Alaska Medicaid Pharmacy and Therapeutics Meeting

MINUTES OF MEETING
April 19, 2024

Committee Members Present:
Charles Semling PharmD, DHSS
John Riley, PA, Acting Chairman
Robert Carlson, MD
Sara Atchison, PharmD
Claudia Phillips, MD
Charles Ryan, MD
Trisha White, R.Ph.
Valarie Bixler, PharmD

Committee Members Absent:
Casey Gokey

Others Present:
Ryan Ruggles, Pharm D
Nina Huynh
Matthew Parrott, Pharm D DOH
Shirley Quach, Novartis
Kimberly Simpson, Humana Therapeutics Corporation

1. Call to Order – Chair

Mr. Riley called the meeting to order.

2. Roll Call

The roll call was taken, and a quorum was present.

3. Public Comments - Local Public/Health Practitioners

None.

4. Class Review, Discussion & Vote

4-A. Single Class Review: Hereditary Angioedema (Green), Hemophilia (Red).

Single Class Review: Hereditary Angioedema (Green)

Ryan Ruggles stated that this is a green class. In the last quarter there was no utilization. Previous motion was class effect moved by Dr. Ryan and seconded by Dr. Phillips and passed unanimously.

DR. RYAN MOVED THAT THE DRUGS WERE THERAPEUTIC ALTERNATIVES, SECONDED BY DR PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Single Acting Agents: Hemophilia (Red Class)

Given that this is a red class the floor was opened for industry testimony for which there was none.

Ryan Ruggles gave the Magellan presentation for hemophilia. He gave the disease state description for hemophilia.

Next, he gave the treatment guidelines for hemophilia.

In April 2023, the FDA approved Coagadex for the indication for perioperative management of bleeding to include patients with severe hereditary Factor X deficiency; previously approved for perioperative management of bleeding only in patients with mild or moderate hereditary Factor X deficiency. Indications, warnings, dosage, and availability were given.

In June 2023, the FDA approved Roctavian, an adeno-associated virus vector based gene therapy for the treatment of adults with severe hemophilia A without preexisting antibodies to adeno-associated virus serotype 5 detected by an FDA approved test. Indications, warnings, dosage, and availability were given.

Utilization was 100% in line with PDL. Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternatives to include at least one prophylactic medication, seconded by Dr. Phillips and passed unanimously.

Claudia Phillips stated she researched the drug and was curious because it stated that it diminishes over time and she is wondering why that is. Charles Semling stated that they have been looking into it as well and there is some wearing off effect of the medication. Claudia stated the other issue is that some people get thromboembolic events because it is working too well which is another concern she has. Matthew ParroTt stated that in the initial six months that has been observed. When the drug was initially presented to the FDA, they actually delayed adoption for the exact reasons Dr. Phillips brought up. There is also another product called Hemgenix which is a similar gene therapy that is also being used except for hemophilia B both of them do not have that much long term data depending on what they are looking at. They have, at most, three to five years at this point. Over that time there is a decrease in factor concentrations. The argument at present is that the actual percentage of patients, as far as their research goes out that needs to have actual factor replacement the prevent bleeds, is very small and in most cases zero. The data just doesn't go out that far and if you follow the curve out to its natural conclusion that will occur. The ultimate question is, are these therapies truly curative? The best research he has seen on that question at this point is actually done by an organization

called ICER. They have a very compelling report on whether or not these therapies are cost effective, in particular this one relative to Hemlibra. The actual FDA approval occurred in a patient population of less than 50.

DR. RYAN MOVED THE DRUGS IN THE CLASS ARE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE PROPHYLACTIC MEDICATION, SECONDED BY DR. *. THE MOTION PASSED UNANIMOUSLY.

4-B. Cardiovascular: Ace Inhibitors and Renin Inhibitors (Green); Angiotensin Receptor Inhibitors (Green); Angiotensin Modulator/* Combined (Green); Antianginal and Anti-ischemic Agents (Green); Anticoagulants (Green); Betablockers (Green); Calcium Channel Blockers (Green); Erythropoiesis Stimulating agents (Blue); Lipotropics, other (Blue); PCSK 9 Inhibitors (Green); Platelet Aggressive Inhibitors (Green); Pulmonary Arterial Hypertension (Blue)

Cardiovascular: Ace Inhibitors and Renin Inhibitors (Green Class)

Cardiovascular: Angiotensin Receptor Inhibitors (Green Class)

Both the Ace Inhibitors and Renin Inhibitors class as well as the Angiotensin Receptor Inhibitor Class were bundled into one motion last year.

Utilization for the Ace and Renin Inhibitors was 95.8 percent in line with PDL and utilization for Angiotensin Receptor Inhibitors was 87.4 percent in line with PDL and ARBs was 92.2 percent in line with PDL.

Last year Dr. Phillips moved that all three subgroups in the class were therapeutic alternatives, seconded by Dr. Ryan and passed unanimously.

DR. PHILLIPS MOVED THAT ALL THREE SUBGROUPS IN THE CLASS ARE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Cardiovascular: Angiotensin Modulator/* Combined (Green Class)

Given this is a green class they moved directly to utilization. Utilization was 99.8% in line with PDL. Previous motion Dr. Doran-Atchison moved a class effect to exclude Zileuton, seconded by Dr. Ryan. The motion passed unanimously.

DR. ATCHISON MOVED A CLASS EFFECT TO EXCLUDE ZILEUTON. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Cardiovascular: Antianginal and Anti-ischemic Agents (Green Class)

Given this is a green class they moved directly to utilization. Utilization was 100% in line with PDL. Previous motion Dr. Phillips moved the drugs were therapeutic alternatives, seconded by Dr. Ryan and passed unanimously.

DR. PHILLIPS MOVED THE DRUGS ARE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Cardiovascular: Anticoagulants (Green Class)

Given this is a green class they moved directly to utilization. Utilization was 99.1% in line with PDL. Previous motion Dr. Ryan moved the drugs were therapeutic alternatives to include one oral agent, one injectable agent, one DOAC that can be used for PE and CV prophylaxis, and Warfarin. This was seconded by Dr. White and passed unanimously.

DR. RYAN MOVED THE DRUGS ARE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE ORAL AGENT, ONE INJECTABLE AGENT, ONE DOAC THAT CAN BE USED FOR PE AND CV PROPHYLAXIS, AND WARFARIN. SECONDED BY TRISH WHITE. THE MOTION PASSED UNANIMOUSLY.

Cardiovascular: Betablockers (Green Class)

Given this is a green class they moved directly to utilization. Utilization was 95.3% in line with PDL. Previous motion Dr. Ryan moved that it be considered a class effect to include at least one medication and indication for heart failure, seconded by Dr. Phillips and passed unanimously.

DR. RYAN MOVED THE DRUGS BE CONSIDERED A CLASS EFFECT TO INCLUDE AT LEAST ONE MEDICATION AND INDICATION FOR HEART FAILURE. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Cardiovascular: Calcium Channel Blockers (Green Class)

Given this is a green class they moved directly to utilization. Utilization was 98.8% in line with PDL. Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternatives to include at least one short acting agent, one extended release agent, and one non-dihydropyridine agent. Seconded by Dr. Ryan and passed unanimously.

DR. RYAN MOVED THE DRUGS ARE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE SHORT ACTING AGENT, ONE EXTENDED RELEASE AGENT, AND ONE NON-DIHYDOPYRIDINE AGENT. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Cardiovascular: Erythropoiesis Stimulating Agents (Blue Class)

This is a blue class so Ryan paused for any testimony. There was no one present wishing to give testimony.

Ryan Ruggles gave the disease state description of anemia.

In September 2023, the FDA approved luspatercept-aamt (Reblozyl) for anemia without previous erythropoiesis stimulating agent use in adults with very low to intermediate risk myelodysplastic syndromes who may require regular RBC transfusions. The indications, warnings, dosage, and formulations were given.

Utilization last quarter was 100 percent in line with PDL.

Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternatives, seconded by Dr. Carlson and passed unanimously.

DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Cardiovascular: Lipotropics, other (Blue Class)

Given that this is a blue class Ryan paused to allow testimony.

SHIRLEY QUACH, Novartis, gave testimony on Leqvio. Leqvio is a small interfering RNA lowering LDL cholesterol through RNA interference by preventing production of PCSK9. Last summer the FDA announced a label update for Leqvio. The updated indication for primary hyperlipidemia allows of the expanded use for Leqvio as an adjunct to diet and therapy beyond the previously approved ASCVD and HEFH patient population. This expanded population comprises of those with an increased risk of ASCVD defined as patients with HEFH type II diabetes or ten year ASCVD risk greater than or equal to twenty percent as studied in the ORION-11 pivotal trial. There was also removal of four adverse effects from the safety section due to no numerical difference versus placebo. In August of 2023 results of the ORION-8 open label extension study was released and that demonstrated that LDL cholesterol lower effects of 50 percent with nearly 80 percent of patients achieving their prespecified LDL cholesterol and no knew safety signals with Leqvio. Patients in the open label extension, some were treated up to six years. Just last week the V-INITIATE Study was published. This is a pragmatically designed trial that evaluated immediate Leqvio use implementation strategy after max tolerated statins versus a usual care arm and this was reflected with current US clinical practice. LDL cholesterol was reduced by 60 percent from baseline in the Leqvio arm versus seven percent in the usual care arm with a significantly greater proportion of patients in the Leqvio arm achieving guideline recommended LDL goals of less than 70 and less than 55. Cardiovascular disease remains the leading cause of death in the US disproportionately affecting populations with low socioeconomic status and despite the extensive clinical trial evidence that supports improved cardiovascular outcomes with intensive lowering of LDL real-world studies consistently demonstrate that up to 80 percent of patients with ASCVD fail to achieve LDL goals due to clinical inertia, non-adherence, and side effects. With twice yearly HCP administered dosing that allows for observed adherence, durable long term efficacy, and a favorable safety profile Leqvio is an option that addresses these unmet needs. Novartis respectfully request that Leqvio be added as preferred to the PDL.

Ryan Ruggles gave the presentation on lipotropics, other with giving the disease state description.

In March 2023, the indication for evinacumab-dgnb as an adjunct to other LDL cholesterol lowering therapies for the treatment of patient with homozygous familiar hypercholesterolemia has been expanded to pediatric patients aged five to eleven, previously approved for patients twelve years of age and older. The indications, warnings, dosage, and formulation were given.

In July 2023, the FDA expanded approval of the indication of Leqvio as an adjunct to diet and maximally tolerated statin therapy to reduce LDL-C to include adults with primary hyperlipidemia; indication previously only included adults with HeFH or clinical ASCVD. Indications, warnings, dosage, and formulations were given.

March 2023, Pfizer will be discontinuing the brand name Colestid (colestipol HCI granules).

October 2023, FDA reported that AbbVie discontinued manufacture of brand-name Tricor tablets in the strength of 145 mg and 48 mg.

Utilization was 52.7 percent in line with PDL.

Previous motion Dr. Semling moved for therapeutic alternatives, seconded by Dr. Ryan. The motion passed unanimously. (of note – Ryan stated he feels that Dr. Semling having made the previous motion was a typo).

Dr. Phillips stated she read that Niacin was actually inflammatory and is wondering if that is on the formulary.

Dr. Semling stated that they do have a Niacin ER that is preferred. There were 22 claims for it.

Dr. Semling stated that he feels the next time the class is reviewed it will be more in line with PDL.

DR. RYAN MOVED FOR THERAPEUTIC ALTERNATIVES. SECONDED BY DR. ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Cardiovascular: PCSK 9 Inhibitors (Green Class)

This is a green class so Ryan moved directly to utilization. Utilization was 100 percent in line with PDL.

Previous years motion Dr. Ryan moved a class effect, seconded by Dr. Phillips, and passed unanimously.

DR. PHILLIPS MOVED CLASS EFFECT. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.

Cardiovascular: Platelet Aggregation Inhibitors (Green Class)

This is a green class so Ryan moved directly to utilization. There were 769 claims last year and utilization was 100 percent in line with PDL.

Previous years motion Dr. Ryan moved the drugs in the class were therapeutic alternatives to include at least clopidogrel, seconded by Dr. Phillips and passed unanimously.

DR. ATCHISON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST CLOPIDOGREL. SECONDED BY DR. PHILLIPS. THE MOTIN PASSED UNANIMOUSLY.

Cardiovascular: Pulmonary Arterial Hypertension (Blue Class)

Given that this is a blue class Ryan Ruggles asked for any testimony.

KIMBERLY SIMPSON, Humana Therapeutics Corporation, spoke on a clinical update for their inhaled tryplasma (SP?) products, Tyvaso and Tyvaso DPI. In May 2022, the FDA approved Tyvaso DPI, a new formation and inhalation device for Tyvaso for the treatment of pulmonary arterial hypertension, and pulmonary hypertension associated with interstitial lung disease, to improve exercisability. Tyvaso and Tyvaso DPI are the only FDA approved therapies for the treatment of patients of PHILD, a serious condition which furthers symptoms and decreases survival in patients with ILD. The FDA approval of Tyvaso DPI was supported by data from an open labeled study of 51 patients. Tyvaso is taken 4 times a day while other medications are taken 6 – 9 times a day. She asked that they consider moving Tyvaso and Tyvaso DPI to on formulary for the Alaska Medicaid PDL.

Given that there were no other testimonies Ryan moved forward with the presentation of Pulmonary Arterial Hypertension and gave the disease state description.

In 2022, the European Society of Cardiology and the European Respiratory Society stated the guidelines for the diagnosis and treatment of pulmonary hypertension includes selexipag and oral treprostinil. In patients with idiopathic heritable or drug associated PAH negative for vasoreactivity without cardiopulmonary comorbidities and at low or intermediate risk of death Selexipag may be added to ERA and PDE-5 inhibitor therapy. Sequential drug combination therapy to reduce the risk of morbidity/mortality events includes the addition of selexipag to ERAs and/or PDE-5 inhibitors and the addition of oral treprostinil to ERA, PDE-5 inhibitor, or riociguat monotherapy.

In March 2023, sildenafil oral suspension has been approved for treatment of PAH in adults to improve exercise ability and to delay clinical worsening. Indications, warnings, dosage, and availability were given.

In June 2023, the FFDA approved bosentan 32 mg round tablet for oral suspension that is bisected on one side. Already approved is a 32 mg clover-shaped tablet for oral suspension that is quadrisected. Indications, warnings, dosage, and availability were given.

In November 2023, the FDA has approved the first generic for Actelion's Uptravi 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1400 mcg, and 1600 mcg tablets by Alembic.

Utilization was 61 percent in line with PDL.

Prior motion Dr. Phillips moved the drugs in the class were therapeutic alternatives to include one from each class plus one inhaled product. Seconded by Dr. Carlson and passed unanimously.

DR. CARLSON MOVED THE DRUGS IN THE CLASS ARE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE FROM EACH CLASS PLUS ONE INHALED PRODUCT. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.

4-C. Anti-Infective: Antifungals, oral (Green); Antifungals, topical (Green)**;** Antivirals, influenza (Green); Fluoroquinolones, oral (Green); Hepatitis B agents (Green); Hepatitis C agents (Green); Otic Antibiotics (Green)

Anti-Infective: Antifungals, oral (Green Class)

Since this is a green class Ryan went straight to utilization which was 98.1 percent in line with PDL.

Previous motion Dr. Ryan moved that the drugs were therapeutic alternatives to include at least one fluconazole tablet, one oral terbinafine preparation, and one pediatric preparation. Seconded by Dr. Gokey and motion passed unanimously.

DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT ONE FLUCONAZOLE TABLET, ONE ORAL TERBINAFINE PREPARATION, AND ONE PEDIATRIC PREPARATION. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Anti-Infective: Antifungals, topical (Green Class)

Given that this is a green class Ryan went straight to utilization.

Utilization was 96.3 percent in line with PDL.

Previous motion Dr. Ryan moved that the drugs in the class were therapeutic alternatives to include at least one solution, one shampoo, and one topical cream or ointment. This was seconded by Dr. Phillips and passed unanimously.

DR. RYAN MOVED THAT THE DRUGS IN THE CLASS ARE THERAPEUTIC ALTERNTIVES TO INCLUDE AT LEAST ONE SOLUTION, ONE SHAMPOO, AND ONE TOPICAL CREAM OR OINTMENT. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Anti-Infective: Antivirals, influenza (Greem Class)

This is a green class so Ryan moved directly to utilization.

Utilization was 96.1 percent in line with PDL.

Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternatives to include oseltamivir. Seconded by Dr. Carlson and passed unanimously.

DR. RYAN MOVED THE DRUGS IN THE CLASS ARE THERAPEUTIC ALTERNATIVES TO INCLUDE OSELTAMIVIR. SECONDED BY DR. ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Anti-Infective: Fluoroquinolones (Green Class)

This is a green class so Ryan moved directly to utilization.

Utilization was 98.7 percent in line with PDL.

Previous motion Dr. Ryan moved a class effect, seconded by Dr. Phillips, and passed unanimously.

DR. RYAN MOVED A CLASS EFFECT. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Anti-Infective: Hepatitis B Agents (Greem Class)

This is a green class so Ryan moved directly to utilization.

Utilization was 77 percent in line with PDL.

Prior motion Dr. Ryan moved the drugs in the class were therapeutic alternatives, seconded by Dr. Carlson and passed unanimously.

DR. RYAN MOVED THE DRUGS IN THE CLASS ARE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

Anti-Infective: Hepatitis C Agents (Green Class)

This is a green class so Ryan moved directly to utilization.

Utilization was 99.6 percent in line with PDL. Ryan stated that he feels the math is wrong given 82 current treatments and 0 non-PDL treatments so the utilization should actually be 100 percent in line with PDL.

Prior motion Dr. Ryan moved the drugs were therapeutic alternatives, seconded by Dr. Phillips and passed unanimously.

DR. ATCHISON MOVED THE DRUGS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.

Anti-Infective: Otic Antibiotics (Green Class)

This is a green class so Ryan moved directly to utilization.

Utilization is 40 percent in line with PDL. He states it looks like this is a brand preferred situation where the non-preferred is Cipro dexamethasone.

Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternatives to include one otic glucocorticoid combination. Seconded by Dr. Gokey and passed unanimously.

Mr. Riley stated he could not tell from the list that there was an otic glucocorticoid combination available and is wondering if there is one. Dr. Semling stated it is the medication brand name Ciprodex.

Trish White is wondering if that is why the non-PDL scripts were so high. Dr. Semling stated it was brand over generic opportunity.

Matthew Parrott stated that at this time there is some question as to whether the brand Ciprodex will continue to be manufactured. They are monitoring that.

DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ON OTIC GLUCOCORTICOID COMBINATION. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Claudia Phillips abstained from voting as she was not present for the motion or discussion.

4-D. Genitourinary: Benign Prostatic Hyperplasia (Green); Bladder Reluctant Preparation (Green); Vaginal Antibiotics (Green)

Genitourinary: Benign Prostatic Hyperplasia (Green Class)

This is a green class so Ryan went directly to utilization.

Utilization was 93.1 percent in line with PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives to include one alpha blocker and one androgen hormone inhibitor. Seconded by Dr. Ryan and passed unanimously.

DR. PHILLIPS MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE ALPHA BLOCKER AND ONE ANDROGEN HORMONE INHIBITOR. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.

Genitourinary: Bladder Reluctant Preparations (Green Class)

This is a green class so Ryan went directly to utilization.

Utilization was 68.4 percent in line with PDL.

Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternatives. Seconded by Dr. Phillips and passed unanimously.

DR. RYAN MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Genitourinary: Vaginal Antibiotics (Green Class)

Given that this is a green class they went straight into utilization.

Utilization was 91.2% in line with PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives, seconded by Dr. Ryan and passed unanimously.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS ARE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.

5. End of Public Meeting

6. Comments From Committee Members

7. Adjourn

THE NEXT MEETING WAS SCHEDULE FOR SEPTEMBER 20, 2024.