WY P&T Committee Meeting Minutes
Thursday, August 15, 2019
Cheyenne, WY
10 a.m – 1 p.m.

Members present: Hoo Fang Choo, Joseph Horam, Paul Johnson, Scott Johnston, Rhonda McLaughlin, Robert Monger, Chris Mosier, Garry Needham, Scot Schmidt, Patrick Yost

Ex-officio: Cori Cooper, Melissa Hunter

Excused: Tonja Woods

Guests: Michael Ceballos, Sandra Deaver, Donna Artery, Nikki Yost (CHC), Kerri Koski (CHC), Tiffany Surles, Barbara Boner (Novartis), Lydia Shenouda, Paul Bonham (Avexis), Tim Hartman (Pfizer), Laura Hill, Todd Ness (Abbvie), Susan Kelly (Spark Therapeutics), Lynda Finch, Aimee Redhair (Biogen), Marilyn Semenchuk (Biocodex), Amy Rodenburg (Allergan), Rhonda Clark (Indivior), Jennifer Shidler (Sanofi Genzyme), Mary Claire Wohletz (Merck), Chris DiSimone (Akcea), Mike Donabedian (Sarepta).

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

Introductions were made. Aimee was pleased to introduce the new Program Assistant, Karly Thompson. She brings new skills to the table and will be a great asset to the DUR program.

Approval of Minutes

The minutes of the May 8, 2019 meeting were approved as submitted.

Department of Health

A. Department of Health Director Report: Mike Ceballos gave an overview of his background and his approach to directing the Department of Health. He asked the Committee to feel free to email him and give him feedback about what is working and what needs improvement.

B. Pharmacy Program Manager Report: Cori reported that CMS has provided guidance on the SUPPORT Act which was passed in October 2018. We have already implemented the requirements, with the exception of an intervention to review concurrent use of opioids and antipsychotics. She also indicated that the Medication Donation Program has a new Program Manager. They are in the process of hiring another pharmacist.

C. Medical Director Report: None

D. DUR Manager Report: None

Old Business:

A. The antidepressant tapering policy was discussed. Change Health Care did

some research and found that changing the current process would result in extensive programming, which is not reasonable considering the number of PA's received. The length of time allowed for taper has been extended. No further comments have been heard. Cori will follow up with Dr. Collison to see how things are going.

B. Aimee reviewed the utilization of high dose opioids and cancer diagnoses. There were only a handful of patients who were exceeding opioid limits with a cancer diagnosis that is not expected to result in ongoing pain. At this time, utilization does not support changing the cancer exclusion from the opioid prescribing limits.

New Business

A. PA Criteria

1. Review existing criteria

2. New Drugs

i. Mayzent is approved for treatment of relapsing forms of Multiple Sclerosis in adults. Tiffany Surles (Novartis) provided public comment. She asked that the Committee allow Mayzent for secondary progressive multiple sclerosis based on provider attestation. This form presents approximately 15 – 20 years after relapsing forms are diagnosed. These patients are mid to late 40's, have longer disease duration and are very disabled. This will be a specialty pharmacy only product.

The Committee agreed that there was no evidence of a difference in safety or efficacy. There was a motion, second and all were in favor of referring to the Department of Health for a cost analysis.

ii. Mavenclad is also approved for treatment of relapsing forms of Multiple Sclerosis for patients who have not had adequate response from other treatment. It holds a boxed warning for potential malignancy. EMD Serono provided public comment.

The Committee discussed that this product should be second or third line based on potential safety risks. There is evidence of a potential increase in safety risk over other available products. There was a motion, second and all were in favor of making Mavenclad a non-preferred agent.

Lynda Finch (Biogen) provided public comment. She indicated that there was an update to all Multiple Sclerosis agents using more contemporary language to allow treatment of relapsing forms including secondary progressive and clinically isolated syndrome. As such, this is not a unique indication to the new drugs reviewed.

iii. Evenity is indicated for osteoporosis. The data shows evidence of decreased fractures. There is concern about safety, specifically cardiac safety and questions about concurrent use with other products. The Committee would like to wait on additional data. Aimee will follow up with Amgen.

There was a motion, second and all were in favor of making Evenity non-preferred, limiting to indication, a maximum of twelve months use, and no concurrent use of other osteoporosis products.

iv. Skyrizi is new immune modulator approved for treatment of plaque psoriasis. Laura Hill (Abbvie) provided comment. She asked the Committee to consider allowing Skyrizi as a step 2 agent after trial of Enbrel based on superiority data with Humira. Skyrizi also showed superiority to Stelara. It is also being studied for psoriatic arthritis, Crohn's disease, ulcerative colitis.

Britt Boehner (Lilly) indicated that Taltz has superiority data over Enbrel and remains in the non-preferred category for psoriatic arthritis.

The Committee indicated that there is evidence of increased efficacy and possibly safety for Skyrizi over the other agents. There was a motion, second and all were in favor of referring to the Department of Health for cost analysis.

v. Vyndaqel and Vyndamax are approved for treatment of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults. Tim Hartmann (Pfizer) provided public comment. This is a rare disease with survival of two to three years following diagnosis. There are an estimated 135,000 to 150,000 people with the condition, of which, only 1% are diagnosed. Chris DiSimone (Akcea) provided additional comment regarding the amyloidosis spectrum to include bilateral carpal tunnel and polyneuropathy.

There was a motion, second and all were in favor of limiting to indication.

vi. Diacomit is an anticonvulsant that has been used for many years outside of the US. It is approved for adjunctive treatment of Dravet syndrome in patients two years and older. Diacomit must be used in conjunction with clobazam. Marilyn Semenchuk (Biocodex) provided comment. There was a questions regarding safety when used with CBD oil. There is no outcome data in the US, however, Ms. Semenchuk will provide additional data after the meeting.

There was a motion, second and all were in favor of limiting to indication. Monotherapy will not be allowed. The Committee will review the follow up data and make additional recommendations if necessary.

vii. Zolgensma is a new gene therapy that inserts a gene into the patient's cells and propagates the correct protein, presumably for a lifetime. It is approved for infants up to two years old who are diagnosed with spinal muscular atrophy. It carries a boxed warning for acute serious liver injury and elevated aminotransferases. Patients must be monitored for at least three months after infusion and corticosteroids must be administered. Lydia Shenouda (Avexis) provided public comment. Early diagnosis and treatment is critical. Zolgensma cannot repair neuron damage but will stop the progression. The Committee asked if the therapy is 100% effective. Phase 1 studies were 100% effective for survival, with four to five years duration to date. Phase 3 is ongoing with an 87% survival rate at 14 months. One patient withdrew from treatment and another patient died, however the death was deemed not related to therapy. There

has been discussion about the number of backup copies of the SMN1 gene a patient has. Currently, diagnosis is only made based on the number of developmental milestones achieved. Newborn screening will identify early, however, can only predict the type and therefore not severity.

The data manipulation news was discussed. The manipulation occurred in an old in vivo mouse assay that is no longer used. Product made today does not use the assay and hasn't been impacted. The company is trying to determine what this news means, however, the FDA and the company stand by the product's approval and safety.

The Committee asked if we should expect Zolgensma to be used with Spinraza. There is no data to support use of both. Lynda Finch (Biogen) provided public comment on Spinraza. It is approved for children and adults. In post-marketing safety studies, serious infection from lumbar puncture has been observed. There are no combination trials, however, of 15 patients in the Zolgensma trial, 7 went on Spinraza later.

There was a motion, second and all were in favor of putting a hard prior authorization on the product to limit to indication.

There was further discussion about the high cost to the pharmacy side, though it will result in a decrease in medical costs. Dr. Horam has seen two patients in his career. There was also question about medical tourism. There is currently a high concentration around specialty care centers.

viii. Ruzurgi is indicated for Lambert-Eaton myasthenic syndrome in pediatric patients aged 6 -17. There was a motion, second, and all were in favor of limiting to indication.

ix. Sunosi is indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea. Patients should be treated for underlying airway obstruction for at least one month prior to and during therapy. There is no comparative data. The Committee expressed concern regarding compliance with treatment for obstructive sleep apnea.

There was a motion, second and all were in favor of referring Sunosi to the Department of Health for a cost analysis. Sunosi will be limited to indication and approval will require evidence of compliance with obstructive sleep apnea treatment as well as a post-treatment Eppworth Scale of 8+.

3. Determine need for criteria

i. Enbrace HR is a prenatal vitamin that is marketed as an alternative treatment of depression in pregnant women. The data is not convincing of effectiveness. The Committee saw no evidence of a benefit over other prenatal vitamins. There is no FDA indication for treatment of depression. There was a motion, second and all were in favor of making Enbrace HR non-preferred. Prior authorization requests will be referred to the wide variety of other prenatal vitamin products that are preferred agents.

Other

There being no further business, the open portion of the meeting was adjourned at 1:00 pm and the Committee met in closed session. During closed session, Kerri Koski presented a demonstration of the Change Health Care Provider Portal that will be rolling out soon.

Respectfully Submitted,

Aimee Lewis
WYDUR Manager