WY P&T Committee Meeting Minutes
Thursday, May 9, 2024
Cheyenne, WY and via Zoom
10 a.m – 1 p.m.

Members present: Tracie Caller, Melinda Carroll, Hoo Feng Choo, Evan Crump, Scott Johnston, Kristen Lovas, Layne Lash, Robert Monger, Chris Mosier, Danae Stampfli, Patrick Yost

Ex-officio: Cori Cooper, Melissa Hunter

Excused: Garry Needham

Guests: Melissa Eames, Sandra Deaver, Collin Townsend, Matt Robison (CHC), Corwyn Moss (CHC), Melissa Mehle (CHC), Nancy Stortz (CHC), Kat Khachatourian (Novo Nordisk), Tara McKinley (Madrigal), Lavinia Salama (UW Family Practice), Brielle Dozier (Artia Solutions), Jason Smith (Gilead), Joe Sullivan (Vertex), Rebecca Clifford (Madrigal), Yenyen Tran (Gilead), Natalie Rose (Gilead), Doug Johnson (Sobi), Maya Armstrong (Genentech), Kimberly Raymer (Novo Nordisk), Gina Heinen (Novo Nordisk), Kurt Hendrickson (Abbvie), Jeff Houston, Michele Sabados (Alkermes), Esther Jarvis (IHS), Kaysen Bala (Bluebird Bio), Heather Kelsey (Lilly), Danielle Walters, Chad Duncan (Vertex)

Chris Mosier called the meeting to order at 10:00 a.m.

Introductions were made.

Approval of Minutes

The minutes of the February 8, 2024 meeting were approved.

Department of Health

Pharmacy Program Manager Report: None.

A. Medical Director Report: None.

B. DUR Manager Report: None.

Old Business:

There was no old business to discuss.

New Business

A. Change Healthcare (CHC) has experienced an outage beginning February 21, 2024. A cyber threat was identified, and all applications and connections were shut down to contain the threat. Pharmacy claims were unable to be processed until March 15 when a new system was stood up in a "clean" Optum environment. Pharmacies were allowed to process the backlog of claims. The claims system was the first priority followed by the rebate system. The focus is now on the formulary and pricing system. After that, the prior authorization system will be stood up. Refill too soon, maximum day supply and

dose limits were implemented this week. We will have to review claims to see what went through and how medications were priced. We expect to have patients who have been started on medications that typically require prior authorization during this period.

CHC has not yet been able to identify what, if any, Wyoming client data was exfiltrated. We are working with OCR to determine what needs to be done. Credit monitoring has been offered for any clients who may be at risk. CHC is a large company covering much more than Wyoming Medicaid. They continue to work on connections to other vendors.

Advance payments were offered to all enrolled pharmacies to make sure that pharmacies were kept solvent during this time. State general funds were used for this with a total exposure of $650,000. Payments continued for 3 – 4 weeks. 19 pharmacies opted in to this and were given the equivalent of their historical weekly average payment. Advance payments will be paid back once historical claims are adjudicated. Pharmacies have been asked to return these advanced payments by June 6 and June 30 is the absolute deadline for repayments since its the end of the fiscal biennium.

Collin, Melissa, and Sandra took an extraordinary number of calls and worked to make sure patients could receive their medications. The Department worked with pharmacies to make sure that they were comfortable filling medications. In some cases, claims paid where the patient or the prescriber wasn't enrolled. The Department is finding workarounds to make sure the pharmacies get paid for these. There are about 100 claims currently falling in this bucket. There have been no reports of patients being harmed by the outage. Many of these patients moved to a pharmacy that would help them. Some corporate pharmacies had mixed messaging that made it difficult for people.

Evan thanked CHC and the Department of Health for all their work to make this work for pharmacies.

CHC estimates that they are at about 50% capacity for all services provided. For claims processing, the system was at 100% capacity within 2 -3 days of standing the system up. Prior authorization functionality is anticipated to be up by the end of June.

Dr. Monger mentioned that a couple of hospitals were attacked by Ransomware and paid off the ransom. This was also a ransomware attack. It is our understanding that the ransom was paid. Fortunately, the merge had already occurred with Optum which allowed them to rebuild systems much more quickly than they could have otherwise.

Six states have been affected by this. CHC testified to Congress last week. The FBI is involved.

B. PA Criteria
    1. Review existing criteria
        i. There were no medications in this category
    2. New Drugs
        i. Wainua is indicated for polyneuropathy of hereditary

transthyretin-mediated amyloidosis. There is no evidence of a difference in safety and efficacy. There was a motion to limit to indication and refer for cost analysis and PDL placement. All were in favor

ii. Zilbrysq is indicated for treatment of generalized myasthenia gravis in adults who are anti-acetylcholine receptor (AChR) antibody positive. This would be a second-line agent. Many of the second-line agents are IV infusion. This is a consideration for patients who may have difficulty getting to an infusion center. It is not clear why inhibition of complement works in myasthenia gravis. Dr. Caller recommends a trial and failure of one first-line oral agent for six months. There was a motion to limit to indication and require a trial of one first-line agent for six months. All were in favor.

iii. Voydeya is indicated for the treatment of extravascular hemolysis, as add-on therapy to ravulizumab or eculizumab, in adults with paroxysmal nocturnal hemoglobinuria. There was a motion to limit to indication and require treatment with ravulizumab or eculizumab for the previous six months. All were inf

iv. Vafseo is approved for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for three months or more. There is no comparative evidence regarding safety or efficacy with the other oral agents. There was a motion to refer for cost analysis and PDL placement. All were in favor.

v. Winrevair is indicated for the treatment of pulmonary arterial hypertension to increase exercise capacity, improve WHO functional class, and reduce the risk of clinical worsening events in adults. There is no evidence of a difference in safety and efficacy. There was a motion to refer for cost analysis and PDL placement. All were in favor

vi. Rezdiffra is indicated for treatment of noncirrhotic metabolic dysfunction-associated steatotic liver disease (formerly termed nonalcoholic steatohepatitis) with moderate to advanced liver fibrosis (consistent with F2 to F3 fibrosis), in conjunction with diet and exercise. Tara McKinley (Madrigal) provided public comment. Statin doses may be limited when used in combination. It is indicated in conjunction with diet and exercise. Diet and exercise may lead to improvement in 1/5 patients by themselves. Diet and exercise were part of the treatment protocol though the protocol was not formalized. There is no data regarding fibrosis improvement with diet and exercise alone. How do you know if it is working? There was a variety of non-invasive tests utilized in addition to biopsy (based on FDA requirements). Fibroscan looks at steatosis and fibrosis and is one of the most common non-invasive tests used. Patients should see both improvement and stability in fibrosis score. 80% of patients with fibrosis score of 1b had improvement or no worsening. What's the typical duration of treatment? This is new territory as it's the first drug approved for this condition. At this point we don't know what the duration of treatment will be. Clinical outcomes are not yet available.

There is not enough data yet to say this is a primary pharmacologic treatment and there are some safety concerns. There was a motion to limit to indication and approve for one year with verification of efficacy. All were in favor. We will monitor the usage and bring it back if necessary. Clinical outcomes are expected to be completed in 2027 or 2028. This was approved under accelerated approval.

vii. Zelsuvmi is approved to treat molluscum contagiosum in adults

and pediatrics older than one year of age. There is no evidence of a difference in safety and efficacy. There was a motion to limit to indication and refer for cost analysis and PDL placement. All were in favor.

viii. Eohilia is indicated for the treatment of eosinophilic esophagitis. Pharmacies may already be compounding a similar product. We do see a fair number of claims for compounded agents. There is no evidence of a difference in safety and efficacy. There was a motion to limit to indication. All were in favor.

ix. Agamree is approved for treatment of Duchenne muscular dystrophy in patients aged two years and older. Anne Stratton, MD provided written public comment. There is evidence of a difference in safety, particularly in bone turnover markers. There was a motion to limit to indication and recertify annually that they are skeletally immature. All were in favor.

x. Duvyzat is approved for the treatment of Duchenne muscular dystrophy in patients 6 years of age and older. Anne Stratton, MD provided written public comment. There was a motion to limit to indication as adjunct treatment or following a failure or contraindication to corticosteroids. All were in favor. It was noted that there are some serious safety concerns associated with this medication.

3. Determine need for criteria

i. Wegovy is approved for reduction of risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adult patients with established cardiovascular disease and either obesity or overweight. Lavinia Salama, PharmD (UW Family Practice) provided public comment. Kat Khachatourian (Novo Nordisk) also provided public comment. Wegovy was given in conjunction with standard of care for other cardiovascular conditions including high cholesterol, high blood pressure and heart failure medications. There were no new safety signals observed in this trial. Symptomatic peripheral artery disease is measured by the ankle/brachial pressure differences. This leads to inability or challenges with walking. The number needed to treat is 67 people for 40 months to prevent one event.

As a clarification, Medicaid agencies do not have to cover medications solely indicated for weight loss unless the medication is covered in their state plan amendment. Wyoming does not currently cover these. Medicaid is required to cover for the non-excluded indication of cardiovascular disease.

Is there any data about cardiac event outcomes for the higher doses in diabetic patients? The SUSTAIN trial has led to an indication for Ozempic which led to the cardiovascular indication for Ozempic.

There are reports of worsening depression. It does not appear to be related to the semaglutide molecule. There are no recommendations for evaluation while on therapy. Dr. Salama screens all her patients for depression and works along with providers to manage any depression identified. Anecdotally, in her patients she sees depression improving, however, she has not done any type of study around this.

The other medications with a cardiovascular indication are currently covered without prior authorization. The BMI in the study is based on the previous indication of Wegovy.

There is no evidence of a difference in safety or efficacy. There was a motion to limit to indication and refer for cost analysis and PDL placement. All were in favor.

It seems that smoking cessation should also be required. It is not part of the label, but smoking cessation is a part of any guideline for chronic disease management. There was a motion to require smoking cessation. The Committee did not feel that this was a reasonable request at this time. The motion failed.

4. Physician Administered Drugs

i. Casgevy is indicated for treatment of transfusion-dependent beta-thalassemia in adult and pediatric patients aged 12 years and older and for treatment of sickle cell disease in adults and pediatrics aged 12 years and older with recurrent vaso-occlusive crisis. Chad Duncan (Vertex) provided public comment. These are given in an authorized treatment center. Cells are sent to Vertex where cells are manufactured and sent back to the treatment center in a transplant unit. They will remain in the unit for around 40 days depending on diagnosis due to myeloablative conditioning.

Cori clarified that these treatments will be carved out of the regular hospital payment under diagnosis related groups. The treatment cost will be considered separately. Contracts are still in process with treatment centers. Texas, Chicago, or California are the closest currently. They are looking to have 50 eventually. Cori reviewed medical claims and found 8 patients with a sickle cell diagnosis in the last year and zero beta-thalassemia. At this time, there are no patients who would qualify for Casgevy or Lyfgenia. There is one who may eventually qualify if they have vaso-occlusive crises. Casgevy works by increasing fetal hemoglobin expression which decreases sickling of adult hemoglobin. Natural history studies show that if 30% of hemoglobin is fetal, there are no symptoms.

ii. Lyfgenia is indicated for the treatment of sickle cell disease in adult and pediatric patients aged 12 years and older with a history of vaso-occlusive events. Kaysen Bala (Bluebird Bio) provided public comment. Long-term data have been presented at the American Society of Hematology. The mean follow up is 35.5 months. For patients who did not have a complete resolution, 50% decrease in vaso-occlusion was seen. The hematologic malignancies are an inherent risk for sickle cell disease. In trials, there were two patients who had malignancies. These two patients were treated with an early manufacture process. This process has changed which improves the quality of cells. No additional cases have been identified. The closest treatment center is at Colorado Children's Hospital in Denver. They are in the same process of contracting treatment centers. Is there financial assistance for travel and the long-term stay? The family will go back home during the manufacturing process. They do have a patient services hub that is available for all products. They can assess patient need. For Medicaid patients, the travel expenses would likely fall to the Medicaid program. Also, fertility issues must be taken care of before treatment.

There was a motion to limit both products to indication. All were in favor.

Other

There being no further business, the open portion of the meeting adjourned at 12:15 pm and the Committee met in closed session.

Respectfully Submitted,

Aimee Lewis
WYDUR Manager