# Alaska MEDICAID
# PHARMACY AND THERAPEUTICS COMMITTEE
# (ZOOM Meeting)
# April 15, 2022
# 8:00 a.m.

**Committee Members Present:**
John Riley, PA, Acting Chairman
Charles Ryan, MD
Diane Liljegren, R.Ph.
Robert Carlson, MD
Trisha White, R.Ph.
Matthew Begay-Bruno, PharmD
Sarah Doran-Atchison, PharmD
Claudia Phillips, MD
Jonathan Harrison, PharmD

**Others Present:**
Charles Semling PharmD, DHSS
Erin Narus PharmD, MSJ, DHSS
Umang Patel, Pharm D, R.Ph., Magellan Medical Administration
Kyle Downey, Medical Affairs Executive Director, Genentech
Phil Wettestad, Medical Science Liaison, Novartis
Debby Dunaway, PA-C, Medical Science Liaison, United Therapeutics Corporation
Charlie Lovan Medical Outcomes and Science Liaison, AbbVie
Stuart Obershada

## 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

No Public comments were provided.

## 4. Class Review, Discussion & Vote

## 4-A. *Hereditary Angioedema (Green Class)*

Dr. Umang Patel gave the Magellan presentation on Hereditary Angioedema. There was no significant update. The utilization report was reviewed and it was found that 100% of the utilization is in line with the PDL.

Previous year's motion, Dr. Phillips moved the drugs in the class were therapeutic alternatives to include at least one prophylaxis and one treatment intervention. This was seconded by Mr. Greer and passed unanimously.

**DR. LILJEGREN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE PROPHYLAXIS AND ONE TREATMENT INTERVENTION. SECONDED BY MRS. WHITE. THE MOTION PASSED UNANIMOUSLY.**

**4-B.** ***Hemophilia (Blue Class)***

**KYLE DOWNEY,** a representative from Genentech**,** discussed Hemlibra. Hemlibra is indicated for the routine prophylaxis to prevent and reduce the frequency of bleeding both in adults and pediatric patients, for newborns and older patients with hemophilia A with and without inhibitors. I refer everyone to the package inserts. Overall, Hemlibra is administered as a subcutaneous injection either weekly, every two weeks or every four weeks, allowing flexibility for this patient population. In the HAVEN clinical trial patient populations, patients included age ranges from less than age of 2 years of age all the way to 77 years, and the majority of those patients receiving Hemlibra had zero bleeds requiring additional treatment, regardless of the dosing schedule.

From a safety perspective, please again, refer to our USPI. And there is an important information on a box warning for thrombotic microangiopathy as well as thromboembolism as well as warnings and precautions of laboratory coagulation test interference and the most common adverse events are injection site reaction, headache, and arthralgia. I believe the class has been reviewed in the past, and I would really like to hone in on the economic considerations for Hemlibra.

The Institute for Clinical and Economic Review reviewed Hemlibra twice, once in 2018 in comparison with the other factor VIII Inhibitors and released positive statements then as well as in 2020, ICER released the reports profiling Hemlibra for the treatment of hemophilia A without inhibitors with the following recommendations: The payer should ensure appropriate access to Hemlibra, payer should work with clinicians and patients to evaluate the use of Hemlibra for their pertinent patient population, and payers may wish to share information with clinicians and patients regarding potential benefits of Hemlibra for eligible patient populations.

In a retrospective analysis of US Claims for those switched from factor VIII to those patients on Hemlibra, there were no significant differences in overall healthcare costs as well as patients on Hemlibra experienced reductions in health resource utilization, including statistically significant [indiscernible 23:51], less hospitalizations, fewer outpatient hospital visits and fewer physician visits.

With that all information, overall, we would respectfully like to ask that Hemlibra be added or be maintained on the Alaska State's PDL and has demonstrated efficacy and safety for patients with hemophilia A and should be considered preferred agent on the Alaska State's PDL.

Dr. Umang Patel gave the Magellan presentation on Hemophilia. Hemophilia is a rare inherited bleeding disorder. The blood does not clot properly due to an absence of one of the coagulation factors that is present in normal blood. Hemophilia is identified as an X-linked congenital bleeding disorder that has an estimated frequency of 1 in 5,000 or 10,000 births. Typically, affects males on the maternal side due to X-linked inheritance. However, females may also rarely be affected, but are more commonly carriers of the disease. Up to 30% of newly diagnosed cases occur with no prior family history and are attributed to spontaneous mutations in either the F8 or F9 gene. The World Federation of Hemophilia estimates the global prevalence of hemophilia at around 400,000 patients.

It is estimated that there are approximately 20,000 to 33,000 males in the US that are afflicted with hemophilia and there are two main types. Type A is also known as factor VIII deficiency, classical hemophilia or standard hemophilia. This is way more common than hemophilia B. And it presents in 80% to 85% of all hemophilia cases. And patients with type A exhibit lower missing levels of clotting factor VIII. Type B is also known as factor IX deficiency or Christmas disease. Those with type B have lower missing levels of clotting factor IX.

Hemophilia can encompass a lot of other rare factor deficiencies as well. These disorders include deficiencies involving the following factor. Factor I is fibrinogen deficiency, II is prothrombin, V is proconvertin, X is Stuart-Prower, XI is hemophilia C or plasma thromboplastin, XII is Hageman factor deficiency, and XIII is fibrin-stabilizing deficiency. These disorders are far less common than A and B identified by factor XIII, which is estimated to occur in 1 in 5 million persons.

There is also von Willebrand disease, and similar to hemophilia A, this is a group of inherited bleeding disorders related to the absence of protein S of the von Willebrand factor, clotting protein needed to achieve hemostasis. Combines the factor VIII and platelets to generate a platelet plug during the clotting process, and the disease leads to bleeding from impaired platelet adhesion and aggregation, which may be accompanied by reduced levels of factor VIII. The prevalence of disease is estimated 1 in a 100 to 10,000 individuals, and it is equal in male and females. There are three subtypes of von Willebrand. Type 1 is partial quantitative deficiency of the von Willebrand deficiency and accounts for 75% of all patients. Type 2 is the more pronounced qualitative deficiency and comprises almost all the remaining 25% of the patients. Type 2 disease is further divided into four variants in 2A, 2B, 2M and 2N. Type 3 is characterized as a complete von Willebrand factor deficiency and occurs very rarely. In type 3, their inherent factor VIII levels are typically very low.

Treatment guidelines from the World Federation of Hemophilia were reviewed.

The FDA 2020 guidelines are more comprehensive than prior editions and include new chapters on genetic assessment, prophylaxis with hemostatic agents for prevention of bleeding,

management of patients with inhibitors, [indiscernible 30:02] practical assessment, as well as the principles of managing hemophilia to provide benchmarks to care.

So regarding side effects, in April 2021, the package insert updated to remove use for routine prophylaxis in patients less than 16 years of age with hemophilia B. All other information remains the same.

In February 2022, the FDA extended the indication to include routine prophylaxis to reduce the frequency of bleeding episodes in adults diagnosed with severe type 3 von Willebrand disease receiving on-demand therapy already approved as on-demand treatment and control of bleeding episodes in perioperative management of bleeding in adults with von Willebrand disease. Again, just reminding the committee, when there are clinical updates, we try to bold the relevant information. If it is not bolded in here, it remains the same. So again, expanded indications to include routine prophylaxis; no changes to other indications, to warnings, precautions; the dosing is stratified by indication, which can be found in the PCRs and the package insert. There are no changes to the availability here.

The utilization report was reviewed and 100% was in line with the PDL. Previous year's motion, Dr. Phillips moved the drugs in the class were therapeutic alternatives. Seconded by Dr. Doran-Atchison and it passed unanimously.

**MRS. WHITE MOVED THAT THERAPEUTIC ALTERNATIVES INCLUDE AT LEAST ONE PROPHYLACTIC MEDICATION. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.**

**4-C. Hypertension/Ace Inhibitors:** Angiotensin Receptor Blocker Class (Blue); Case-In Renin Inhibitors (Green); Angiotensin Receptor Blockers and CCB combos (Green)

Dr. Umang Patel gave the Magellan presentation Hypertension. Hypertension affects approximately 108 million or 25% adults in the United States. And 1 in 3 have prehypertension. The highest prevalence is among African American men and women, approximately 55% of African American men and women have high blood pressure compared to 46% of Caucasian men and women compared 9% of non-Hispanic Asians and 36% of Hispanics. It is estimated that hypertension is controlled in only 24% of those [indiscernible 35:24] working condition. Pivoting over to guideline updates, the KDIGO (Kidney Disease: Improving Global Outcomes) guidelines updated in 2021. For blood pressure management in patients with CKD, they recommend the use of ARBs (angiotensin receptor blockers) or of renin-angiotensin system inhibitors for patients with CKD, diabetes, hypertension, and moderate-to-severe increased albuminuria. They recommend avoiding the combination of an ACE inhibitor, ARB, or direct renin inhibitor in patients with CKD, regardless of diabetes diagnosis.

In 2020, The U.S. Preventive Task Force updated its 2013 recommendations on screening for high blood pressure in pediatric patients, and they conclude that the current evidence is insufficient to assess the balance of benefits and harms for screening high blood pressure in children and adolescents 3 to 18 years of age. And this is in contrast to the American Academy

of Pediatrics who recommend annual screening of all patients for hypertension and screening at each visit beginning at age 3 for those at high risk.

***Hypertension: Case-In Renin Inhibitors (Green Class); Angiotensin Receptor Blockers and CCB Combos (Green Class)***

Moving right onto the updates for the angiotensin receptor blockers. In April 2021, Diovan had the hypertension indication expanded to include patients as young as 1 year of age. Previously, it was approved for hypertension for patients as young as 6 years of age. And it also has other indications that are not affected, such as select adults with post myocardial infarctions or with heart failure as well. As I mentioned earlier, non-bolded indicates no clinical updates. So, there are no changes to the black box warnings that all angiotensin medications have for fetal injury. Dosing, as you can imagine, is stratified by indication and age and no changes to the availabilities here.

For valsartan, losartan and irbesartan in May 2021, the FDA updated the searchable list of recalled ARBs. And in October 2021, for irbesartan, Lupin issued a voluntary recall of its tablets and its irbesartan hydrochlorothiazide tablets to the consumer level which has selected tested batches of the active pharmaceutical ingredient were above the specification limit for the impurity and all batches were recalled and they discontinued marketing of these agents in January 2021 as well.

Just again reminding the committee, these motions were all bundled together. As you can see for the utilization, the case in renin inhibitors were almost 100% in line with PDL. The angiotensin modulators and CCB combos were roughly about 89% in line with PDL.

***Hypertension: Angiotensin Receptor Blocker Class (Blue Class)***

ARBs roughly 66% in line with PDL.

Previous year's motion, Mr. Greer moved that all three subgroups in the class were therapeutic alternatives to include at least one ACE inhibitor, one ARB and one ARNI. This was seconded by Dr. Carlson and the motion passed unanimously.

Dr. Liljegren asked why compliance was not great on the ARBs.

Dr. Patel stated that when the utilizations were pulled, Magellan had these angiotensin modulator groups bundled all together. And he thinks that when they were breaking these down into the three subgroups, the ARBs may have been slightly miscalculated.

Dr. Ryan stated that it was closer to 99%.

Dr. Patel agreed.

Dr. Ryan stated that just for losartan alone there were 3000 claims.

Dr. Liljegren stated that made smart sense.

Dr. Ryan agreed.

Dr. Patel stated that it was 93.1% in line with PDL.

**DR. LILJEGREN MOVED THE THREE SUBGROUPS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE ACE, ONE ARB AND ONE ARNI AGENT. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.**

**4-D.** ***Antianginals and Anti-Ischemic Agents (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Antianginals and Anti-Ischemic Agents. The utilization report was reviewed and utilization was roughly 94% was in line with PDL. Previous year's motion, Dr. Carlson moved the class effect, which was seconded by Mrs. White and it passed unanimously.

**DR. LILJEGREN MOVED THE CLASS EFFECT, SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.**

**4-E.** ***Anticoagulants (Blue Class)***

Dr. Umang Patel gave the Magellan presentation on Anticoagulants. There are a lot of diseases that fall under anticoagulants, and so he tried to just provide the relevant ones that tie into the clinical updates.

The first one being venous thromboembolism, it manifests as a DVT or pulmonary embolism and is a major consequence of various surgical procedures in medical conditions. It occurs when a thrombus composes cellular material bound together with fibrin strands forms in the deep venous portion of the extremities, more commonly the legs. The exact number of patients affected by DVT and PEs is unknown. However, it is estimated that these conditions affect between up to 900,000 people in the US every year. If left untreated, approximately 30% of patients who develop PE will die within the first few hours of the event. And generally the risk of VTE increases with the number of risk factors present, major traumas, and age. Due to the risk of morbidity and fatal PE associated with DVT, prophylaxis has become the standard of care in patients at high risk for thrombosis. CAD or PAD affects approximately 14 million Americans for CAD and 8.5 million for PAD in individuals over the age of 40. Prevention and treatment of atherosclerosis focuses on modifiable risk factors, including lifestyle changes in the medical treatment of hypertension, hyperlipidemia, and diabetes. Antiplatelet medications such as aspirin, clopidogrel, prasugrel, ticagralor or vorapaxar are indicated for the reduction of thrombotic CV events in patients with established PAD or CAD.

Atrial fibrillation is a common arrhythmia ranging in prevalence from 2% in patients under 65 years of age to 9% in those 65 years or older. The prevalence is higher in men than in women and increases with age. I think the third of patients with AFib are 80 years of age or older. And

patients with AFib can have a reduction in cardiac output resulting in pooling of the blood in the heart, atrial thrombus formation and potential systemic embolization. Ischemic stroke is the most frequent clinical manifestation of AFib-associated embolization and AFib increases the risk of stroke by fivefold. In patients with AFib, ACC recommends measuring the thromboembolism risk using the CHADS2-VASc score which considers risk factors such as gender, age, history of stroke, TIA, or thromboembolism as well as history of congestive heart failure, hypertension, diabetes, or vascular disease. The scores range from 0 to 9 with the higher numbers indicating more risk.

The ACC in 2020 published an expert consensus decision pathway on managing bleeding episodes in patients taking oral anticoagulants, as part of the 2017 ACC Expert Consensus Decision Pathway to carry procedural management of anticoagulation in patients with nonvalvular AFib. They provide the guidance for temporary or permanent interruption of therapy, general approaches to bleeding management, decision support for treatment with a reversal agent and indications and timing for reinstituting anticoagulant treatments. The panel does not recommend routine administration of platelets for patients on antiplatelet agents for major bleeding, and they do not recommend routine oral anticoagulant reversal for non-major bleeding, but clinicians may interrupt therapy until patient is clinically stable and hemostasis is achieved.

According to the American Heart Association and the ACC in tandem in 2020 published guidelines on the diagnosis and treatment of hypertrophic cardiomyopathy. Notable recommendations include for symptomatic patients with left ventricular outflow tract obstruction, non-vasodilating beta-blockers are recommended. Alternatives for patients include verapamil, diltiazem, and disopyramide. For non-obstructive HCM with preserved left ventricular ejection fraction, beta blockers, verapamil or diltiazem are recommended. And then the most relevant consideration of anticoagulants has default treatment option for patients who also have AFib independent of the CHADS2-VASc score. And additional guidance on the use of antiarrhythmic therapy and heart failure agents are included in the guideline update as well.

For the first clinical update here, we have Pradaxa. In June 2021, FDA approved Pradaxa for the treatment of VTE to reduce the risk of VTE in pediatric patients 3 months or older. Previously, it was only indicated for adults. As you can see here, just updates to the clinical indications. No changes to any of its warnings or black box warnings here. The dosage, as you can imagine, is stratified by age and weight since the indication goes as low as 2 months. And the availability here were oral pellets; 20 mg, 30, 40, 50, 110 and 150 per packet.

Next is Xarelto. In August 2021, Xarelto is now indicated in combination with aspirin to reduce the risk of major thrombotic vascular events, such as MIs, ischemic strokes, acute limb ischemia, and major indication of vascular etiology in patients with peripheral artery disease, including patients who have recently undergone a lower extremity revascularization procedure due to symptomatic CAD. And then in December 2021, the FDA approved a new oral suspension formulation, which is 1 mg/mL once reconstituted and two additional indications, which is the treatment of VTE and reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years of age and for thromboprophylaxis in pediatric patients 2 years of age or older with congenital heart disease after the Fontan procedure. As you can see, it has got a long list of

indications now. No changes to the warnings and precautions. No changes to dosing as it is stratified by indication and age, and for availability, there were tablets already here and now the new oral suspension as well.

In December 2021, Apotex voluntary recalled 2 batches of enoxaparin injection to the consumer level due to a packaging error, some syringe barrels contained 150 mg/mL marking and vice versa. This could lead to miscalculation and inaccurate dose administration. Too low of a dose could lead to blood clotting complications and too high could lead to bleeding. No adverse events were reported. And in December 2021, additionally Sandoz recalled one lot of enoxaparin sodium injection for the 3 mg and 0.4 mL single-dose syringes to consumer level as part of the lot exposed to temperature excursions during shipment. Exposure to high temperatures may impact the products effectiveness and could put patients at risk for blood clots resulting in pain, swelling, stroke, pulmonary embolism, or death due to the patients underlying condition.

The utilization report was reviewed and roughly 99.4% was in line with the PDL. And the previous motion, Mr. Greer moved the drugs in the class were therapeutic alternatives to include one oral agent, one injectable, one DOAC that can be used for PE and DVT prophylaxis or warfarin. And this was seconded by Dr. Doran-Atchison and it passed unanimously.

**DR. DORAN-ATCHISON MOVED FOR THE SAME MOTION AS LAST TIME WITH THE THERAPEUTIC ALTERNATIVES, ONE ORAL, ONE INJECTABLE, ONE DOAC AND WARFARIN. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.**

### 4-F. *Beta Blockers (Green Class)*

Dr. Umang Patel gave the Magellan presentation on Beta Blockers. The utilization report was reviewed and about 96% was in line with PDL. Previous year's motion, Dr. Ryan moved the class effect to include both carvedilol and metoprolol succinate, which was seconded by Mr. Riley and passed unanimously.

**DR. LILJEGREN MOVED THAT IT BE CONSIDERED A CLASS EFFECT TO INCLUDE AT LEAST ONE MEDICATION AND INDICATION FOR HEART FAILURE. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.**

### 4-G. *Calcium Channel Blockers (Green Class)*

Dr. Umang Patel gave the Magellan presentation on Calcium Channel Blockers. The utilization report was reviewed and about 99.4% is in line with the PDL. Previous year's motion, Dr. Ryan moved the drugs to class were therapeutic alternatives to include at least one short-acting agent, one extended-release agent, and one non-dihydropyridine agent. Seconded by Dr. Carlson and passed unanimously.

**DR. LILJEGREN MOVED LAST YEAR'S MOTION. SECONDED BY DR. BEGAY-BRUNO. THE MOTION PASSED UNANIMOUSLY.**

**4-H.** ***Stimulating Agents (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Stimulating Agents. The utilization report was reviewed and about 82% was in line with the PDL. Previous year's motion shows that Mr. Greer moved the drugs in the class were the therapeutic alternatives. This was seconded by Dr. Phillips and it passed unanimously.

Dr. Liljegren asked what caused the compliance to be only 82%.

Dr. Ryan stated that this occurred with just one drug that had 98 claims for Epogen.

**DR. LILJEGREN MOVED THAT THE DRUGS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.**

**4-I. Hyper-Lipidemia:** Lipotropic Others (Blue Class); PCSK9 Inhibitors (Green Class)

***Lipotropic Others (Blue Class)***

**PHIL WEDESTEAD,** a representative from Novartis, discussed Leqvio. Leqvio or inclisiran was approved by the FDA late last year as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease who require additional lowering of LDL cholesterol or LDL-C. Leqvio is the first in class small interfering RNA LDL-C lowering agent which uses the body's natural process of RNA interference to prevent the production of PCSK9 protein, thereby resulting in increased clearance of LDL-C. The recommended dosage of Leqvio in combination with maximally tolerated statin therapy is 284 mg administered by healthcare professional as a single subcutaneous injection initially, again at three months, and then every six months. The effects of Leqvio in cardiovascular morbidity and mortality has not been determined. Cardiovascular disease remains the leading cause of death in the US with ASCVD being the main contributor to cardiovascular disease.

Despite the availability of numerous lipid-lowering therapies, effective and sustained LDL-C reduction remains a challenge with approximately 80% of patients with ASCVD unable to achieve guideline-recommended LDL-C goals on statins alone. In three pivotal phase III clinical trials, Leqvio resulted in an effective and sustained reduction in LDL-C of a 52% compared to placebo at month-17 in patients with heterozygous FH or clinical ASCVD and elevated LDL-C levels despite receiving maximally tolerated statin therapy. Leqvio was reported to be well tolerated with a safety profile comparable to placebo and with no dose adjustments required in patients with impaired renal or hepatic function. Leqvio has no known drug-drug interactions, has no contraindications, precautions or warnings in the FDA approved label. Leqvio is administered twice a year after initial dosage just in three months on top of maximally tolerated

statin therapy by an HCP, which can potentially overcome the suboptimal treatment adherence often seen with patient self-administration of lipid-lowering therapies.

In summary, Leqvio offers a highly effective and well-tolerated therapy for patients who require additional LDL-C lowering despite maximally tolerated statin therapy. With that, Novartis respectfully requests that Leqvio be added as preferred and unrestricted to the PDL.

Dr. Umang Patel gave the Magellan presentation on lipotropics other and PCSK9 inhibitors as [indiscernible 1:03:33] statins dealing the world of hyperlipidemia. The National Health and Nutrition Examination Survey reported that in 2015 to 2018, approximately 11% of adults had high total cholesterol and 18% had low HDL. Higher prevalence was in women compared to men. And many clinical trials have demonstrated that a high serum concentration of LDL and low levels of HDL are major risk factors for coronary heart disease.

According to the American Association of Clinical Endocrinologists and American College of Endocrinology 2020, although CV outcome trials with colesevelam and bempedoic acid are not published outcome trials, but statins and ezetimibe or a PCSK9 inhibitor suggests further reduction in LDL, though any combination of drugs would provide ASCVD benefit. Thereby, the 2020 AACE algorithm advocates for progression of therapy and to be in order to reach LDL targets. The 2019 approval of icosapent ethyl marks the first FDA approval for medication that lowers triglycerides and reduces ASCVD. As a reducer trial used for approval showed a triglyceride decrease of only 18%. The 2020 AACE/ACE algorithm states CV outcome benefit does not appear to be related to reduction in triglycerides.

In patients with hypertriglyceridemia who do not have established ASCVD or diabetes with two or more risk factors and are not at the triglyceride goal of less than 150 with a statin therapy, a fibrate omega-3 fatty acid or niacin can be considered. In order to decrease the potential for acute pancreatitis, all patients with severe hypertriglyceridemia should receive a fibrate prescription grade omega-3 fatty acid and/or niacin. According to the AHA in 2021, they published a scientific statement on physical activity as a crucial component in the first time treatment for increased blood pressure or cholesterol. The statement details mild-to-moderate risk patient groups are appropriate for lifestyle only treatment of increased cholesterol as well as description of the recommendations, usual effects and considerations for lifestyle management with physical activity. Guidance and resources are also provided for evaluating, prescribing, counseling and referring to assist in increased physical activity.

In December 2021, the FDA approved Leqvio, a small interfering RNA directed to PCSK9 mRNA indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hyperlipidemia or clinical ASCVD to require additional lowering of LDL. And the effects of Leqvio on CV morbidity and mortality has not yet been established. Warnings and precautions, common adverse reactions in clinical trials are injection site reaction, arthralgia, urinary tract infection, diarrhea, bronchitis, pain in extremity, and dyspnea. Recommended dosage in combination with maximally tolerated statin therapy is 284 mg as a single subcutaneous injection and then again at three months and then after that, every six months. As you can imagine, the formulation available is an injection in a single-dose prefilled syringe. Additional information about this medication, safety and efficacy has not been

established in pediatric patients. There is no dose adjustment necessary for your patients with mild, moderate and severe renal impairment. And there is no dose adjustment for mild or moderate hepatic impairment and has not been yet studied in patients with severe hepatic impairment.

In February 2022, REMS modified to update the format of the document to align with the recommendations in the format and content of a REMS document. Program materials were updated from findings of the competed QR around the deficit of prescriber knowledge on program requirements around liver monitoring as demonstrated in recent [indiscernible 1:07:56] KAB survey score.

Moving right along, now we have Praluent. In April 2021, FDA approved new indication as an adjunct to other LDL-lowering therapies in adult patients with homozygous familial hypercholesterolemia to reduce LDL. Again, no changes to any of the other indications. The dosage for the new indication here is 150 mg once every two weeks administered subcutaneously and no changes to formulations as well.

On the next slide here for Repatha, in October 2021, FDA approved Repatha to reduce LDL as an adjunct to diet and other LDL-lowering therapies in pediatric patients 10 years of age or older with heterozygous familial hypercholesterolemia and in adults and pediatric patients 10 years of age or older with homozygous familial hypercholesterolemia. Previously, it was only approved in pediatric patients 13 years of age or older, so it is expanded to 10 years of age. No changes to warnings and precautions. Dosing is stratified by indication and age and no changes to formulations here as well.

This was bundled together for clinical sake since there is overlap. However, this is one of those where there are two separate motions. So, I will present the lipotropics other for committee's vote and then I will present the PCSK9. The utilization report was reviewed and for lipotropic others, roughly 73% was in line with PDL. Dr. Phillips last year moved the drugs in the class were therapeutic alternatives. Seconded by Dr. Ryan and passed unanimously.

**DR. LILJEGREN MOVED THAT THE DRUGS IN THIS CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.**

***PCSK9 Inhibitors (Green Class)***

Dr. Umang Patel gave the Magellan presentation on PCSK9 Inhibitors. He stated that they were not in line with the PDL. And as you can see from the utilization reports, the Praluent and Repatha are non-preferred. Previous year's motion, Dr. Ryan moved the class effects which was seconded by Dr. Phillips and passed unanimously.

**DR. RYAN MOVED THE SAME MOTION AS LAST YEAR. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.**

**4-J.** ***Platelet Aggregation Inhibitors (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Platelet Aggregation Inhibitors. The utilization revealed that the utilization and the motion were roughly 99% is in line with the PDL. Previous motion, Dr. Ryan moved the drugs in the class were therapeutic alternatives to include at least clopidogrel. This was seconded by Dr. Doran-Atchison and it passed unanimously.

**DR. DORAN-ATCHISON MOVED FOR THE SAME MOTION AS LAST YEAR: SHE MOVED THE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST CLOPIDOGREL. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.**

**4-K.** ***Pulmonary Arterial Hypertension (Blue Class)***

**DEBBY DUNAWAY,** a representative from United Therapeutics Corporation, discussed Tyvaso. Tyvaso was first FDA approved in 2009 to improve exercise capacity in patients with pulmonary arterial hypertension or WHO Group 1. On March 31, 2021, Tyvaso became the first and only FDA approved therapy in the United States for the treatment of patients with pulmonary hypertension associated with interstitial lung disease for PH-ILD WHO Group 3 to improve exercise ability. Pulmonary hypertension is a frequent complication of ILD that is associated with poor prognosis, worsened functional status measured by exercise capacity, increased supplemental oxygen needs, decreased quality of life and reduced survival.

Typically, results from the INCREASE clinical trial that was recently published in the New England Journal of Medicine and served as the basis for FDA approval of Tyvaso in patients with PH-ILD. INCREASE was the largest and most comprehensive completed study of adult patients with PH-ILD with 326 patients randomized one to one to the Tyvaso or placebo. The primary efficacy endpoint was change in 6-minute walk distance at peak plasma Tyvaso exposure from baseline to week 16. Baseline participants were on average 66-1/2 years of age with an average 6-minute walk distance of 260 meters. The most common etiologies of PH-ILD or idiopathic interstitial pneumonia inclusive of idiopathic pulmonary fibrosis that was 45%, combined pulmonary fibrosis and emphysema 25%, and WHO Group 3 connective tissue disease 22%. For the primary endpoint at 16, patients who received Tyvaso had a placebo-corrected difference in peak 6-minute walk distance of 21 meters using Hodges-Lehmann estimate with a P value of 0.004. Benefits of Tyvaso were observed across key secondary endpoints including the 42% reduction in NT-proBNP when compared to placebo that was significant and a 39% reduction in the risk of a clinical worsening event when compared to placebo.

Additionally, patients who received Tyvaso experienced significantly fewer exacerbations of underlying lung disease. 26.4% of Tyvaso patients experienced exacerbation compared to 38.7% of placebo patients and that was significant. The safety profile of Tyvaso was consistent with previous studies and treatment-related adverse events were mild to moderate in intensity. Given the findings of INCREASE and lack of FDA-approved treatments in PH-ILD, we ask that you consider recommending that Tyvaso being the preferred on the Alaska Medicaid PDL.

Dr. Umang Patel gave the Magellan presentation on Pulmonary Arterial Hypertension. For

Pulmonary arterial hypertension, the prevalence varies substantially depending on the etiology and underlying conditions, estimated to be about 15 per million people. It is characterized by increase in pulmonary arterial pressure and secondary right ventricular failure defined as resting mean pulmonary arterial pressure (mPAP) as 25 mmHg or greater. Symptoms include dyspnea, dizziness, syncope, fatigue, peripheral edema, angina, palpitations, and other symptoms, all of which are exacerbated by exertion. It does not have a cure, and if left untreated, it is a life-threatening disease with poor prognosis. The management of pulmonary hypertension should be limited to specialized centers and clinicians who are experienced in evaluation of treatment of patients with pulmonary hypertension. Although the number of approved therapies has grown in the past years, the prognosis is still poor with approximately 50% mortality within the first five years after diagnosis.

There are many causes of pulmonary arterial hypertension including idiopathic or underlying disease and hereditary causes. Cellular change in the walls of the pulmonary arteries and it appears that mutations in the bone morphogenetic protein receptor type 2, gene plays a key role in the pathogenesis. Other etiologies include drugs and toxins, collagen vascular resistance, HIV, portal hypertension, chronic thromboembolism and congenital heart disease. World Health Organization classifies this into five groups. Group 1 now refers to pulmonary arterial hypertension, Group 2 refers to pulmonary hypertension due to left heart disease, Group 3 due to lung disease, Group 4 is due to blood clots in the lungs, and Group 5 is due to blood and other rare disorders. In 2013, clinical classifications were updated to provide the same classifications for adults and pediatric patients. In addition, the individual categorization of the persistent pulmonary hypertension with neonates was included. In April 2021, FDA approved Tyvaso for the treatment of pulmonary hypertension associated with interstitial lung disease to improve exercise ability. Effectiveness was established predominantly in patients with etiology of idiopathic interstitial pneumonia, inclusive of idiopathic pulmonary fibrosis, combined pulmonary fibrosis and emphysema, and WHO Group 3 connective tissue damage. Keep in mind, it already did have another indication for WHO Group 1 as you can see on bolded section. No changes to warnings, precautions, dosage or availability for this medication.

And in August 2021, FDA approved a 1800-mcg formulation of Uptravi as a lyophilized powder for a single-dose vial for reconstitution and dilution for IV administration twice daily over 80 minutes in patients with pulmonary arterial hypertension who are temporarily unable to take oral therapy. Again, no changes to indications, warning and dosage. It did come in a tablet form, and this is the new injection form for patients who are NPO.

The next and final slide, roughly 71% was in line with the PDL. Previous year's motion, Dr. Ryan moved the drugs were therapeutic alternatives to include one from each class plus one inhaled product. This was seconded by Ms. White and it passed unanimously.

Dr. Liljegren asked if the prescriptions go through utilization review when they are written.

Dr. Semling stated that the majority of them do because they are on prior authorization currently.

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

**4-L. Antifungals:** Oral Antifungals (Red Class); Topical Antifungals (Green Class)

***Oral Antifungals (Red Class)***

Dr. Patel gave the Magellan presentation on Antifungals. So, for oral antifungals, first being opportunistic fungal infections that are particularly likely to occur in patients during corticosteroid, immunosuppressant or antimetabolite therapy or in patients with AIDS, azomtemia, diabetes, bronchiectasis, emphysema, tuberculosis, lymphoma, leukemia or burns. Histoplasmosis, coccidiomycosis, Cryptococcus, blastomycosis, paracoccidioidomycosis, and sporotrichosis are systemic mycoses which can cause disease in both healthy and immunocompromised individuals. In contrast, mycoses caused by opportunistic fungi, such as Candida albicans, Aspergillus, Trichosporon, Torulopsis, Fusarium, Alternaria and Mucor are generally found in immunocompromised folks.

I kept the guidelines in here. Usually, I do not review guidelines that are over a year old. As you can see, this is six years old. But I just kept it here for reference for the committee for treatment guidelines.

On the next slide, we have vulvovaginal candidiasis. And this is caused by an overgrowth of Candida in the vagina and results in symptoms of vaginal itching and soreness, abnormal vaginal discharge, painful intercourse and dysuria. After bacterial and vaginal infections, VVC is the most common type of vaginal infection in the US causing an estimated 1.4 million outpatient visits. It is estimated that treatment with azole antifungals provides relief of symptoms and [indiscernible 1:26:42] cultures in 80% to 90% of patients with uncomplicated VVC. Again, IDSA guidelines here are six years old, so I am not going to review them, but here just for the committee's reference for treatment of VVC.

Onto the next slide. In June 2021, the FDA approved a new formulation of Noxafil, which is Noxafil PowderMix delayed release oral suspension indicated for the prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant recipients with graft versus host disease or those with hematologic malignancies with prolonged neutropenia from chemotherapy for the pediatric patients 2 years of age or older who weigh 40 kg or less.

As you can see, Noxafil does have other indications here, no changes there. The dosing is stratified by indication and formulations and it already comes in an injection form, delayed release tablet, and now, we have the new powder mix for delayed release oral suspension here.

And on the next slide, in June 2021, the FDA approved Brexafemme, a triterpenoid antifungal, indicated for the treatment of adults and postmenarchal pediatric females with vulvovaginal candidiasis. In terms of precautions and contraindications, there is a risk of fetal toxicity. It may

cause fetal harm based on animal studies and advise females of reproductive potential to use effective contraception during treatment. Dosages recommended for adults and postmenarchal pediatric females are 300 mg twice daily or one in a day for a total treatment dosage of 600 mg. Again, prior to initiating treatment, verify pregnancy statuses in females that are of reproductive age. And the formulation available is 150-mg tablet.

The utilization report was reviewed and stated that roughly 90% is in line with PDL. Previous year's motion, Dr. Ryan moved the drugs in class were therapeutic alternatives to include at least one fluconazole tablet, one oral terbinafine preparation and one pediatric preparation and this was seconded by Dr. Doran-Atchison and it passed unanimously.

**DR. LILJEGREN MOVED THE SAME MOTION AS LAST YEAR. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.**

***Topical Antifungals (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Topical Antifungals. The utilization report was reviewed and was roughly 97% is in line with the PDL. Previous year, Dr. Ryan moved the drugs in the class were therapeutic alternatives to include at least one solution in shampoo, one topical cream or ointment, which was seconded by Dr. Phillips and passed unanimously.

**DR. RYAN MOVED TO RENEW THE MOTION. SECONDED BY DR. LILJEGREN. THE MOTION PASSED UNANIMOUSLY.**

**4-M.** ***Influenza Antivirals (Blue Class)***

Dr. Umang Patel gave the Magellan presentation on Influenza/Antivirals. Influenza is a common illness that affects most people at least once in their lifetime. It is an uncomplicated illness, typically resolves after three to seven days, often self-limiting. Patients at higher risk for influenza complications are patients younger than 2, over 65 years of age, immunocompromised, pregnant, postpartum pediatric patients that are on long-term aspirin therapy, Native Americans, Alaskan Native, extremely obese patients; nursing home or other chronic care facility patients and patients with specific chronic disease states.

Influenza vaccination is a primary method of preventing influenza. Inactivated influenza vaccines are available in quadrivalent and trivalent formulations while recombinant influenza vaccines and LAIV4 are available in quadrivalent formulations. There is a high-dose inactivated influenza vaccine and adjuvanted inactivated influenza vaccine available in trivalent formulations. For the 2021/2022 season, inactivated influenza vaccines, recombinant and live attenuated influenza vaccines are available. The virus strains included in this cycle contain derivatives from the following list of influenza strains. The cell culture-based inactivated and recombinant influenza vaccine contains derivatives from the following list of strains as well.

On the next slide here, according to the CDC, in 2021, there are three FDA approved neuraminidase inhibitors, antiviral drugs that are recommended; Tamiflu, Relenza and Rapivab. The fourth recommended product is a cap-dependent endonuclease inhibitor, which is Xofluza.

Amantadine is not recommended for the use in the US due to resistance to these drugs by many, influenza A antivirus. Empiric antiviral treatment without waiting for laboratory confirmation is recommended as early as possible for any patient with confirmed or suspected influenza who has severe complicated or progressive illnesses, is hospitalized, or is at high risk for influenza complication.

In addition, empiric antiviral treatment of non-high-risk outpatients with suspected influenza can be started based on clinical judgment without an office visit. According to the CDC, oseltamivir is recommended antiviral for patients with severe complicated or progressive illness or who are hospitalized. There is institution data for Relenza, Rapivab or Xofluza in patients with severe influenza and a co-infection with influenza A or B virus and COVID, SARS-CoV-2 can occur and should be considered particularly in hospitalized patients with severe respiratory diseases.

In October 2021, Xofluza formulation updated to include a new 80-mg tablet strength and the 40-mg package as a one tablet single dose. Previously, it was a two-tablet presentation. And now, the 20-mg tablet strength is removed. Again, no changes to the indications, warnings or dosage. We still have the tablet strengths.

The utilization report was reviewed and roughly 97% of the utilization is in line with the PDL. Previous year's motion, Dr. Ryan moved the drugs in the class were therapeutic alternatives to include oseltamivir. Seconded by Dr. Doran-Atchison and passed unanimously.

**DR. RYAN MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE OSELTAMIVIR. SECONDED BY DR. BEGAY-BRUNO. THE MOTION PASSED UNANIMOUSLY.**

**4-N.** ***Fluoroquinolones (Green Class)***

Dr. Umang Patel gave the Magellan presentation on fluoroquinolones. The utilization was reviewed and they were almost 99% in line with PDL. Previous motion, Mr. Greer moved the class effect which was seconded by Dr. Phillips and passed unanimously.

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

**4-O.** ***Hepatitis B Agents (Green Class)***

Dr. Umang Patel gave the Magellan presentation on hepatitis D agents. The utilization was reviewed and about 90% was in line with PDL. Previous motion, Mr. Greer moved the drugs in class were therapeutic alternatives, which was seconded by Dr. Carlson and it passed unanimously.

**DR. RYAN MOVED THE SAME MOTION. SECONDED BY DR. LILJEGREN. THE MOTION PASSED UNANIMOUSLY AGAIN.**

**4-P.** ***Hepatitis C (Blue Class)***

**CHARLIE LOVAN,** a representative from AbbVie Medical Affairs stated that he did not have any specific testimony to give, but just wanted everyone to know he was on the call and they had any questions, he could answer them. He also stated that Margaret Olmon had retired.

**STUART OBERSHADA** gave a presentation on Epclusa or SOF/VEL Ag, which is the authorized generic for Epclusa for the treatment of chronic hepatitis C. I would also like to request that the Alaska Medicaid add SOF/VEL to their PDL to allow providers and patients' choice between the two current pan-genotypic HIG therapies.

Epclusa or SOF/VEL is the only one pill, once daily pan-genotypic, pan-fibrotic and importantly, PI-free 12-week regimen for all patients without food restrictions. Characteristic of food restrictions is important in a vulnerable Medicaid population where food security and insecurity is not an uncommon issue. I would like to highlight the PI-free characteristic. Not containing a PI allows for safety of using SOL/VEL in all stages of liver disease, even decompensation.

As you are probably aware, PI-based therapies hold a FDA safety warning for worsening liver function or even acute liver failure when you used in decompensation. It is important that when using a PI in cirrhotic patients, provider is trained and able to detect and monitor for decompensating events. In a virtual and rural environment such as Alaska, this can be sometimes a challenge. So, with most HIG therapy moving to nursing home care and recognizing that it is the case with Alaska, it is important to have both the safest and effective therapies available without restriction.

Using an EASL published and actually simplified HCV treatment algorithm, which I shared with Dr. Semling previously that includes both GLE/PIB, Mavyret and Epclusa, SOF/Vel as essentially equal with the limitations for G/P or Mavyret being more drug interactions than as already mentioned decompensation. They also point out the ease of HCV therapy and need for simplified treatment removing barriers such as [indiscernible 1:45:00] PAs to ensure we meet the national HCV elimination targets. COVID and increasing substance abuse has impacted the national HCV elimination efforts and there is a need to ramp up efforts and remove barriers and allow providers to make the best and effective choice for HCV therapy between the available agents. So, I would again ask and respectively ask based on the safety and efficacy of SOF/VEL to just be an equal option on your PDL to the current G/P choice.

Dr. Umang Patel gave the Magellan presentation on Hepatitis C. Hep C infection is the most common chronic blood-borne infection in the United States. In approximately 15% to 25% of patients who become infected with hep C, the virus is eliminated during the acute phase of the infection with T-cell mediated antiviral mechanisms. However, in the other 75% to 85%, the hep C virus persists [indiscernible 1:46:46]. It affects approximately 23,000 to 46,000 children in the US. Approximately 2.7 million people in the US are chronically infected. Although it is estimated nearly 75% of these people may be unaware of their infections due to the insidious progression of [indiscernible 1:47:03] that accounts for 40% of chronic liver disease in the US. In patients with chronic hep C infection followed for 20 years, the disease progression to cirrhosis occurs in 20% to 25%. Of those who develop cirrhosis, approximately 30% will develop end-stage liver disease over the next 10 years and 1% to 2% will develop hepatocellular

carcinoma. It is the most common reason for liver transplantation and results in an estimated 8000 to 10,000 deaths per year. The most common risk factor with hep C infection is injection drug use, which accounts for at least 60% of acute hep C infections. Other modes of transmission include mother to infant, receiving a blood or organ donation prior to 1992, occupational exposure, chronic hemodialysis and contaminated devices shared for non-injection drugs [indiscernible 1:47:55]. Sexual transmission also occurs, but generally seems to be inefficient except among HIV-infected men, who have unprotected sex with them. Other risk factors include incarceration and receiving a tattoo in an unregulated setting. It is estimated that 59% of incarcerated persons in North America are anti-hep C positive.

On the next slide here, hep C viral genotype was the most important factor in selecting the optimal treatment planning, including drug selection dose and duration of treatment. Are of 6 genotypes and more than 50 subtypes and distribution of genotypes varies across the world. Type 1 is the most common and accounts for 70% to 75%. Amongst the Americans, the frequency of genotypes 1 is even higher at an estimated 90%. And in the US, genotype 1A and 1B represent about 25% and 25% respectively. Genotypes 2 and 3 account for the majority of the other approximate 25% to 30% of infections in the US. Type 4 predominates in Egypt. Type 5 is localized to South Africa, and type 6 is to Hong Kong and Southeast Asia.

On the next side here, the US Preventative Services Task Force in 2020 expanded the population for a one time screening in asymptomatic adults 18 to 79 years of age. Similarly, joint guidelines from the AASLD and the IDSA recommended one-time routine opt-out testing for anyone 18 years of age or older. The CDC in 2020 recommended that in areas where hep C infection rate is over 0.1%, all adults should be screened at least once for hep C infection and that all pregnant women should be screened during each pregnancy.

On the next slide, in June 2021, FDA approved use of Mavyret in patients as young as 3 years old who have hep C genotype only 6 without cirrhosis or compensated or with compensated cirrhosis or with hep C genotype 1 who had prior treatment with a hep C NS5A inhibitor or NS3/4A protease inhibitor [indiscernible 1:50:11]. Previously, this was only indicated in patients 12 years of age or older. No changes to any of the precautions, contraindications, dosing, or formulations here.

On the next slide, in June 2021, there were two updates to Epclusa. First being an expanded indication for treatment of hep C, genotypes 1 through 6, in patients 3 years of age or older without cirrhosis or with compensated cirrhosis or with decompensated cirrhosis used in combination with ribavirin. Previously, this was only for patients 6 years of age or older. And the FDA approved two strengths of oral pellets containing 250 mg and 150 and 37.5 mg of the restricted medication. No changes to the precautions, dosage. Again, just expanded age for indication and new formulation to go with. And lastly, in December 2021, FDA approved expanded indication to include pediatric patient 12 years of age or older or weighing 30 kg or more for the treatment of chronic hep C genotype 1 or 4 infection. Again, no changes to precautions, dosage, or formulation here.

On the next and final slide, we will get utilization where roughly 97% is in line with PDL. Previous year's motion, Dr. Ryan moved the drugs were therapeutic alternatives, which was seconded by Dr. Phillips and it passed unanimously.

**DR. DORAN-ATCHISON MOVED THE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.**

**4-Q. Otic *Antibiotics (Green Class)***

Dr. Umang Patel gave the Magellan presentation on otic antibiotics. The utilization report revealed that utilization was 55% was in line with PDL. Previous motion, Dr. Ryan moved the drugs in the class were therapeutic alternatives to include one at least glucocorticoid combination. Seconded by Dr. Carlson and passed unanimously. And I believe one of the questions may be a utilization and that is primarily due to a specific generic and authorized generic or as ciprofloxacin/dexamethasone.

**DR. RYAN MOVED FOR THE SAME MOTION AS LAST YEAR. SECONDED BY DR. RILEY. THE MOTION PASSED UNANIMOUSLY.**

**4-R. *Benign Prostatic Hyperplasia (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Benign Prostatic Hyperplasia. The utilization report revealed that roughly 97% is in line with the PDL. Previous motion, Dr. Ryan moved the drugs in the class were therapeutic alternatives to include one alpha blocker, one androgen hormone inhibitor, which was seconded by Dr. Doran-Atchison and passed unanimously.

**DR. RYAN MOVED FOR THE SAME MOTION AS LAST YEAR. SECONDED BY DR. LILJEGREN. THE MOTION PASSED UNANIMOUSLY.**

**4-S. *Overactive Bladder: Bladder Relaxant Preparations (Blue Class)***

Dr. Umang Patel gave the Magellan presentation on overactive bladder. Overactive bladder is a chronic and debilitating syndrome that is characterized by urinary urgency with or without urge incontinence, usually in combination with urinary frequency, eight or more voiding episodes for 24 hours and nocturia, which is awakening one or more times per night to void. Prevalent in roughly 16% of men and 17% of women and it is 20% in those over 60 years of age. According to the UAU, the first line of therapy is behavioral. Second line is oral antimuscarinics, including darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine and trospium. And surgery is reserved for patients with severe refractory symptoms or who are not candidates for oral therapy.

Our next slide here, in April 2021, FDA approved Myrbetriq in the treatment of neurogenic detrusor overactivity in pediatric patients 3 years of age or older. Previously, it was only approved in adults. In tandem, they also approved a new dosage form for use in this younger population, which were granules and extended release oral suspension with the strength of 8 mg/mL following reconstitution. And no changes to any of the other indications or precautions.

Dosing is stratified by indication and age, and there was just an expanded indication from the younger age and the new formulation of granules here.

In June 2021, FDA approved Toviaz for the treatment of neurogenic detrusor overactivity in pediatric patients 6 years of age and older and 25 kg or more. Previously, it was only in adults. Similar to the previous, had no changes to the precautions or other indications. Dosing, as you can see, pediatric patients weighing greater than 25 kg up to 35, doses 4 mg once daily, and it can be increased to 8 mg. And for pediatric patients weighing greater than 35, recommended starting doses 4 mg once daily, and after one week, it can be increased to 8 mg. No other changes to formulations for this medication here. And moving to the utilization, you can see roughly 75% in line with PDL. Dr. Ryan moved the drugs in this class were therapeutic alternatives which was seconded by Dr. Carlson and it passed unanimously.

**DR. RYAN MADE THE MOTION THAT THE DRUGS IN THIS CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. LILJEGREN. THE MOTION PASSED UNANIMOUSLY.**

**4-T.** ***Bacterial Vaginosis: Vaginal Antibiotics (Blue Class)***

Dr. Umang Patel gave the Magellan presentation on Bacterial Vaginosis. Bacterial vaginosis is a polymicrobial clinical syndrome resulting from the replacement of Lactobacillus with anaerobic bacteria such as G vaginalis, Ureaplasma, Mycoplasma and numerous fastidious and anaerobes. Symptoms include vaginal discharge, pain, itching or malodor and can be asymptomatic. It is associated with STDs and other female genital tract infections. A diagnosis requires three or four Amsel criteria, abnormal gray discharge, vaginal pH over 4.5, a positive amine test or over 20% of the epithelial cells being clue cells.

Nugent score is considered the standard to diagnosing bacterial vaginosis. Culture and sensitivity testing of bacteria are not routinely performed. Bacterial vaginosis may recur in up to 30% of women within three months after treatment. According to the CDC, in 2021, they recommend regimens after the treatment of bacterial vaginosis in non-pregnant women to include oral metronidazole, metronidazole gel and clindamycin 2% cream. Topical clindamycin prescription should be used in pregnancy only if clearly indicated. Alternative regimens include oral clindamycin, clindamycin ovules, single-dose oral Secnidazole, oral tinidazole and oral metronidazole 2 g as a single dose has a low efficacy for bacterial vaginosis and is no longer recommended as an alternative regimen by the CDC. Additionally, Flagyl ER and Nuvessa as a single dose intravaginally and clindamycin 2% cream as a single dose intravaginally are FDA approved treatments for bacterial vaginosis.

In December 2021, FDA approved a new formulation of Xaciato which is a lincosamide antibacterial indicated for the treatment of bacterial vaginosis in female patients 12 years of age or older. No changes to any of the existing contraindication warnings, dosage or the formulation here. There is a vaginal gel 2% now in a 25-g tube as well.

The utilization report showed that these drugs were roughly 90% in line with PDL. Previous year's motion, Dr. Ryan moved the drugs in the class were therapeutic alternatives, which was second by Mr. Greer and passed unanimously.

**DR. RYAN MOVED FOR THE SAME MOTION AS LAST YEAR. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.**

**5. Review Minutes from January 2022**

Dr. Semling stated that a different company was working on transcribing the minutes. He sent them the last two meetings worth of recordings, but they have not gotten anything back yet. So, when he sends this, he will follow up on the other two and hopefully by September they will have the last three meetings worth of minutes.

**6. Other Business**

There was no other business.

**7. End of public meeting**

**8. Comments from Committee Members or Chair**

**9. Adjourn**

**AS NO ONE HAD ANYTHING ELSE TO SHARE, MR. RILEY WISHED EVERYONE A GOOD SUMMER AND STATED HE HOPED THE COVID OUTLOOK WAS GOOD BETWEEN NOW AND SEPTEMBER. WITHOUT OBJECTION, THE MEETING WAS ADJOURNED.**