WY P&T Committee Meeting Minutes Thursday, May 14, 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), Nikki Yost (CHC),

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

Introductions were made. Aimee announced that Karly is moving to Oregon. She will stay with us until someone is hired.

Approval of Minutes

The minutes of the February 13, 2020 meeting were approved. The minutes of the March 30, 2020 email meeting were approved.

Department of Health

A. Pharmacy Program Manager Report: Sara Howe has moved to a different position with Change HealthCare. Her replacement, Matthew Robison, starts Monday May 18th. The Department continues to work on integrating data with the System Integrator, Data Warehouse and new Provider Enrollment system. In terms of COVID response, Hydroxychloroquine was limited to diagnosis and 90-day fills are allowed for a wider variety of medications. There has been no feedback of major issues. The PA Help Desk has kept up and we have received more provider enrollments for electronic PAs. Medicaid is moving to the Herschler building, on the 4th floor, on Monday May 18th.

B. Medical Director Report: Telemedicine is greatly expanding as a result of COVID. Over 300 primary care providers and more than 500 mental health providers are now enrolled. One issue identified is that physicians have broadband, but patients do not. As a result, they are doing more telephonic visits. Telehealth is a priority for the legislature in their emergency session.

C. DUR Manager Report: None

Old Business:

A. PharmD Candidate, Kelly Zhang, provided a clinical review of the osteoporosis agents. Aimee reported that the vast majority of our utilization is in alendronate, in accordance with the PDL. We have very little use of calcitonin at this time. The Committee took no action, and asked that we monitor utilization and bring it back if we see an uptick in calcitonin utilization.

B. Synagis was discussed in regard to the request for continued prophylaxis after

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active RSV infection. Dr. Horam indicated that both the AAP and Redbook indicate that there is no sound basis for maintaining prophylaxis after infection. There is <1% benefit in preventing an additional infection. The Committee took no action.

C. Talicia was tabled in May in order to get information regarding local sensitivity. Wendy Borgerson (RedHill Pharma) provided public comment. Dr. Choo indicated that there is no local sensitivity data that would require the use of this new product. In addition, he is concerned about drug interactions. Ms. Borgerson indicated that rifabutin is no worse than other antibiotics for interactions with oral contraceptives. The Committee upheld the decision in May to defer to the Department of Health for a cost analysis and PDL placement.

New Business

A. PA Criteria

- 1. Review existing criteria i. None
- 2. New Drugs

i. Vumerity is approved for relapsing forms of Multiple Sclerosis. Lynda Finch (Biogen) provided public comment. It is a distinct molecule from Tecfidera, but is metabolized to the same active entity. It is expected to have similar efficacy and safety. 73% of patients had no relapse and 64% had no progression in disability over 10 years with Tecfidera. It has better GI tolerability than Tecfidera. There was a question regarding statistical significance vs. clinical significance in GI tolerability. Lynda indicated that clinical significance is related to discontinuation which as 0.8% with Vumerity vs. 4.8% with Tecfidera. There are no comparative studies with Vumerity, but many with Tecfidera. The Committee agreed that there is no evidence of a difference in safety or efficacy. Vumerity was referred to the Department of Health for a cost analysis and PDL placement. There was a motion, second and all were in favor. ii. Valtoco is approved for acute treatment of intermittent,

stereotypic episodes of frequent seizure activity (seizure clusters, acute repetitive seizures). Cindy Hartsfield (Neurelis) provided public comment. It is the only intranasal form of diazepam and the FDA has determined it to be superior to the rectal gel. This is based on pharmacokinetic studies. Dr. Horam noted that the diazepam rectal gel is fairly inconsistent and can be uncomfortable to administer, particularly in school and public settings. This is a better delivery method. There were questions regarding the comparison between nasal midazolam and Voltoco, the risk for respiratory depression and overdose. Cindy indicated that rectal diazepam data was used for approval, and only bioavailability and safety studies were completed for Valtoco. The Committee acknowledged that there was a paucity of data and no comparative studies. However, due to the difficulties associated with the administration of the rectal gel, Valtoco should be available. Valtoco will be limited to indication, in line with other anticonvulsants. There was a motion, second and all were in favor.

iii. Reyvow is a serotonergic agent approved for acute treatment of

migraine in adults. Anthony Wheeler (Lilly) provided public comment. Reyvow does work differently from the triptans. It does cross the blood brain barrier and causes some sedation. As a result, patients should not drive for 8 hours after administration. The Committee agreed that there is no evidence of a difference in safety or efficacy. It was referred to the Department of Health for a cost analysis and PDL placement. There was a motion, second and all were in favor. Should Reyvow be non-preferred, a minimum one or two week efficacy trial of triptans was proposed. It is currently unknown whether concurrent use with a triptan is safe.

iv. Ubrelvy is a CGRP receptor antagonist approved for acute treatment of migraine. Colleen Smith (Abbvie) provided public comment. These agents do not cause vasoconstriction or overuse headaches. Ubrelvy does cause drug interactions associated with the CYP3A4 system. There is no data regarding combining Ubrelvy with the CGRP preventive agents, and no comparative data with any other acute agents. However, the data among the two recently approved CGRP agents is very similar. Somnolence is noted, but very mild and similar to placebo. The Committee determined that there was no evidence of a difference in safety or efficacy and referred Ubrelvy for cost analysis and PDL placement. There was a motion, second and all were in favor.

v. Nurtec is an ODT form CGRP receptor antagonist approved for acute treatment of migraine. Chelsea Laroue (BioHaven Pharmaceuticals) provided public comment. There are no cardiovascular effects from this medication. Its half-life is approximately 11 hours. There was a numerical difference in symptoms at 15 minutes and statistically significant difference at 60 minutes. Benefits were maintained through 48 hours. There was a question regarding UTIs as an adverse effect. This was similar to placebo. The Committee found no evidence of a difference in safety or efficacy and referred Nurtec to the Department of Health for cost analysis and PDL placement. There was a motion, second and all were in favor.

Dr. Choo asked about the risk of serotonin syndrome with Reyvow. Anthony Wheeler said there is a caution regarding the syndrome in the package insert. Two confirmed cases were identified across 4,000 patients and 10 or 12 cases were suspected. There does not seem to be a dose-relationship or time-relationship.

vi. Caplyta is an atypical antipsychotic approved for schizophrenia in adults. Bill Rowe (Intra-Cellular Therapies) provided public comment. Somnolence/sedation and dry mouth were the most significant adverse reactions. As with other atypical agents, patients should be monitored for metabolic adverse events. There is no comparative evidence, though risperidone was used as an active control. There is no increase in prolactin levels with Caplyta. The Committee determined that there was no evidence of a difference in safety or efficacy and referred to the Department of Health for cost analysis and PDL placement. There was a motion, second and all were in favor.

vii. Nexletol is approved for treatment of established atherosclerotic cardiovascular disease and heterozygous familial hypercholesterolemia as adjunct to diet and maximally tolerated statin therapy. The Committee determined that there was no evidence of a difference in safety or efficacy and referred to the Department of Health for cost analysis and PDL placement. There was a motion, second and all were in favor.

3. Determine need for criteria

i. None

There being no further business, the open portion of the meeting adjourned at 11:30 am and the Committee met in closed session.

Respectfully Submitted,

Aimee Lewis WYDUR Manager