It was also noted that it should not be used in patients with a history of thromboembolic events, osteoporosis, or smoking. The motion was seconded and all were in favor.

v. Kynmobi is used for the treatment of intermittent “off” episodes associated with Parkinson’s disease. William O’Neill (Sunovion) provided public comment. The medication is titrated to a level that is effective and can be tolerated. No medication tolerance has been noted. There was a motion to limit to indication. Aimee will bring back utilization data. There was a second and all were in favor.

vi. Fintepla is indicated for the treatment of seizures associated

with Dravet syndrome in patients two years and older. Sibin Stephen provided public comment. Efficacy has been shown in two studies. Dr. Johnston pointed out that this is the same drug that was commonly used in the 90s in combination with phentermine. There have been no findings of valvular issues or pulmonary hypertension in these patients. Data on the benefit of placebo doesn't match that of the CBD study. Was there a problem with randomization? The baseline data in general is not similar between placebo and treatment groups. It is not indicated in combination with CBD, however, no dosage adjustments are needed. Dosage adjustments are needed with stripentol. There was a motion, and second to limit to indication. All were in favor.

vii. Rukobia is indicated for treatment of HIV-1 infection, in combination with other antivirals, in heavily treatment-experienced adults with multidrug-resistant HIV infection failing their current antiretroviral regimen. Terra Stone provided public comment. This is the first agent that binds to the virus and not the host CD-4 cell. Dr. Choo indicated that it is in a class of its own. It is a salvage ART and is added to backbone antiviral therapy. Multi-drug resistance is defined as having active infection with at least two different drugs from two different classes. There was a motion, second, and all were in favor or limiting to indication.

3. Determine need for criteria

i. Vyondys 53 is an exon skipping medication for the treatment of Duchenne Muscular Dystrophy. It was approved through the FDA accelerated approval process based on two early studies. Anne Stratton, a pediatric rehabilitation physician provided public comment. This is a lifetime therapy. The studies show an increase in dystrophin, however, outcomes studies are currently in process. Dr. Stratton has been involved in the clinical studies. Dr. Horam noted that the benefits have been underwhelming, with <1% increase in dystrophin levels. Dr. Stratton indicated that any increase in dystrophin is helpful and her patients seem to be slowing in the rate of decline. She further indicated that it is hard to predict what response patients will have. In patients with little functional muscle mass, there is probably a higher risk than benefit.

Dr. Johnston noted that this is a very political approval. Exondys 51 was not recommended for approval by the neurology committee, however, was overruled at a higher level in the FDA. Vyondys 53 was not approved on the initial application, but was approved later. Dr. Johnston also noted that the placebo arm was very different in baseline characteristics compared to the treatment arm. This suggests a problem with randomization. Dr. Stratton indicated that this is likely more of a recruitment and numbers issue. Melissa brought up the concern that, with no clinical data, we are conducting research on these patients. She also asked how long we need to keep them on the medication to see efficacy. Dr. Stratton said she would have a conversation with the patient about efficacy and let them decide whether to continue on therapy. She monitors her patients closely. Many of her patients are in the study. Many commercial insurers are not covering as they consider it experimental. Is it experimental? Dr. Stratton mentioned that some patients are not eligible for a study and only have access through Medicaid and other payers. It was asked whether this medication should be used in adults. Children were recruited as it is easier to see outcomes in younger patients. Dr. Bush asked if they were measuring and following dystrophin levels. They are not.

Leslie Zanetti (Sarepta) provided additional public comment. She addressed some of the questions that were raised. Vyondys is not experimental. It was FDA approved through the accelerated pathway. A confirmatory trial is in process. The Complete Response Letter from the FDA had two questions, regarding infections and renal toxicities. No toxicities were seen in humans. Newborn screening was discussed. In regards to the original denial of Vyondys, additional data was provided that suggested an increase in dystrophin levels. Leslie indicated that outcome studies show a 50% improvement over natural selection, showing a significant slowing of progression. This is not yet published, but will be presented by the end of August. It was asked what, besides patient preference, would cause discontinuation of this drug. Dr. Stratton indicated that a rapid functional decline, loss of arm strength or the ability to self-feed and pulmonary data would be considerations.

Aimee provided some information on criteria published by Kansas and North Dakota. The studies are conducted in boys aged 6 – 15. When asked if it should be used outside of this age range, Dr. Stratton said she would argue for use in younger patients as the benefit is expected to be greater with earlier treatment. Dr. Johnston reiterated the concern that this medication has no evidence of efficacy, but does have evidence of harm. There were questions about requirements of coverage under EPSDT. Dr. Horam suggested that we defer to gather more precise language and more precise measurements in clinical outcome. Dr. Stratton indicated that one patient in her practice would qualify for Vyondys 53 now and is a Wyoming Medicaid patient. In terms of how long we should allow before looking for efficacy, Dr. Stratton recommended following every 1 to two years for strength testing. The Committee asked to defer to the November meeting for additional information.

There being no further business, the open portion of the meeting adjourned at 12:36 pm and the Committee met in closed session.

Respectfully Submitted,

Aimee Lewis
WYDUR Manager