WY P&T Committee Meeting Minutes
Thursday, May 13, 2021
Cheyenne, WY via Zoom
10 a.m – 1 p.m.

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

Excused: Kristen Lovas

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

Guests: Melissa Eames, Sandra Deaver, Matt Robison (CHC), Nikki Yost (CHC), Misty Helenbolt (CHC), Corwyn Moss (CHC), Britt Boehner (Lilly), Camille Kerr (Regeneron), Chi Kohlhoff (Horizon Therapeutics), Chris Yates (Merck), Doug Wood (Viiv Healthcare), David Testerman (CHC), Dwight Fierle (Aurinia), Kim Walter (Johnson & Johnson), Leslie Zanetti (Sarepta Therapeutics), Lindsey Walter (Novartis), Mike Donabedian (Sarepta Therapeutics), Mindy Cameron, Russell Smith, Scott Anderson (Regeneron), Susan Kelly (Spark Therapeutics), Tom Parmalee (Aurinia), Blaine Fritz (GSK), Joe Ferroli (Takeda), Natalie Rose (Gilead), Laurie Krekemeyer (Bridgebio), Chris Santarone (BMS)

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

Introductions were made. Aimee welcomed Dr. Danae Stampfli to the Committee. She is filling the vacancy left by Dr. Horam.

Approval of Minutes

The minutes of the February 11, 2021 meeting were approved.

Department of Health

A. Pharmacy Program Manager Report: Cori reported that the amendment to extend the DUR contract by two years is in the signature process. The J-code contract is also near completion. Prior Authorizations will go through Change Healthcare and we will start to review the medications clinically through the P&T Committee process. The Medical Claims system is going into user acceptance testing. CNSI is taking over the contract from Conduent. Cori is the Chair of the combined WMPAA/AMPAA meeting this year. It will take place in Denver in August.

B. Medical Director Report: Dr. Bush reported that we will be tasked with creating criteria around medications used for transgender therapy. These requests have previously been handled on a case-by-case basis, however due to an increase in requests for irreversible hormone therapy; we need to create a clinical policy.

C. DUR Manager Report: Aimee reported that Karly has returned and is replacing Meghan as the DUR Assistant. The Parkinson's PDL and criteria were sent to neurologists for review and public comment. No response was received.

Old Business:

A. The Suboxone PA statistics were reviewed. In addition, a Cochrane review submitted by Dr. Robitaille was provided to the Committee for review. Dr. Johnston noted that the Cochrane review noted that doses above 16 mg per day were generally for heroin abuse and methadone was statistically better in treating patients on heroin. Unfortunately, there are no outpatient treatment centers in Wyoming who can provide methadone for this purpose.

After review by the Department of Health, Change Healthcare and DUR personnel, it was proposed that the 2-year limit and requirement to taper to 8 mg be removed. In addition, the requirement for a PA for any dose under 16 mg per day will be removed. Going forward, Suboxone will require a diagnosis of opioid dependence or abuse and doses above 16 mg per day will require prior authorization.

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

New Business

A. PA Criteria

1. Review existing criteria

i. The PA Help desk is receiving a fair number of requests for gabapentin and pregabalin for post-operative pain. A summary of published literature was provided to the Committee for review. There was a motion, second and all were in favor of approving for this purpose with a 14-day limit on duration.

ii. Protopic currently requires trial and failure of a medium and high potency steroid for approval. The PA Help Desk has asked that we re-evaluate these criteria for use on the face in pediatrics. There was a motion, second and all were in favor or allowing Protopic to be approved after a mild (low dose) steroid for application on the face and for patients aged 12 and under.

2. New Drugs

i. Orladeyo is a new drug approved for the prevention of attacks of hereditary angioedema (HAE) in adults and pediatric patients aged 12 years and older. There was a motion, second and all were in favor of limiting it to indication.

ii. Zokinvy is approved for reduction of mortality risk in Hutchinson-Gilford progeria syndrome. There are no other drugs approved for this indication. There was a motion, second and all were in favor of approving for indication.

iii. Gemtasa is approved for the treatment of overactive bladder. The Committee found no evidence of a difference in safety and efficacy over existing drugs in the class and referred it to the Department of Health for cost analysis and PDL placement.

iv. Verquvo is approved for reduction of the risk of cardiovascular death and heart failure hospitalization in adults with symptomatic heart failure and ejection fraction <45%. Mary Claire Wohletz (Merck) was available for questions. She noted that about 14% of study participants were on Entresto. There is no requirement or

contraindication for the combination. Verquvo should be used on top of standard of care for congestive heart failure. There was a motion, second and all were in favor of limiting to indication.

v. Klisyri is indicated for actinic keratosis of the face and scalp. Alissa indicated that the current medications are very effective and when fluoruracil and diclofenac are used in combination, can be used for only 5 days. The Committee noted no evidence of a difference in safety or efficacy over existing drugs and referred to the Department of Health for cost analysis.

vi. Evkeeza is approved as adjunct therapy to other LDL-lowering therapies for treatment of homozygous familial hypercholesterolemia. Scott Anderson (Regeneron) provided public comment. This is a severe, but rare form, of high cholesterol. The specific genetic mutations do not matter with this drug. There was a motion, second and all were in favor of limiting to indication.

vii. Lupkynis is indicated for adults with active lupus nephritis. Tom Parmalee (Aurinia) provided public comment. This is the first and only oral therapy approved. It is to be used with background immunosuppressant therapy but has not been studied with cyclophosphamide. There was a motion, second and all were in favor of limiting to indication.

viii. Amondys-45 is indicated for treatment of Duchenne Muscular Dystrophy (DMD) in patients with gene mutation that is amenable to exon 45 skipping. Leslie Zanetti (Sarepta) provided public comment. She noted that the approval studies showed a statistically significant increase in dystrophin production. Functional data will not be available until 2024. There was a motion, second and all were in favor of applying the same criteria that has been implemented for other DMD drugs.

> Patients will be required to have oversight by a pediatric neurologist and/or a rehabilitation specialist. Prior authorizations will be review on an annual basis, specifically looking at ventilation requirements, the Brooks Upper Limb scale (6 or less), and the NSAA (overall drop greater than 5) for ambulatory patients. In addition, patients will be referred to the Pharmacy Case Management program.

There was a question regarding whether Medicaid would disapprove these medications if clinical outcomes are not shown in the ongoing studies. This is dependent on the FDA. Medicaid is required to cover these drugs as long as they have FDA approval. Dr. Bush mentioned that the Medicaid Medical Directors are writing a white paper on this topic. Further, recommendations have been made to Congress asking them to require an increase in rebate on accelerated approval drugs.

ix. Ponvory is approved for treatment of relapsing forms of multiple sclerosis. One study has been published showing superiority to Aubagio. The Committee noted that there was limited evidence showing a significant difference in safety and efficacy compared to existing drugs in the class and referred it to the Department of Health for a cost analysis.

x. Qelbree is a new non-stimulant option for the treatment of ADHD. The Committee noted no evidence of a significant difference in safety or efficacy and referred it to the Department of Health for cost analysis.

3. Determine need for criteria
    i. The medications for treatment of eosinophilic asthma (Xolair, Fasenra, Nucala and Dupixent) were reviewed. A Cochrane review of the class was provided. There was a motion, second and all were in favor of limiting these medications to approved indication. In addition, the Department of Health will do a cost analysis to determine if PDL placement is appropriate.

4. Other
    i. Aimee worked with Dr. Anne Stratton via email to identify clinical exams that can be used to show efficacy of the spinal muscular atrophy (SMA) drugs (listed below).

- Bayley Scales: not as common, but useful sometimes and known amongst community therapists. Use in young infants/ toddlers
- CHOP INTEND: gold standard assessment in weak SMA non-sitters
- Hammersmith Functional motor scale expanded (HFMSE) and revised (HFMSR): HFMSR is newer and includes measures for stronger children. This can measure SMA sitters and walkers
- Revised Upper Limb Module (RULM): used to look at upper extremity strength and function in older SMA sitters
- 6 Min Walk test: used in stronger SMA walkers.

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