WY P&T Committee Meeting Minutes Wednesday, August 10, 2017 Cheyenne, WY 10 a.m – 1 p.m.

Members present: Joseph Horam, Paul Johnson, Scott Johnston, Rhonda McLaughlin, Robert Monger, Chris Mosier, Scot Schmidt, David Sy, Tonja Woods, Pat Yost

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

Excused: Garry Needham

Guests: Sara Howe (CHC), Nikki Yost (CHC), Melissa Eames, B. Boehner (Lilly), Jennifer Shidler (Sanofi Genzyme), D. Allen (Sanofi Genzyme), Todd Miller (Sanofi Genzyme), Jane Stephen (Allergan), N. Hartman (Neurocrine), Ali Norbash (Neurocrine), Brian Landberg (Arkray Diabetes), Jeff Mussack (Otsuka), Michele Puyear (Gilead), Rick Kegler (Otsuka), Deron Groth (Teva).

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

Introductions were made.

Approval of Minutes

The minutes of the May 10, 2017 meeting were approved as submitted.

Department of Health

A. Pharmacy Program Manager Report: The new PBM system is live and the transition went very well. Based on an ACA requirement, Medicaid cannot pay for prescriptions from providers who are not enrolled. This caused some coincidental issues, but were not related to the system transition. The requirement requires providers to enroll every five years. Most Wyoming providers are enrolled. A recent access study shows that Medicaid recipients are not complaining about access to medical care. The larger issue is out-of-state providers and nurse practitioners and physician's assistants who have not had to enroll individually in the past.

The RFP for DUR services is due to go out. Cori is working on getting the business case through ETS so it can be released.

B. Medical Director Report: Medicity has been selected as the Health Information Exchange contractor for the state. They are looking at an October implementation date. This project has a large amount of federal funds (90%), so if this isn't successful, the chances of having an exchange in our state is slim. There is a Sustainability Committee looking at the costs of maintaining the system when federal funds go away. The intention of the exchange is to facilitate the transfer of information. It will hopefully link to neighboring states eventually.

C. DUR Manager Report: As Cori mentioned, it is time for the RFP. The School of Pharmacy intends to respond to the RFP again and Aimee will be reaching to out some members for letters of support.

Old Business: None

New Business

A. PA Criteria

- 1. Review existing criteria
 - i. None

2. New Drugs

i. Dupixent is a new agent approved for adults with severe atopic dermatitis. Dan Allen (Sanofi/Genzyme) provided public comment. There are trials in pediatrics underway, however, there is not yet any efficacy or safety data. It was noted that interference with interleukins has the potential for significant adverse effects in children. The incidence or antibody formation against the drug was low with no specific trends resulting in inefficacy in 52 week trials. No live vaccines should be given with the medication and patients should be reminded not to stop their asthma medications. Cancer patients were excluded from studies.

The Committee concluded that there was no evidence of a benefit in safety and efficacy over other drugs for atopic dermatitis. It should be limited to adults, 18 years and older, and should be a step 3 agent on the Preferred Drug List. There was a motion, second and all were in favor.

- ii. Austedo is approved for chorea associated with Huntington's disease. There was a motion, second and all were in favor of limiting Austedo to this specific indication. The FDA is considering it for tardive dyskinesia. If it receives this indication, it will be reviewed by the Committee again.
- iii. Esbriet is a new treatment for idiopathic pulmonary fibrosis. There was a motion, second and all were in favor of limiting to indication. A pulmonary consult within the last year will also be required for approval.
- iv. Ingrezza is a new medication approved for treatment of tardive dyskinesia. Ali Norbash (Neurocrine) provided public comment. It is a highly selective VMAT-2 inhibitor. The key adverse reaction was somnolence. There may be an increase in QT interval, however at expected doses there were no significant changes. There were no safety signals for depression or suicidality. Though it is an MAO inhibitor, it has a different mechanism of action and does not carry the same dietary restrictions and contraindications as traditional MAO inhibitors.

There was a motion, second and all were in favor of limiting Ingrezza to its approved indication. It was requested that Aimee do additional education on tardive dyskinesia.

v. Tymlos is a human parathyroid hormone peptide analog for postmenopausal osteoporosis. It is specifically approved for patients with a history of osteoporotic fracture, multiple risk factors for fracture, or those who have failed or are intolerant to other therapy. There was a motion, second and all were in favor of limiting to indication. A 12 month trial and failure of other therapy will be required.

Aimee will do a utilization review of osteoporosis agents to see how these medications are being used.

- vi. Xadago is approved as adjunctive treatment to levodopa/carbidopa for Parkinson's Disease. There was a motion, second and all were in favor of limiting to indication.
- vii. Kevzara is a new monocolonal antibody approved for moderate to severe rheumatoid arthritis in adults with inadequate response or intolerance to one or more disease-modifying agents. Dan Allen (Sanofi/Genzyme) provided public comment. The Committee determined that there was no evidence of a safety or efficacy benefit over existing medications. The Department of Health will do a cost analysis to determine placement on the PDL. It should be limited to approved indications and have dose limits similar to the other agents in this class.
- viii. Siliq is approved for plaque psoriasis in adults who have failed or lost response to other systemic therapies. It was noted that there are potential safety issues based on a black box warning for suicidal ideation and behavior. The Committee concluded there was no evidence of a benefit in efficacy. The Department of Health will review cost and determine placement on the PDL.
- ix. Vosevi is a new, pangenotypic, treatment for Hepatitis C. It is specifically approved for patients who have been previously treated. Michele Puyear (Gilead) provided public comment. Utilization of this medication is expected to be limited. Failure was defined as a positive SVR12. This medication was studied in treatment naiive patients, however, Gilead did not go for the indication as there are already drugs that are pangenotypic with 8 week duration.

It is important to note that failure due to non-compliance is not included, only failure due to side effects or SVR following completed therapy. There was further discussion regarding how to differentiate relapse and reinfection. A clear SVR12 that becomes positive again later is likely reinfection.

There was a motion, second and all were in favor of limiting this medication to indication with a manual review of each prior authorization request. Failure due to non-compliance will not be considered for approval.

x. Ocrevus is the first medication approved for primary progressive multiple sclerosis. It is also approved for relapsing forms. There are some safety concerns compared to other agents approved for relapsing. There was a motion, second and all were in favor or approving Ocrevus for patients with a diagnosis of primary progressive multiple sclerosis. For patients with relapsing forms, trial and failure of the traditional agents will be required prior to use.

- 3. Determine need for criteria
 - i. None

Other

The medications that are billed on the medical side (J codes) currently have no clinical management. The P&T Committee is ready and willing to help with the clinical review process and prior authorization criteria. The process of managing the prior authorization requests and enforcing and policy needs to be worked through. The Committee recommended that the Department of Health begin to create a process for clinically managing these expensive medications.

The meeting adjourned at 11:45 and the Committee met in closed session. The annual planning meeting was held at this time. Topics of discussion included offering CME for the meetings and potential education topics for the next year.

Respectfully Submitted,

Aimee Lewis WYDUR Manager