WY P&T Committee Meeting Minutes Thursday, November 12, 2015 Cheyenne, WY 10 a.m – 1 p.m.

Members present: Joe Horam, Robert Monger, Scot Schmidt, Dean Winsch, Tonja Woods

Via phone: David Sy, Rhonda McLaughlin, Pat Yost

Excused: Andrew Beaulieu, Garry Needham, Brent Sherard

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

Guests: Sara Howe (GHS), Amy Stockton (GHS), Nikki Yost (GHS – Via phone), Derek Traister (Biogen), Christopher DeSimone (Aegerion), Bridget Hernandez (BMS), Charlotte Nutt (UW SoP), Paul Bachem (Novo), Bradley Haas (AstraZeneca), Jeff Knappen (Allergan), Carole Hemmelgoen (Pfizer), Scott Budsberg (Amgen) John Battisti (Otsuka), Aimee Rehair (UCB), Kelli Strother (Otsuka), Pace Owens (DoH intern).

Dr. Monger called the meeting to order at 10:06 a.m.

Introductions were made.

Approval of Minutes

The minutes of the August 13, 2015 meeting were approved as submitted.

Department of Health

- A. Pharmacy Program Manager Report: The process to extend the DUR contract with the University for two more years has begun. The RFP for PBM services is complete and that contract is in process as well.
- B. Medical Director Report: Dr. Bush is on the Governor's Marijuana Impact Committee and is learning a lot. He will report back at future meetings.
- C. DUR Manager Report: The narcotic limits will go into effect December 1. Provider reports and letters have been sent to providers who may be affected.

Old Business

None

New Business

A. PA Criteria

1. Review existing PA criteria:

i. The maximum dose for methylphenidate was set at a consistent 90 mg per day for all forms of methylphenidate. This affects a handful of patients who will be grandfathered at the higher dose.

2. New Drugs

i. Rexulti is a new atypical antipsychotic approved for schizophrenia and as adjunctive treatment for major depressive disorder. John Battisti (Otsuka) provided public comment on this product. He is unable to say whether weight gain is similar to other as there are no head to head trials currently published. There may be a benefit in terms of adverse effects such as akathisia.

The Committee determined that there is no evidence of a difference in safety or efficacy. The Department of Health should do a cost analysis to determine placement on the PDL. The drug should be limited to patients aged 18 and above per label as well as 150% of the labeled maximum dosage. There was a motion, second and all were in favor of these limits.

ii. Daklinza is a new treatment approved for Hepatitis C genotype 3 in combination with sofosbuvir. Bridget Hernandez (BMS) provided public comment. This medication in combination with sofosbuvir allows for shorter treatment duration. Genotype 3 is the hardest to treat and has the highest risk of cirrhosis and hepatocellular carcinoma. The current recommendation is to test for SVR at 12 weeks (SVR-12), however, there are no recommendations for additional viral load testing after this point. Daklinza does have activity against all six genotypes and there are currently two additional SNDAs under review by the FDA currently.

There was a motion, second and all were in favor of limiting Daklinza to its labeled indication and apply the existing clinical criteria for the class.

iii. Technivie is approved for treatment of Hepatitis C genotype 4. It does have a new warning regarding hepatic decompensation in patients with advanced liver disease. There was concern that this drug may have potential safety issues over sofosbuvir which is also approved to treat genotype 4.

There was a motion, second and all were in favor of limiting to approved indication (including contraindication in advanced liver disease) and applying the clinical criteria for the class.

iv. Repatha is a new PCSK9 inhibitor for the treatment of hypercholesterolemia in patients on other lipid-lowering therapy. Scott Budsberg (Amgen) provided public comment. This medication decreases LDL 54-77%. LDL levels hit the minimum at two to three weeks after initiation and are maintained over time. Safety was maintained out to 52 weeks.

The Committee asked Aimee to reach out to cardiologists and endocrinologists to determine which patients will be most benefited by this treatment. It will require a prior

authorization with review by the Department of Health until it can be reviewed again in February.

- v. Praluent is another PCSK9 inhibitor for the treatment of hypercholesterolemia. It will be treated the same as Repatha until further review.
- vi. Varubi is a new antiemetic to be used for delayed nausea and vomiting associated emetogenic cancer chemotherapy. It is used in combination with the 5HT-3 antagonists.

There was a motion, second and all were in favor of limiting to patients with cancer.

3. Humira is now approved for hidradenitis supperativa. There are no available treatment guidelines for this disease; however, there are several potential treatment options that have been used over time. A recent Cochrane review indicated that the evidence in this area is fairly weak. The Committee decided to leave this as a hard prior authorization requiring review by the Department of Health.

**This decision was amended during closed session. This medication will be approved for this indication with a trial and failure of other treatment options for hidradenitis supperativa.

B. The PDL for 2016 was reviewed. It is current with the exception of the narcotic limits. There were no concerns from the Committee. The PDL will be posted on the DUR website for public comment.

Other: The meetings dates for 2016 will be:

- Thursday, February 11, 2016
- Wednesday, May 11, 2016
- Thursday, August 11, 2016
- Thursday, November 10, 2016

There being no further business, the open portion of the meeting adjourned. The Committee met for closed session. Dr. Scott Johnston was chosen as the replacement for Dr. Brown's vacancy on the Committee.

Respectfully Submitted,

Aimee Lewis WYDUR Manager