

WY P&T Committee Meeting Minutes
Wednesday, November 9, 2017
Cheyenne, WY
10 a.m – 1 p.m.

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

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

Excused: Rhonda McLaughlin, Andrew Beaulieu

Guests: Sara Howe (CHC), Nikki Yost (CHC), Melissa Eames, Amy Stockton (CHC), Danny McNatty (Janssen), Sharon Cahoon-Metzger (Bioverativ), Brad Buckle (Bioverativ), John Sanstrom (Shire), Nick Cassotos (Shire), Jason Smith (Gilead), Jodi Rudell (Rocky Mountain Hemophilia), Julie Tucker, Susan Kelly, Mark Germann (Novartis), Maggie Murphy (Teva), Ray Kong (Amgen),

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

Introductions were made.

Approval of Minutes

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

Department of Health

A. Pharmacy Program Manager Report: The new POS system has been in place for about four months. All is going well and running smoothly. The RFP for the DUR contract is in the approval process at the Department of Health.

B. Medical Director Report: No report

C. DUR Manager Report: The opiate limits went into place. The change has been relatively smooth. The School of Pharmacy will be responding to the RFP when it is released. Dr. Beaulieu has resigned from the Committee as he is getting married and moving. We are very happy for him and will need to consider a replacement.

Old Business: Osteoporosis utilization was reviewed. The majority of utilization is in alendronate. No further action is needed at this time.

New Business

A. PA Criteria

1. Review existing criteria

i. The PA help desk has received several requests for Trokendi XR for migraine. It is currently allowed for epilepsy without PA. There is one review that indicates the long-acting is more convenient and may lead to better outcomes than short-acting. However, adherence studies indicate little difference in twice daily formulations versus once daily. There was a motion, second and all were in favor of requiring a prior authorization for all indications besides epilepsy.

ii. An updated Hepatitis C form was reviewed. The number of prescriptions continue to increase. This form includes information about SVR 12 and retreatment.

iii. Rocky Mountain Oncology requested that two additional diagnoses be added to the cancer exception for opiates: Neoplasm-related pain and treatment-related pain. The intent of the exception is to allow cancer patients to receive necessary doses of pain medications in the acute treatment stage or end of life. The exception is not intended to address chronic pain after the acute period of the disease. At this time, no changes will be made.

iv. A pharmacy student brought to our attention that the Angiotensin Receptor blocker (ARB) class still requires a step through an ACE inhibitor despite updated guidelines and changes in pricing. There was a motion, second and all were in favor to remove this step for the ARB class.

v. The PCSK9 medication criteria was reviewed. There has only been one request that did meet existing criteria. The medications are approved for ASCVD. Ray Kong (Amgen) provided comment on the class. Repatha is the only one with cardiovascular outcomes data. The number needed to treat is 50. Diet and exercise are not used to their full potential in these patients. The ACC guidelines specify that PCSK9s are an option for therapy after maximum dose of a high-potency statin fails to reach goal, for secondary prevention for ASCVD and those with familial hypercholesterolemia. There was a motion, second and all were in favor to update the criteria to include trial and failure of a high-potency statin and to allow for secondary prevention of ASCVD. Familial hypercholesterolemia is included in the current criteria.

vi. Austedo was recently approved for tardive dyskinesia. Maggie Murphy (Teva) provided public comment. Long-term safety studies are ongoing. There is a relative lack of other treatment options for tardive dyskinesia. There is a black box for risk of depression and suicidality. Tardive dyskinesia occurs after use of dopamine blockers such as antipsychotics. It worsens over time and doesn't necessarily resolve with removal of the causal agent. There was a motion, second and all were in favor of allowing for tardive dyskinesia.

2. New Drugs

i. Haegarda is a C1 inhibitor approved for routine prophylaxis against angioedema attacks in adults and adolescents with hereditary angioedema (HAE). There was a motion, second and all were in favor of approving for FDA indication. The class as a whole will be brought back in February with guidelines for further review.

ii. Tremfya is a new IL-23 inhibitor approved for treatment of moderate to severe plaque psoriasis in adults. Danny McNatty (Janssen) provided public comment asking the Committee to add it as a preferred agent. It does have superiority

data compared to Humira. There is no evidence that increasing dose has a benefit, so dose creep should not be an issue. It is only approved for plaque psoriasis at this time. There was discussion regarding whether it was still appropriate to use other treatments first. Stelara is available and has IL-23 activity as well. Tremfya has better outcomes data. The Committee concluded that there was no evidence of a difference in safety, however, there is evidence of superiority in efficacy at least against Humira. They recommend that it be a preferred product for plaque psoriasis. There was a motion, second and all were in favor of the above.

iii. Mavyret is approved for treatment of Hepatitis C and retreatment for those who have failed an NS5A inhibitor or NS3/4A protease inhibitor. It is a pangenotypic agent. The Committee concluded that there is no evidence of a difference in safety or efficacy. There was a motion, second and all were in favor of limiting to clinical criteria currently applied to the class and referred to the Department of Health for cost analysis and PDL placement.

iv. Bevyxxa is a Factor Xa inhibitor approved for prophylaxis of VTE in adults hospitalized for acute medical illness who are at risk for thromboembolic events. Because this medication will be started in the hospital, management will be very difficult. There was a motion, second and all were in favor of limiting to indication. Retrospective review will be done to ensure appropriate length of therapy.

3. Determine need for criteria

i. Imbruvica has recently been approved for chronic graft-versus-host disease after failure of one or more lines of systemic therapy. It is also approved for certain cancers. There was a motion, second and all were in favor of limiting to indication for graft-versus-host disease. This will not affect its use for cancer treatment.

ii. Benlysta is now available in a subcutaneous, self-administered formulation for treatment of systemic lupus erythematosus. There was a motion, second and all were in favor of limiting to indication.

iii. The Department of Health will be making Xiidra non-preferred to Restasis for 2018 due to significant cost differences. Criteria will be necessary to access Xiidra. There was a motion, second and all were in favor of requiring a twelve-week trial of Restasis prior to approval of Xiidra.

iv. Hemophilia agents were discussed. There is no comparative evidence in this class. Sharon Metzger (Bioverativ) provided public comment. Adherence is very important in this class and can be difficult as kids get older in the adolescent and teen years. The longer half-life allows patients to remain adherent with fewer infusions per week. The studies are predominantly open-label and focus on whether prophylaxis is better than on-demand treatment. As expected, prophylaxis comes out on top. We will be hard pressed to find differences in safety and efficacy among the agents. Up to 1/3 of Hemophilia A patients will develop inhibitors. This generally occurs in untreated patients in the first 50 days of treatment. The Committee asked how “switchers” do in the studies. They do fine, however, they are very closely monitored. These are not “real life” situations. They are a very protective group and don’t switch frequently.

John Sandstrom (Shire) also provided public comment. The plasma-derived products still have some risk of transmission despite very tight controls. The jury is still out on whether plasma-derived is less likely to have inhibitor production than recombinant forms. Patients that develop inhibitors are very expensive, up to \$1 million/year while going through inhibitor treatment protocols. Advate has one dose range twice weekly and comes in seven different vial sizes. The same question was asked regarding “switchers” and the answer was the same. These patients are monitored very closely in studies. There is no real difference in safety or efficacy. Some have more data than others, but there are no head to head studies.

Jodi Rudell (Rocky Mountain Hemophilia Foundation) provided comment regarding her two daughters who have severe Von Willebrand Disease. These are expensive drugs. They do stockpile to make sure they are covered if a bleed occurs. They prophylax twice a week. These are life and death drugs. They are currently considering switching products. She urged access to all available therapies. These patients are all very different and complex. Her daughters have very similar numbers on paper but bleed very differently. There was discussion about the funding of the Foundations, often funded by pharmaceutical companies.

The Committee indicated that there was no comparative safety and efficacy data and requested that patients be grandfathered on current therapy if anything would be restricted. There was a motion, second and all were in favor of this recommendation.

Aimee reminded everyone that putting these medications on the PDL does not mean they are not covered. Anything that is non-preferred will require prior authorization which is a reasonable and quick process. All existing users would be grandfathered.

Other: The 2018 draft PDL was presented. Comments should be provided as soon as possible.

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