WY P&T Committee Meeting Minutes
Thursday, February 9, 2023
Cheyenne, WY and via Zoom
10 a.m – 1 p.m.

Members present: Paul Bongat, Melinda Carroll, Evan Crump, Paul Johnson, Kristen Lovas, Layne Lash, Garry Needham, Danae Stampfli, Patrick Yost

Ex-officio: Cori Cooper, Melissa Hunter

Excused: Hoo Feng Choo, Chris Mosier, Scott Johnston

Guests: Melissa Eames, Patrick Johnson, Brenda Stout, Matt Robison (CHC), Corwyn Moss (CHC), Melissa Mehle (CHC), Nikki Yost (CHC), Ben Zoller, Alex Hayward, Tracie Caller (CRMC), Nirmal Ghuman (J&J), Dennis Murphy (Axsome), Heather Kelsey (Lilly), Lisa Pulver (J&J), Sandee Merrick (Prevention Bio), Michele Sabados (Alkermes), Chris Gilbert (Gene), Paul Thompson (Alkermes), Chris Tanaka (Viiv), Lindsey Walter (Novartis), Tami Sova (Biogen), Sherry Betthauser (Jazz), Aimee Redhair (Biogen), Zachariah Thomas (Axsome), John Aldridge (Proventionbio), Heather Freml (Abbvie), Garth Wright (Gene), Paul Ford (J&J), Natalie Rose (Gilead), Bill Gittinger (MT Pharma), Craig Bloom (Vifor), Amy Breen (Teva), Rochelle Yang (Teva), Roy Lindfield (Sunovion), Clemise Hurst (Eisai), Julie Overman (Corium), Melissa Abbott (Eisai), David Block (Corium), Esther Jarvis (HIS), Kurt Hendrickson (Abbvie)

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

Introductions were made. Paul Johnson has accepted the Wyoming Medicaid Medical Director effective April 1. He will remain ex-officio on the Committee.

Approval of Minutes

The minutes of the November 10, 2022 meeting were approved.

Department of Health

A. Pharmacy Program Manager Report: The DUR RFP was posted and is open for response. Responses are due March 10. A vendor will be chosen by the end of March so contracting can be done by the end of June. Legislative session has been busy with pharmacy bills. SF 151 regarding PBM Transparency is active. Medicaid would like an explicit exclusion as we do not use a commercial PBM. It is the intention of the legislature to leave Medicaid out, so language just needs to be added. The Medicaid expansion bill died without being placed on the schedule. Illicit fentanyl was added to the law for illicit methamphetamine exposure to children. HB 119 would allow all off-label prescribing without any administrative or legal action on providers. Providers can still be sued in civil court for liability. Medicaid cannot cover off-label prescriptions, only FDA-approved and medically-accepted uses. This will be a red flag to OIG. HB 191 was another PBM transparency bill and has died without being scheduled. SF 7 broadens the definition of opioid antagonist. SF 9 adds pharmacists to the list of providers that can

bill Medicaid for services. SF 109 bans chemical abortions. SF 111 and 144 are related to gender transition in children. SF 111 makes gender transition a felony for all involved. SF 144 takes action against a provider's license but excludes action against parents. Cori has a meeting with CMS this afternoon about naloxone going over the counter in March 2023.

B. Medical Director Report: No report

C. DUR Manager Report: The School of Pharmacy is working on its proposal for the DUR RFP.

Old Business:

There was no old business to discuss.

New Business

A. PA Criteria

1. Review existing criteria

i. Dr. Caller provided her insight as a neurologist on Botox and CGRPs used concurrently for migraine. She waited for some data on this issue before using the combination and has seen benefit in the use of these medications together. Sometimes Botox monotherapy does not last the full twelve weeks. They have great success for a couple of months and the third month they struggle. It is a small proportion of patients for whom it makes a difference. Typically, patients need to go through two cycles of Botox to determine efficacy which is supported by the data. Continued use of CGRP adds increasing benefit over several months. There should be a minimum requirement of monotherapy before using the combo. Botox is only approved for chronic migraines. A CGRP antagonist can be used for episodic. At some point, we will need to look at concurrent GPANT therapy with Botox. With Botox, we are looking for 50% reduction in headache days or headache pain to define efficacy. If a patient doesn't get full response from Botox, Dr. Caller generally switches to monotherapy CGRP. If there is some response to both, but the patient still has a significant amount of migraine days, then she will do dual therapy.

A trial of two cycles of Botox monotherapy showing efficacy AND two months of a CGRP antagonist monotherapy showing efficacy will be required prior to allowing concurrent use. There was a vote, second and all were in favor.

ii. Multiple Sclerosis was discussed, particularly for the highly efficacious medications. MS is a spectrum disease. Some patients do fine with a couple trials of the older medications. And others present much more progressively, requiring the more effective agents first-line. Patients on these more aggressive medications are having fewer relapses. Some patients are able to start on the highly efficacious medications and then switch to the interferons and Copaxone. The tolerability data of these drugs is often better than the other agents. There is a cost savings over time if patients are treated more aggressively up front. We need to add ocrelizumab to the list of highly efficacious drugs in the guidelines. She would like to see more flexibility in the

available options for patients. There are a lot of reasons that patients don't want to use a self-injectable. The definition of highly active disease is not very clear which could be a barrier for policy-making.

There was a motion to allow alemtuzumab, fingolimod, natalizumab and ocrelizumab first-line for highly active disease. We will bring data back in a year to determine the impact.

Tami Sova (Biogen) provided public comment, indicating that Tysabri has a REMS program and all prescribers must be enrolled in the MS Touch program to have access to the medication.

There was a motion, second and all were in favor of this criteria.

Briumvi is approved for treatment of relapsing forms of MS. Dr. Caller indicated that this class of medications is very efficacious but cannot speak to efficacy of this agent over others in the class. There is no evidence of a difference in safety and efficacy for Briumvi and the Committee voted to refer to the Department of Health for a cost analysis.

iii. Medicaid currently has criteria that allows only one short-acting medication and allowing one long-acting plus one short-acting medication. There is no language indicating that we will not cover two long-acting agents concurrently. There was a motion and second to limit to one long-acting stimulant at a time.

iv. New diabetes guidelines allow GLP-1 or SGLT2 for ASCVD or risk factors. There was a motion, second and all were in favor of updating the prior authorization criteria to allow a GLP-1 or SGLT2 for patients with ASCVD or risk factors without a trial of metformin.

v. Non-preferred 5-alpha reductase inhibitors will now require a 30 day trial and failure of the preferred agent (currently finasteride) before approval.

vi. Molnupiravir for COVID-19 is now an option for the circulating variants. There was a motion, second and all were in favor of limiting to indication for patients aged 18 and up.

vii. A provider contacted the PA Help Desk frustrated about the PA process for growth hormones as a PA was needed for every NDC which is challenging with drug shortages. The PA Help Desk has indicated that PA requests for growth hormones have not been denied for a long time. There was a motion, second and all were in favor of removing PA criteria for preferred growth hormones. Non-preferred agents will continue to require PA.

2. New Drugs

i. Auvelity is indicated for the treatment of unipolar major depressive disorder in adults. Zach Thomas (Axsome) provided public comment. The Committee referred Auvelity to the Department of Health for cost analysis.

ii. Relyvrio is indicated for the treatment of adults with amyotrophic lateral sclerosis. The Committee voted to limit to indication and refer for a cost analysis.

iii. Rebyota is indicated for prevention of recurrence of C.

difficile infection (CDI) in patients 18 years and older following antibiotic treatment of recurrent CDI. The Committee referred to the Department of Health for a cost analysis.

iv. Sunlenca is an antiviral agent approved for treatment of HIV-1 infection in combination with other antiretroviral agents, in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current regimen. Natalie Rose (Gilead) provided public comment. In the study, resistance to lenacapravir occurred in monotherapy. There was a motion, second and all were in favor of limiting to indication and referring to the Department of Health for cost analysis.

3. Determine need for criteria
4. Physician Administered Drugs

i. Tzield is indicated to delay the onset of stage 3 type 1 diabetes mellitus in adults and pediatric patients aged 8 years and older with stage 2 diabetes mellitus. John Aldridge (Prevention Bio) provided public comment. Stage 2 disease is defined as dysglycemia without overt hyperglycemia and two pancreatic autoantibodies. Once these individuals progress to stage 3, they will be on exogenous insulin for the remainder of their lives. Many patients are diagnosed for the first time when they present with diabetic ketoacidosis. These individuals are not yet on insulin, they are identified via screening. This medication can delay onset by a median of two years. Most of these patients are screened due to a family history of type 1 diabetes. With screening alone, the DKA rate decreases significantly. There is no data showing that the drug alters presentation of disease. This is a one-time infusion given for 14 consecutive days. There was a motion, second and all were in favor to require prior authorization.

ii. Leqembi is indicated for the treatment of Alzheimer's disease, to be initiated in patients with mild cognitive impairment or mild dementia stage of disease, with confirmed presence of amyloid beta pathology prior to treatment. There was a motion, second and all were in favor of requiring prior authorization with a limit to indication.

<u>Other</u>

There being no further business, the open portion of the meeting adjourned at 11:30 am and the Committee met in closed session. During closed session, Dr. Tracie Caller was chosen to fill the Committee position that is left by Dr. Johnson.

Respectfully Submitted,

Aimee Lewis
WYDUR Manager