Members present: Melinda Carroll, Joseph Horam, Paul Johnson, Scott Johnston, Kristen Lovas, Robert Monger, Chris Mosier, Garry Needham, Scot Schmidt, Patrick Yost

Ex-officio: Cori Cooper, Melissa Hunter

Excused: Hoo Fang Choo

Guests: Sandra Deaver, Donna Artery, Melissa Eames, Andrew Chapin, Sara Howe (CHC), Nikki Yost (CHC), Jacqueline Steel (UW), Suzanne Hensley and William Lai (Xeris), Danny McNatty and John Madigan (JNJ), Lee Stout (Chiesi), Jeff Mussack, Ashley Johnson and Joe Cirrincione (Otsuka), Sean Parker (Bristol-Myers Squibb Co.), Patrick Moty (Horizon), Rhonda Clark and Valerie Ng (Indivior), Jenna Gianninoto and Laura Hill (Abbvie), Jody Legg (Alkermes), Fallon Wacasey (Pfizer), Amy Rodenburg (Allergan), Britt Boehner (Lilly)

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

Introductions were made. Aimee was pleased to introduce the two new pharmacist members, Kristen Lovas and Melinda Carroll.

Approval of Minutes
The minutes of the August 15, 2019 meeting were approved with amendments. Michael Ceballos needs to be added to the guest list and two clarifications were made to the Zolgensma discussion.

Department of Health
A. Pharmacy Program Manager Report: Cori reported that the state plan amendment (SPA) has been written and posted for public comment. We will begin a retrospective review process for concurrent use of antipsychotics and opioids that will be similar to the current pregnancy/narcotic program. There have been ongoing discussions with the Board of Pharmacy regarding access to the PDMP. They feel that taking a position one way or another would be lobbying. They will not stand for or against any legislation that may be introduced. The Department is currently working to implement a new system whereby a system integrator will stand as the conduit between all of the Medicaid modules including pharmacy claims, medical claims, and others. Lindsey Schilling has taken a new opportunity with Department of Family Services. Jan Stall will be taking her place. She brings a great amount of experience and institutional knowledge to the table.
B. Medical Director Report: None
C. DUR Manager Report: None
Old Business:

A. The Sublocade phase 3 studies have been published and were provided to the Committee for review. Currently it requires prior authorization and is limited to indication. This continues to be appropriate and no changes were recommended.

B. Information from Dr. Tetenta regarding the Sunosi criteria was reviewed for patients with a diagnosis of fatigue associated with sleep apnea. The Sunosi criteria was amended to define compliance as 70% or more use of the CPAP machine for more than 4 hours at a time for one month prior to approval. In addition, an Apnea-Hypopnea Index of 10 or less will be required. The Eppworth Scale requirement was removed. There was a motion, second and all were in favor of this change.

C. Michael Faithe (Amgen) provided public comment regarding Evenity in response to questions that the Committee had at the August meeting. It is approved for post-menopausal women with a history of fracture or multiple risk factors for fracture. There was an increased risk of cardiovascular events including MI, stroke, and cardiovascular death. The mechanism for this is unknown. Concurrent use with other agents for osteoporosis has not been studied. They have studied sequencing and found that the benefits remain when denosumab, zoledronic acid or alendronate follow 12 months of therapy with Evenity. One study looked at redosing after a year and showed a similar increase in bone mineral density. There is no limitation on the lifetime use of the medication, however, the ideal length of break in drug therapy before redosing is unknown. Dr. Johnston asked about “data on file”. Michael will check into what is available and follow up. The Committee recommended no changes to the existing criteria.

D. Rinvoq was moved from the new drug agenda to be reviewed prior to the Targeted Immune Modulators (TIMs) class review. Jenna Gianninoto (Abbvie) provided comment. Rinvoq does show superiority to Humira plus methotrexate in ACR50 and HAQDI. Safety is similar to Humira and it does carry the class-wide black box warning. There is an increased risk of thrombosis among all of the JAK inhibitors, though it is similar to the risk overall in rheumatoid arthritis patients. The Committee concluded that the medication should be limited to indication and included in the overall discussion of TIMs. There was a motion, second and all were in favor of this recommendation.

The TIMs report was reviewed. There is a lot of comparative data in this class, however, much of it is conflicting and makes the class very complicated. Looking at our current utilization, 80% is in Humira and Enbrel, the two preferred agents. Outside of that, there is no trend related to the medications that require one step vs. two. Review of the rheumatoid arthritis and psoriatic arthritis guidelines along with discussion with a local dermatologist indicates that trial and failure of two TNF agents is an acceptable practice. As a result, there was a motion, second and all were in favor of requiring a trial and failure of Humira and Enbrel prior to use of non-preferred agents. The prior authorization process will remain in place with attention paid to those agents that do hold superiority data over one of the preferred agents.

E. Cori has attempted to contact Dr. Collison to get additional feedback regarding the antidepressant tapering process. She did not receive a response and the PA Help Desk reports that all is quiet.
New Business

A. PA Criteria

1. Review existing criteria
   i. Clopidogrel currently requires prior authorization for use beyond one year as there is not data showing additional benefit past one year of use. However, the PA Help Desk receives many requests to continue therapy, mostly in cardiac stent patients. As all of these requests are approved, it seems more efficient to remove the time limit. There was a motion, second and all were in favor.
   ii. Dupixent is currently limited to moderate to severe asthma, however, asthma guidelines indicate that it should be reserved for severe eosinophilic asthma. Dr. Johnston noted significant disclosures for the authors of the GINA guidelines and mentioned that, based on his previous research, nobody follows the guidelines. There was a motion, second and all were in favor of limiting to severe asthma.

2. New Drugs
   i. Baqsimi and Gvoke are two new glucagon products with new delivery devices. As they are the same medication, they were reviewed together. William Lai (Xeris) provide comment regarding Gvoke. There is a multi-step process associated with the current product. Gvoke comes in a pre-filled syringe or auto-injector which is a two-step process (remove the cap and inject). It has a two-year shelf life from the date of manufacture and does not need refrigeration. Britt Boehner (Lilly) provided comment on Baqsimi. Baqsimi is a nasal spray, has an 18-month shelf-life and also does not require refrigeration. Studies have been done with both products showing that they are easier to give and result in more successful rescues than the older product. The Committee agreed that while there was no difference in the two newer products, both seemed to provide a significant benefit over the older product. There was a motion, second and all were in favor.
   ii. Xenleta is a new antibiotic approved for community-acquired pneumonia. The Committee recommended open access and monitoring for appropriate use.
   iii. Nayzilam is an intranasal midazolam product indicated for acute treatment of intermittent, stereotypic episodes of frequent seizure activity in patients aged 12 and older. There was a motion, second and all were in favor of limiting to indication.
   iv. Rybelsus is an oral GLP-1 receptor agonist approved for improvement of glycemic control in adults with type 2 diabetes. The Committee agreed that there was no evidence of a difference in efficacy or safety. There was a motion, second and all agreed that it should require a 90 day trial of metformin similar to other anti-diabetics and be referred to the Department for a cost analysis.
   v. Duaklir is a combination of aclidinium and formoterol and is
approved for maintenance treatment of COPD. The Committee noted no evidence of a difference in safety or efficacy. There was a motion, second and all were in favor of referring to the Department for a cost analysis.

vi. Wakix is indicated for improving wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy. The Committee noted no evidence of a difference in safety or efficacy. There was a motion, second and all were in favor of referring to the Department for a cost analysis.

vii. Fasenra is indicated for severe asthma as add-on maintenance treatment in adults and children 12 years and older with eosinophilic asthma. The Committee noted no evidence of a difference in safety or efficacy. There was a motion, second and all were in favor of referring to the Department for a cost analysis. Fasenra will be limited to indication.

3. Determine need for criteria
   i. Letrozole utilization was reviewed. Nearly half of our utilization is for infertility which is a federally excluded class for Medicaid. Letrozole will be limited to indication and will not be approved for infertility treatment.
   
   ii. There is a list of medications that are “not recommended for initial treatment” of HIV. There was a motion, second and all were in favor of making these medications non-preferred. Descovy has a new indication for prevention. There was a motion, second and all were in favor of limiting to indication and requiring an HIV and pregnancy test prior to therapy and every 3 months, similar to the Truvada criteria.
   
   iii. The epoetin agents were discussed. 99% of our utilization is in Epogen, having only one claim for Procrit in the last year. The Department will be moving Procrit and Aranesp to non-preferred in 2020.
   
   iv. Anticonvulsants Aptiom, Briviact, Oxtellar XR and Trokendi XR were discussed. Due to their similarity to other, much less expensive options, these medications will be non-preferred in 2020. Current patients will be grandfathered.

Other

A. The 2020 PDL was presented. Dr. Chen provided public comment regarding the proposed switch of Abilify Maintena patients to Aristada. The Committee reviewed the data submitted and did not see evidence of a difference in safety or efficacy. However, due to concerns about switching patients who are stabilized, the Committee asked that we grandfather all current patients. New starts will be asked to use Aristada. Providers will have to submit a PA request for new starts with Abilify Maintena. There was a motion, second and all were in favor of the above recommendation.

There being no further business, the open portion of the meeting was adjourned at 12:00 pm and the Committee met in closed session. During closed session, the Committee elected Scot Schmidt as the new Vice Chair and voted to welcome Alissa Aylward to the Committee as the PA/NP representative.

Respectfully Submitted,

Aimee Lewis
WYDUR Manager