WY P&T Committee Meeting Minutes Thursday, February 14, 2019 Cheyenne, WY 10 a.m – 1 p.m.

Members present: Hoo Fang Choo, Joseph Horam, Paul Johnson, Scott Johnston, Robert Monger, Chris Mosier, Scot Schmidt, David Sy, Patrick Yost

Ex-officio: Cori Cooper

Excused: Rhonda McLaughlin, Garry Needham, Tonja Woods

Guests: Sandra Deaver, Melissa Eames, Amy Stockton (CHC), Sara Howe (CHC), Donna Artery, Amy Rodenburg (Allergan), Danny McNath (Johnson and Johnson), Dawn Lease (Johnson and Johnson), Roy Lindfield (Sunovian), Dawn Bina (Novo Nordisk), Karen Einbinder (Greenwich Biosciences), Julie Milder (Greenwich Biosciences)

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

Introductions were made.

Approval of Minutes

The minutes of the November 8, 2018 meeting were approved as submitted.

Department of Health

A. Pharmacy Program Manager Report: CMS has officially provided notification of PBMS Certification. With this project complete, J-code management and prior authorization will be a priority. J-code criteria will come through this Committee. The Medical Claims contract is currently out for RFP. The Department of Health has a new Director, Mike Ceballos. He begins March 1 and is currently doing a lot of listening and learning. The Department of Health will be moving to the Herschler building later this year. There are a few bills going through the legislature right now including a 14 day limit on opioid first fills, mandatory continuing education around opioids and mandatory checking of the prescription drug monitoring program.

- B. Medical Director Report: None
- C. DUR Manager Report: Nothing to report

Old Business:

A. The continued Sublocade discussion will be tabled until May as the data is not yet published.

B. <u>New Business</u>

A. PA Criteria

1. Review existing criteria

i. Data regarding concurrent use of antipsychotics was reviewed. No action is necessary at this time.

ii. The current criteria for adult ADHD was discussed. It is difficult to get to prior authorization data as it is a very manual process. Anecdotally, we are not denying many adult patients. The PA Help Desk received requests indicating that the patient needs the medication to get a job, or cannot function at home without it. Dr. Horam indicated that by the time patients reach age 21, 20 - 40% could stay on the medications into their adult years. At this point, you can predict their ability to be successful without medication. Adult ADHD is very hard to isolate due to the many comorbidities that patients have. There is concern about abuse. The important piece of diagnosis is that ADHD should be diagnosed before age 7. From then on, it is a lifelong condition. Adults should be seen at least twice per year, though, with the comorbidities also present, this is rarely an issue. The question to the Committee is whether "social" should count as an area for symptoms to be present. At this time, work or school are required. The Committee asked for more information. Aimee will pull utilization looking at use before and after the PA was implemented as well as concurrent use with opioids and benzodiazepines.

iii. Vyvanse for binge eating disorder was discussed. When the criteria was approved, only 12 week studies were available. There is now a 12 month safety study published. The criteria will be amended to allow use for 12 months after the initial 12 week check in period. There was a motion, second and all were in favor.

2. New Drugs

i. Epidiolex is a cannabinoid approved for treatment of seizures associated with Lennox-Gastaut syndrome and Dravet Syndrome in patients aged two years and older. Julie Milder (Greenwich Biosciences) provided public comment. She indicated that this is a highly purified form of cannabidiol with no psychoactive or euphoric properties. It is metabolized through cytochrome P450 3A4 and 2C19 and may increase levels of clobazam up to three times. Patients should be monitored and dosages adjusted as needed. All studies were add-on therapy. These patients are intractable and are expected to be on additional therapy. There was a question regarding five studies that were withdrawn. The compound has been studied for a variety of indications with about 104 studies ongoing. However, none of these studies was for these seizure disorders. There are no failed studies for the approved indication. It was noted that in Europe, there was an increased risk of suicide when similar medications attached to the cannabinoid centers and blocked THC. Although human studies have not been done, this form of highly purified cannabidiol does not interact with the cannabinoid receptors. Other mechanisms have been found including regulation of calcium channels, reducing neurotransmission and blocking adenosine reuptake. Liver enzymes should be monitored, especially when used concurrently with valproic acid. A handful of patients did achieve seizure-free status in studies. There was one death in the studies, but it was not related to treatment. Lennox-Gastaut and Dravet are rare conditions, with about 40,000 patients in the US. Epidiolex is a Schedule V substance and is legal in Wyoming. Prior to this, patients were getting it in Colorado for these and other seizure disorders. It was asked if using marijuana would have the same effect. In addition to being illegal,

there is no regulation of products. In addition, in some studies, THC is proconvulsant, so it is not clear what impact it may have.

There was a motion, second to limit to indication. Eight members voted aye and one nay. Dr. Johnston voted against as he believes it should be adjunct therapy and at treatment with at least one other agent should be required.

This discussion presented another, related issue. The Onfi criteria was updated to allow for patients aged 2 years and older for Lennox-Gastaut only. Currently, refractory seizures are also included due to the lack of ICD-9 code for LGS. With the implementation of ICD-10 codes, this is no longer an issue and allowing refractory seizures is no longer necessary. There was a motion, second and all were in favor of this update.

ii. Dupixent is a new medication approved for add-on maintenance therapy for moderate to severe asthma in patients aged 12 and older with eosinophilic or corticosteroid-dependent asthma. There was a motion, second and all were in favor of limiting this medication to indication.

iii. Yupelri is a medication for COPD. The Committee noted that there is no evidence of a difference in safety or efficacy and all were in favor of referring to the Department of Health for cost analysis and PDL placement.

iv. Cequa is a cyclosporine agent approved for keratoconjunctivitis sicca. There being no evidence of a difference in safety or efficacy, all were in favor of referring to the Department of Health for cost analysis and PDL placement.

v. Emgality is a new CGRP inhibitor approved for prevention of migraine in adults. The Committee noted that there is no evidence of a difference in safety or efficacy. All were in favor of limiting to indication with the same criteria as the other CGRP inhibitors (trial and failure of two other preventive agents).

B. Long-acting narcotic preferred agents were discussed. The preferred agents are currently morphine sulfate and fentanyl. Because of the rise in overdose deaths with fentanyl, this is no longer an ideal preferred agent. A literature review will be conducted to see if there are any new comparative studies available. A cost analysis will also be conducted to determine the most cost-effective agents.

There being no further business, the open portion of the meeting was adjourned at 11:47 and the Committee met in closed session.

Respectfully Submitted,

Aimee Lewis WYDUR Manager