WY P&T Committee Meeting Minutes
Thursday, November 8, 2018
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, Tonja Woods

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

Excused: David Sy, Patrick Yost

Guests: Sandra Deaver, Melissa Eames, Amy Stockton (CHC), Sara Howe (CHC), Donna Artery, Maria Agapova (Teva), PJ Arnold (Shire), Chris Holtzer (AbbVie), Christy Skibicki (Indivior),Todd Ness (AbbVie), Mindy Schimpf (UCB), Valeria Cucchiaells (UCB), Micahel Faithe (Amgen), Paul Williams (Takeda), Roy Lindfield (Sunovion), Amy Rodenburg (Allergan)

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

Introductions were made.

Approval of Minutes

The minutes of the August 8, 2018 meeting were approved as submitted.

Department of Health

A. Pharmacy Program Manager Report: Certification of the PBMS is complete. This is a huge accomplishment that has taken a lot of attention.

B. Medical Director Report: None

C. DUR Manager Report: Nothing to report

Old Business:

A. The continued Sublocade discussion will be tabled until February as the data is not yet published.

B. Dr. Del Real's requests for Suboxone were reviewed. Only four of those requests are actionable through the P&T Committee. In order to accommodate some of his requests, the 72 hour emergency fill will be allowed for buprenorphine products. It is currently turned off for all controlled substances. This policy will allow a pharmacy to provide a 72 hour supply (up to two times) to get therapy started immediately. The emergency fill will not stop for dosage requirements, which means 24 mg will go through for up to 144 hours for induction purposes. Beyond that, a PA will be required per current policy. Generic buprenorphine/naloxone tablets will be added to the PDL for 2019. Beyond that, adding additional agents is not cost effective at this time. Other products may be requested through the PA process. No other changes were recommended at this time.

There was a motion, second, and all were in favor of the above changes.

C. Antipsychotic utilization was reviewed for dosages above labeled maximum and duplicate use of injectables and orals. As you increase the dose of atypicals, they become more and more typical in nature, particularly in adverse effects. All patients who exceed 100% of labeled dose will be reviewed and, where appropriate, will be grandfathered. Concurrent use was discussed along with prescriber comments about this use.

There was a motion, second, and all were in favor of limiting atypical dose to 100% of labeled maximum and stopping concurrent use of long-acting injectable and oral products.

New Business

A. PA Criteria

1. Review existing criteria

i. The new diagnosis (plaque psoriasis) and pregnancy data for Cimzia was reviewed. Valeria Cucchiarelli provided comment. She requested that Cimzia be allowed for pregnant women or women of child-bearing age and the Cimzia be allowed after a single step for plaque psoriasis. Dr. Monger discussed his experience with these agents. Humira does cross the placenta, however, is not associated with negative outcomes. However, there is no long-term data on any of these agents. Exposure to baby is minimal for Cimzia, less than 4% placental transfer. Babies cannot receive live vaccine for six months after being born. This is not different for Cimzia.

Cimzia recently received approval for plaque psoriasis, with one study showing superiority over etanercept at the 400 mg dose, and non-inferiority at the 200 mg dose.

Dr. Horam indicated that we need to remain cautious in pregnancy due to limited data and no outcomes. Dr. Johnston pointed out that teratogenicity is due to the drug, not the dose. So, even at 4% placental transfer, it could be teratogenic.

There was a motion, second and all were in favor to allow for pregnancy and breast feeding and to allow for plaque psoriasis after a single step of Humira.

ii. Nikki noticed that different dose forms of triptans are being used concurrently. Due to safety concerns, use of multiple dose forms concurrently will be blocked. There was a motion, second and all were in favor of this change.

iii. Aimovig was reviewed for dosage and concurrent use with Botox. Michael Faithe (Amgen) provided comment. He requested that the Committee decrease the number of trials from three to two drugs as only two classes have level A evidence (anticonvulsants and beta blockers). Compliance to preventive therapy is low due to ineffectiveness and adverse events.

Efficacy between 70 mg and 140 mg was similar, though adverse events were higher in the 140 mg group. Constipation is the most common adverse event, with a slightly higher incidence in the 140 mg group. The Committee asked what the advantage is since efficacy seems to be similar to existing oral agents. Michael indicated that the once/month injectable formulation will increase compliance and adverse events are mild.

There is no data regarding use with Botox, though study patients were not allowed use Botox and had a four month washout period.

Aimovig is available through all retail pharmacies, and is not limited to specialty outlets.

Dr. Johnston pointed out that only two drugs are approved for episodic migraine while Botox is the only agent approved for chronic migraine. Tonja indicated that for maximum efficacy, two to three cycles of Botox should be encouraged.

There was a motion, second, and all were in favor of limiting starting dose to 70 mg, requiring a three month trial of both an anticonvulsant and a beta blocker, and blocking concurrent use of Botox.

Methergine used chronically for prevention, off-label, was discussed. **During closed session, this issue was further discussed. Methergine will be limited to seven days in a 365 day period for post-partum hemorrhage. All other use will require PA. The Committee did not vote on this issue as it was not on the agenda. It was discussed as an FYI from the Department of Health.

iv. Current CHF guidelines recommend Entresto as a first-line agent in Class II and Class III CHF. There was a motion, second and all were in favor of updating the criteria to match guidelines.

2. New Drugs

i. Orilissa is a gonadotropin receptor antagonist approved for pain associated with endometriosis. Chris Holtzer (Abbvie) provided comment. It is appropriate after oral contraceptives and NSAIDs but before Lupron. There is concern about bone density loss. As a result, the 150 mg should not be used longer than 24 months and the 200 mg no longer than 6 months. Orilissa is different from Lupron as Lupron is an agonist, causing an initial disease flare followed by downregulation. Lupron is equivalent to chemical castration. The discontinuation rate was about 5% in clinical trials, with hot flash being the most common adverse effect. There is no data on restarting the medication after the initial recommended timeframe. A risk/benefit assessment will need to occur.

There was a motion, second and all were in favor of limiting Orilissa to the approved indication and timeframe. There is no data regarding comparative safety and efficacy.

ii. Mulpleta is approved for thrombocytopenia associated with chronic liver disease prior to procedure. There is no comparative evidence regarding safety or efficacy vs. other available agents. There was a motion, second and all were in favor of limiting to indication.

iii. Ilumya is an IL-23 antagonist approved for moderate to severe plaque psoriasis. There is no evidence showing a difference in safety or efficacy with existing medications. There was a motion, second and all were in favor of the above and Ilumya was referred to the Department of Health for cost analysis.

iv. Takhzyro is approved for prevention of hereditary angioedema (HAE). Public comment was provided indicating that HAE is an unpredictable and life-threatening disease. Anything and everything can trigger an acute attack with no reliable way to predict. There is no evidence of a difference in safety or efficacy. There was a motion, second and all were in favor of limiting to approved indication. Further, Takhzyro was referred to the Department of Health for possible PDL placement.

v. Ajovy is a CGRP inhibitor, similar to Aimovig. Maria Agapova (TEVA) provided public comment. She was asked how it differs from standard of care and indicated that the onset of efficacy is faster, adherence and persistence are improved. The CGRP inhibitors are directed at the disease pathway of migraine, while standard prophylactic therapies are not. About 20% of patients in the clinical trials were on other oral prophylaxis therapy and an add-on benefit was shown. The same exclusion criteria with Botox applied to Ajovy. However, they did find that patients who failed on Botox had a benefit when switched to Ajovy.

There was a motion, second and all were in favor of requiring a three month trial of both an anticonvulsant and a beta blocker. Botox use will not be allowed concurrently. Further, there is no evidence of a difference in safety and efficacy over Aimovig, and the drug was referred for a cost analysis by the Department of Health.

vi. Lucemyra is an alpha-2 agonist approved for mitigation of opioid withdrawal symptoms for up to fourteen days. It is similar to clonidine, though it may have a lower propensity to cause hypotension. We do not know how many patients could be using clonidine for this purpose. There was a motion, second and all were in favor of limiting to indication with a max duration of fourteen days.

vii. Kevzara is a new IL-6 inhibitor, similar to Actemra, approved for treatment of rheumatoid arthritis. There is no evidence showing a difference in safety or efficacy with existing medications. There was a motion, second and all were in favor of the above and Kevzara was referred to the Department of Health for cost analysis.

viii. Palynziq is approved for adult phenylketonuria patients with levels greater than 600 micromol/liter. There was a motion, second and all in favor of limiting this medication to indication.

ix. Olumiant is a JAK inhibitor approved for treatment of rheumatoid arthritis. The Committee agreed that there was no data showing a difference in safety, though it appears more efficacious than Humira. There was a motion, second and all were in favor of the above recommendation and Olumiant was referred to the Department of Health for cost analysis.

x. Baxdela is a new fluoroquinolone approved for soft tissue infections. There is no evidence of a difference in safety or efficacy. Other fluoroquinolones showed rapid development of resistance. Baxdela has similar potential. There was a motion, second and all were in favor of requiring a trial of Zyvox, ciprofloxacin or levofloxacin prior to Baxdela.

3. Determine need for criteria

i. Concurrent use of Lyrica and gabapentin and gabapentin dosing was reviewed. There was a motion, second and all were in favor of limiting both medications to 100% of labeled maximum and blocking concurrent use. All were in favor. A letter will be sent to affected prescribers prior to implementation.

ii. Concurrent use of long-acting injectable and oral antipsychotics was discussed under a previous agenda item. Concurrent use will require prior authorization.

4. The 2019 PDL was provided for review. It will be posted to the DUR website for public comment.

There being no further business, the open portion of the meeting was adjourned and the Committee met in closed session.

Respectfully Submitted,

Aimee Lewis
WYDUR Manager