WY P&T Committee Meeting Minutes
Thursday, August 8, 2018
Cheyenne, WY
10 a.m. – 1 p.m.

Members present: Hoo Fang Choo, Joseph Horam, Scott Johnston, Rhonda McLaughlin, Robert Monger, Chris Mosier, Tonja Woods

Ex-officio: Melissa Hunter, Cori Cooper

Excused: Paul Johnson, Garry Needham, Scot Schmidt, David Sy, Patrick Yost

Guests: Sandra Deaver, Melissa Eames, Amy Stockton (CHC), Sara Howe (CHC), Jaierie Ng (Indivior), Paul Bragoli (Indivior), Jeff Mussack (Otsuka), Joe Cirrincione (Otsuka), Ray Lindfield (Sunovion), Dawn Bina (Novo Nordisk), Michael Faithe (Amgen), Jody Legg (Alkermes), Frank Del Real (Wyoming Recovery), Britt Bochner (Lilly), Jaime Lund (AstraZeneca), Sean Parker (Bristol-Meyer Squibb), Antoinette Brown (UW School of Pharmacy), Amy Rodenburg (Allergan), Sam Blakeslee (Creighton Pharmacy School)

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

Introductions were made. Dr. Monger pointed out an article in the Wyoming Medical Society Magazine about the opiate crisis and handed out flyers for some upcoming CE sessions at Cheyenne Regional Medical Center.

Approval of Minutes

The minutes of the May 3, 2018 meeting were approved as submitted.

Department of Health

A. Pharmacy Program Manager Report: Certification, the process required to prove that the PBM system works as expected, has been turned in to CMS for final approval. This was an extensive project for CHC and the Office of Pharmacy Services. The last PBMS contract added a medication therapy management program. This program is not a traditional MTM program so is called the Pharmacy Care Management program. This is run by Nikki Yost and Mary Ann Everett at CHC and will focus initially on hemophilia and hepatitis C compliance. So far, they've made very good progress.

B. Medical Director Report: The patient-centered medical home continues to expand. This helps with Medicare reimbursement as well. Some of the best PCMHs were solo practices. Everyone is encouraged to participate. The Statewide HIE, WYFI, is operational. CRMC and the Physician's group are connected. The plan is to connect all 27 hospitals. Real-time notifications will occur for admissions, discharges and transfers. Practitioners will be able to see everything that happens with their patients, including an updated medication list.

C. DUR Manager Report: The DUR contract is fully executed with a three-year

initial contract and option for a two-year extension.

Old Business:

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

B. The 7-day opiate first-fill policy was discussed. Public comment was reviewed as well as a breakdown of utilization by days since last fill. Wal Mart and CVS pharmacies have implemented their own first-fill policies, limiting them to seven days as well. Rhonda indicated that in their chronic pain practice, after surgery, they refer to the surgeon for two weeks to treat acute post-surgical pain and then resume chronic pain treatment. Dr. Del Real was asked his opinion and indicated that he had nothing in particular for this particular topic. Opiates have a place in the treatment of acute pain. Long-term treatment of chronic pain is where problems arise.

The proposed policy in May was a 7-day limit on first-fills with a 30-day lookback period. After reviewing public comment and utilization, the Committee agreed to extend the lookback period to 45 days which helps to focus on the truly-opiate naïve patients we are intending to target. There was a motion, a second, and all were in favor of the amended policy.

New Business

A. PA Criteria

1. Review existing criteria
    i. The Adult ADHD topic was tabled.
    ii. Dr. Del Real came to discuss his thoughts on the buprenorphine prior authorization criteria. Dr. Del Real is a psychiatrist and addiction specialist, treating approximately 250 patients for addiction, 175 – 200 for opiate addiction. His requests included:
        1. Allow up to 24 mg for induction. The prior authorization requirement is a hurdle to beginning therapy when time is of the essence. A delay may result in the patient being lost to follow up. In the beginning, when titration is occurring, it is difficult to get it exactly right. With the PA process, patients are locked in to a dose right away. Dr. Del Real would like to have higher doses allowed for 30 – 60 days.
        2. Allow 16 mg for longer than two years. Currently, the policy requires a taper from 16 mg to 8 mg or less after two years. The vast majority of patients have a difficult time tapering. It is a slow process with a 10-15% taper every two to four weeks. Tapering any faster than that is very difficult, similar from taking a "binky" from a two-year old. This is a chronic illness. We would not consider tapering an insulin-dependent diabetic. A PA above 16 mg per day is reasonable.
        3. Allow a longer period between PA requests, particularly when nothing is changing.
        4. Expand the PDL. Currently, only Suboxone is listed.

Sublocade may be a potential for some patients and will help decrease diversion. Some can't tolerate the film and Bunavail doesn't seem to cause as many side effects, including nausea and headache.

5. Consider changing the requirements for residential treatment, especially for those with co-occurring disorders.

6. Remove the limits on counseling sessions allowed per year. Once a patient is on Suboxone, they have to have counseling. A 12-step program is not sufficient, but sessions per year are limited. It was later verified that Medicaid does not require counseling sessions as a part of the buprenorphine PA criteria.

7. Expand treatment to all low-income adults.

The Committee only has purview over the first four items. In answer to additional questions, Dr. Del Real indicated that 15 – 20% of patients should be started higher than 16 mg. About 50% will need to remain on greater than 8 mg per day after two years. It was noted that national guidelines recommend a taper as soon as possible. In addition, at 16 mg the opiate receptors are saturated, so it is hard to justify going higher. Dr. Del Real said this is true for about 2/3 of patients. However, it is a bell shaped curve and about 1/3 don't fall in that range. Finally, Dr. Del Real indicated that approximately 15 – 20% of patients will be weaned off of Suboxone successfully, often switching to naltrexone. About 1/3 want to come off and 25 – 30% of those are ultimately successful.

Dr. Del Real reiterated his points that a prior authorization on buprenorphine products is inconvenient at best, and a significant impediment at worst. We have a limited opportunity to get into patients into treatment and recovery. As Burt Toews used to say "we have to strike while the iron is hot".

Dr. Johnston requested additional information regarding the receptor saturation point. Are we pushing the dose higher for a medical reason or psychiatric (binky)? It was suggested that it didn't matter the background mechanism if it put someone into recovery.

Amy Stockton provided the prior authorization statistics for the last year. We received 294 requests, of which 240 required action (approval or denial). A total of 64 were denied, 11 for max dose. The rest were denied for eligibility, incomplete prior authorizations, splitting films, or pain diagnosis.

It was noted that fundamentally our charge is to make evidence-based decisions. At this time, the literature does not support lifetime buprenorphine at relatively high doses. This is the underlying issue. If we lift these prior authorization requirements, are we just creating another issue, such as widespread treatment of chronic pain with buprenorphine? The Committee asked for additional research and time to deliberate. The topic will be brought back for discussion in November. Topics for discussion will include whether the dose for induction should be increased to 24 mg per day, the appropriateness of a PA process in general, and any other flags in the system that could be used to ease the burden (such as XDEA numbers).

2. New Drugs
    i. Rhopressa is indicated for treatment of open-angle glaucoma or

ocular hypertension. There are many other medications in the market basket, though, this is a new mechanism of action. The Committee agreed that there is a dearth of evidence regarding comparative safety and efficacy. They referred it to the Department of Health for a cost analysis and placement on the PDL. There was a motion, second and all were in favor.

ii. Cyclosporine in Klarity is indicated for treatment of keratoconjunctivitis sicca. It is the same active ingredient as Restasis but a different strength. The Committee found no evidence of a difference in safety and efficacy and referred it for cost analysis. There was a motion, second and all were in favor.

iii. Jynarque is indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease. Joe Cirrincione (Otsuka) provided public comment. Samsca is the same active ingredient with an indication of treatment of hypervolemic and euvolemic hyponatremia. It is contraindicated in those with autosomal dominant polycystic kidney disease as it does not carry the REMS program that Jynarque has. Both products can cause fatal liver injury and must be monitored closely. Samsca should be initiated in the hospital and has a 30-day supply limit. Nephrologists in Casper generally use it as a one-time dose. The Committee agreed that there was a dearth of evidence regarding safety and efficacy. These medications will be limited to indication. There was a motion, second and all were in favor.

iv. Crysvita is approved for treatment of x-linked hypophosphatemia in children aged one year and older. There is no comparative evidence for this medication. The Committee recommended that it be limited to indication. There was a motion, second and all were in favor.

v. Osmolex ER is a long-acting amantadine indicated for treatment of Parkinson's disease and drug-induced extrapyramidal reactions in adult patients. The Committee indicated that there was a paucity of evidence of a difference in safety or efficacy. The drug should be limited to indication and will be referred to the Department of Health for a cost analysis.

vi. Tavalisse is indicated for treatment of chronic immune thrombocytopenia who have had insufficient response to previous treatment. The Committee noted no evidence of a difference in safety or efficacy. The medication will be limited to indication, including failure to previous treatment.

vii. Aimovig is a new migraine prophylaxis agent with a novel mechanism of action. Michael Faithe (Amgen) provided public comment. Botox is the only other agent approved for prophylaxis of chronic migraine. Other current treatments are all generic and include divalproex, tricyclic antidepressants, beta blockers and topiramate. The Committee recommended a three-month trial of three different generic medications from different classes according to NIH guidelines. The lookback period will be lifetime. There was a motion, second and all were in favor.

3. Determine need for criteria

i. It came to the attention of the Department of Health that there are a variety of isotretinoin products with highly variable pricing. This topic was brought as an FYI that the Department will be doing a cost analysis of the products for placement on the PDL. All are limited to those under age 21.

ii. The Department identified at least one patient using very high doses injectable antipsychotics, leading to a realization that dose limits were never discussed or applied to injectable products. Oral antipsychotics are currently limited to 150% of labeled dose. This raises the additional question of whether 150% is still a reasonable benchmark. It was set historically, 15 years ago or more, with no clinical evidence or other supporting data. The injectable products will be limited to 150% immediately. Additional information will be brought back regarding the appropriateness of a 150% limit as well as patient impact of lowering.

There being no further business, the open portion of the meeting at was adjourned and the Committee met in closed session. A brief annual planning meeting was held during closed session to provide Aimee feedback on the current process as well as brainstorm ideas for future education letters and newsletter articles.

Respectfully Submitted,

Aimee Lewis
WYDUR Manager