# ALASKA MEDICAID
# PHARMACY AND THERAPEUTICS COMMITTEE
# (ZOOM MEETING)

**Location of Meeting**
**Zoom Meeting in Anchorage, Alaska**

## MINUTES OF MEETING
**April 16, 2021**
**8:00 a.m.**

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

**Committee Members Absent:**
Jenna Hiestand, M.D., Chairman (excused)
Diane Liljegren, R.Ph. (excused)

**Others Present:**
Erin Narus, PharmD, R.Ph., State of Alaska
Charles Semling, PharmD, R.Ph.
Umang Patel, Pharm D, R.Ph., Magellan Medical Administration
Ryan Ruggles, PharmD, Magellan Medical Administration
Sarah Martinez, Staff
Scott Andersen, Regenersen
Lois Perry
Betty Caudle, Kron Associates

### 1. Call to Order – Chair

Mr. Riley called the meeting to order at 8:00 a.m.

### 2. Roll Call

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

## 3. Public Comments - Local Public/Health Practitioners

**BILL ROBIE**, senior manager of State Government Relations for the National Hemophilia Foundation (NHF), said NHF has concerns about placing Factor and non-Factor products on a preferred drug lists and appreciates. They appreciate the fact that Alaska decided to include all products as preferred and encourages this going forward as it is important for their patients to have access to all FDA-approved therapies.

## 4. Class Review, Discussion & Vote

**4-A. Single Class Review:** Hereditary Angioedema (Red); Hemophilia (Red)

***Public Comments for Hereditary Angioedema (Red)***

**LOIS PERRY,** a representative of U.S. HAE and a patient, discussed hereditary angioedema (HAE). HAE is a disabling and potentially fatal disorder that causes attacks of massive disfiguring swelling in various body parts that can last from three to five days. From personal experience, she said swelling that occurs in hands, face, feet, and abdomen is extremely painful and debilitating. The biggest fear is laryngeal swelling because it can cause death by suffocation. Research have revealed that inadequately treated HAE causes severe disability with a 30% mortality rate. The HAE's Medical Advisory Board has published recommendations on the management of HAE. MAB has recently crafted a new document, the U.S. HAE Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema, that was published this fall. We urged Alaska Medicaid to allow access to all FDA-approved HAE medications so physicians can determine the optimum treatment. We advocate for the availability of effective on-demand acute therapy for all patients, early treatment to prevent attacks, treatment of attacks irrespective of the site of swelling, and incorporating long-term prophylaxis based on individualized decision-making between the patient and physician. We urge Alaska Medicaid to consider the gravitation towards long-term HAE prophylaxis, fueled by the emergence of novel therapies that have been shown to normalize the lives of all HAE patients. We request that you allow access to all therapies.

Dr. Umang Patel gave the Magellan presentation for Hereditary Angioedema. It is a rare dominant, autosomal genetic disorder that affects about 6,000 individuals in the United States. It is characterized by recurrent episodes of nonpruritic, nonpitting, subcutaneous or submucosal edema involving the skin or mucosal tissues of the upper respiratory and gastrointestinal (GI) tracts. Although swelling can resolve spontaneously in several days without treatment, laryngeal edema may be fatal, and the pain of GI attacks can be incapacitating. Symptoms can begin as early as 2 years of age and persist throughout life with unpredictable severity and frequency. It is thought that minor trauma and stress can lead to an attack; however, many attacks can occur without any apparent trigger. There are two types of C1-INH deficient HAE. Type I is the most common where the body does not produce enough C1-INH. It occurs in about 85% of patients with the condition. Type II is characterized by the presence of normal or high levels of a dysfunctional C1-INH. HAE prophylaxis is needed to reduce potential edema caused by a stressor or a procedure likely to precipitate an attack or decrease the number of and severity of angioedema attacks.

Guidelines from the U.S. Hereditary Angioedema Association was reviewed.

In October 2020, the indication for Haegarda was expanded to include pediatric patients 6 years of age and older for routine prophylaxis to prevent HAE attacks. Warnings, doses, and availability remain the same.

In December 2020, the FDA approved Orladeyo, a plasma kallikrein inhibitor indicated for prophylaxis to prevent attacks of HAE in adults and pediatric patients 12 years of age and older. It should not be used for treatment of acute HAE attacks. An increase in QT prolongation can occur and it is dose specific. Dose adjustments are needed in patients with moderate to severe hepatic impairment, chronic administration of P-gp or BCRP inhibitors, or persistent gastrointestinal reactions. Dosing recommendations were reviewed. It is available as a capsule.

The utilization report was reviewed and 100% of prescriptions were for preferred products. At the last review, a motion of therapeutic alternative to include at least one prophylaxis and one treatment formulation passed unanimously.

**DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE PROPHYLAXIS TREATMENT AND ONE ACUTE TREATMENT INTERVENTION. SECONDED BY MR. GREEAR. THE MOTION PASSED UNANIMOUSLY.**

***Public Comments for Hemophilia (Red Class)***

**JAMIE PARTRIDGE**, a representative of Bayer Pharmaceuticals, discussed Jivi, an extended half-life treatment for hemophilia A. It is indicated for prevention of bleed episodes, on-demand controlled bleeding, and preoperative management of bleeding in treatment experienced patients. Jivi is not for use in patients less than 12 years of age. Hemophilia A, characterized by a deficiency in clotting Factor VIII, is a rare X-linked bleeding disorder. Hemophilia presents mild, moderate, and severe forms based on Factor VIII levels and clinical presentation of bleeding patterns. Treatment guidelines recommend prophylaxis therapy. About 70% of patients with hemophilia in the United States receives care in federally funded hemophilia treatment centers. In Alaska, the Bleeding Disorder Center of Alaska provides comprehensive care for patients. The primary goal in treatment is to provide patients with the missing clotting whey protein to prevent and treat bleeding episodes. The high frequency of these intravenous infusions can be a significant burden for patients and their families. Medications such as Jivi plays a key role in allowing for less frequent infusions and decreasing the burden on both caregivers and patients. Jivi is the only extended half-life Factor VIII product with a unique stepwise regiment that allows for twice-weekly dosing or every five-day dosing, with the additional potential for fewer or more frequent infusions. Accesses to treatments like Jivi is critical to optimize hemophilia care. Several studies and their outcomes were reviewed. Adverse events include headache, cough, nausea, and fever. We request that Jivi be included on the Alaska PDL.

**KYLE DOWNEY**, a representative of Genentech, discussed Hemlibra. It is indicated for both adults and pediatric patients as a subcutaneous injection. Written testimony has been submitted. It is dosed weekly, every two weeks, or every four weeks. It demonstrated an 90% reduction in annualized bleed rates in clinical trials. Since the last review, there have not been any new safety signals, although the

package information has been updated to list a new warning. We request that Hemlibra remain on the Alaska PDL.

Dr. Umang Patel gave the Magellan presentation hemophilia. It is a rare, inherited bleeding disorder where the blood does not clot properly due to an absence of one of the coagulation factors present in normal blood. Hemophilia is identified as an X-linked congenital bleeding disorder that has an estimated frequency of 1 in 5,000 to 10,000 births. It typically affects makes 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 is about 400,000 people. It is estimated there are about 17,000 to 20,000 people in the United States afflicted with hemophilia. There are two main types of hemophilia. Type A is also known as Factor VIII deficiency, classical hemophilia, or standard hemophilia. It is far more common than hemophilia B with hemophilia A presenting in 80 to 85% of all hemophilia patients. Patients with type A hemophilia exhibit low or missing levels of clotting Factor VIII. Type B is also known as Factor IX deficiency or Christmas disease. Those with type B have low or missing levels of clotting Factor IX. Hemophilia can also encompass several other rare deficiencies including Factor I, fibrinogen deficiency; Factor II, prothrombin deficiency; Factor V, proconvertin deficiency; Factor X, Stuart-Prowar deficiency; Factor XI, hemophilia C or plasma thromboplastin deficiency; Factor XII, Hageman factor deficiency; and Factor XIII, fibrin stabilizing deficiency. These disorders are far less common than hemophilia A and B, exemplified by Factor XIII deficiency which is estimated to occur in 1 to 5 million persons.

Von Willebrand disease is similar to hemophilia A. This is a group of inherited bleeding disorder related to the absence or defects of von Willebrand Factor, a lotting protein, needed to achieve hemostasis. Von Willebrand factor binds to Factor VIII and platelets to generate a platelet plug during the clotting process. This disease leads to bleeding from impaired platelet adhesion and aggregation, which may be accompanied by reduced levels of Factor VIII. The prevalence of this disease is estimated to affect between 1 in 100 to 10,000 people, and it is equal in males and females. There are three major subtypes. Type I is a partial quantitative deficiency and accounts for 75% of all patients. Type 2 is a more pronounced qualitative deficiency and comprises almost all the remaining 25% of patients; and it is further divided into four variants of 2A, 2B, 2M and 2N on the basis of identified phenotypes. Type 3 is characterized as a complete von Willebrand deficiency and rarely occurs.

Treatment guidelines from the World Federation of Hemophilia were reviewed.

In April 2020, the FDA approved Sevenfact, a recombinant coagulation factor VIIa-jncw, for the treatment and control of bleeding episodes occurring in adults and adolescents 12 years of age and older with hemophilia A or B with inhibitor. It is not indicated for the treatment of congenital Factor VII deficiency. Serious arterial and venous thrombotic events may occur following administration. Physicians should discuss the risks and explain the signs and symptoms of thrombotic and thromboembolic events to patients who will receive treatment, and monitor patients for signs or symptoms of activation of the coagulation system and for thrombosis. Dosing recommendations were reviewed. It is available as a lyophilized powder in single-use vials.

In July 2020, the FDA approved a new indication for Benefix for routine prophylaxis to reduce the frequency of bleeding episodes in adults and children with hemophilia B. Warnings, precautions, dosage, and availability remain the same.

In August 2020, Xyntha received an expanded indication for the routine prophylaxis to reduce the frequency of bleeding episodes in children and adults with hemophilia A. Warnings, precautions, dosage, and availability remain the same.

In October 2020, the FDA approved Ixinity for patients 12 years of age and older with hemophilia B for routine prophylaxis to reduce the frequency of bleeding episodes. Previously, it was only approved in this population for on-demand treatment and control of bleeding episodes and perioperative management. Warnings, precautions, dosage, and availability remain the same.

The utilization report was reviewed and 100% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

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

**4-B. Cardiovascular:** ACE Inhibitor & Renin Inhibitors (Blue); Angiotensin Receptor Blockers (ARBs) (Green); Angiotensin Modulator/CCB Combinations (Green); Antianginal and Anti-ischemic Agents (Green); Anticoagulants (Blue); Beta-Blockers (Green); Calcium Channel Blockers (Blue); Erythropoiesis Stimulating Agents (Blue); Lipotropics, Other (Red); PCSK-9 Inhibitors (Green); Platelet Aggregation Inhibitors (Blue); Pulmonary Arterial Hypertension (Blue)

***Public Comments for Cardiovascular: ACE Inhibitors & Renin Inhibitors (Blue Class)***
***Cardiovascular: Angiotensin Receptor Blockers (ARBs) (Green Class)***
***Angiotensin Modulator/CCB Combinations (Green Class)***

There were no public comments for Cardiovascular: ACE Inhibitors & Renin Inhibitors.

Dr. Umang Patel gave the Magellan gave a combined presentation on Cardiovascular: ACE Inhibitors & Renin Inhibitors, Angiotensin Receptor Blockers (ARBs), and Angiotensin Modulator/CCB Combinations. Hypertension affects approximately 108 million adults in the United States who have high blood pressure along with 1 of 3 American adults with prehypertension. The highest prevalence is among African American men and women. Approximately 54% of African American men and women have high blood pressure compared to 46% of white men and women, 39% of non-Hispanic Asians, and 36% of Hispanics. It is estimated that hypertension is controlled in only 24% of patients.

Treatment guidelines from the American Heart Association, the Kidney Disease: Improving Global Outcomes, and the U.S. Preventative Task Force were reviewed.

In February 2021, the FDA approved an expanded indication for Entresto to reduce the risk of CV death and hospitalization for HF in adults with chronic HF, and benefits are clearly evident in patients

with LVEF below normal. Previously, this indication read to reduce the risk of CV death and hospitalization for HF in patients with chronic HF, specifying in NYHA Class II-IV and reduced EF. Warnings, precautions, dosage, and availability remain the same.

The utilization report was reviewed and 89.1% prescriptions for ACE inhibitors and renin inhibitors; angiotensin receptor blockers (ARBs) were for preferred products; and 89.1% of prescriptions for angiotensin modulator/CCB combos were for preferred products. At the last review, a motion for all three subgroups as therapeutic alternatives to include at least one ACE-Inhibitor, ARB, and ARNI agent passed unanimously.

**MR. GREEAR MOVED THE DRUGS IN THE THREE SUBGROUPS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE ACE-INHIBITOR, ARB AND ARNI AGENT. SECONDED BY DR. CARSON. THE MOTION PASSED UNANIMOUSLY.**

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

Dr. Umang Patel gave the Magellan presentation on Cardiovascular: Antianginal and Anti-ischemic Agents.

The utilization report was reviewed and 80.6% of prescriptions were for preferred products. At the last review, a motion for class effect passed unanimously.

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

***Public Comments for Cardiovascular: Anticoagulants (Blue Class)***

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Cardiovascular: Anticoagulants. Venous Thromboembolism (VTE) manifests as deep vein thrombosis (DVT) and pulmonary embolism (PE) and is a major consequence of various surgical procedures and medical conditions. DVT occurs when a thrombus composed of cellular material bound together with fibrin strands forms in the deep venous portion of the extremities, most commonly the legs. The exact number of patients impacted by DVT and PE is unknown; however, it is estimated those conditions affect between 300,000 and 600,000 people in the U.S. every year. If left untreated, approximately 30% of patients who develop PE will die within the first few hours of the event. 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 for patients at high risk for thrombosis.

Approximately 14 million Americans have Coronary Artery Disease (CAD) and 8.5 million over 40 years of age have Peripheral Artery Disease (PAD). Prevention and treatment of atherosclerosis focus on modifiable risk factors. Therapy includes lifestyle changes and the medical treatment of hypertension, hyperlipidemia, and diabetes mellitus. Antiplatelet medications such as aspirin,

clopidogrel, prasugrel, ticagrelor, and vorapaxar are indicated for reduction of thrombotic CV events in patients with established CAD or PAD.

Atrial Fibrillation (AF) is a common arrhythmia ranging in prevalence from 2% in patients under 65 years of age to 9% for those 65 years of age and older. The prevalence is higher in men than in women and it increases with age. More than a third of patients with AF are 80 years of age and older. Patients with AF can have a reduction in cardiac output resulting in pooling of blood in the heart, atrial thrombus formation, and potential systemic embolization. Ischemic stroke is the most frequent clinical manifestation of AF associated embolization. AF increases the risk of stroke five-fold. In patients with AF, ACCP recommends measuring thromboembolism risk using the $CHA_2DS$-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 score ranges from 0 to 9, with higher numbers indicating more risk.

Treatment guidelines from the American College of Cardiology and the American Heart Association/American College of Cardiology were reviewed.

Bevyxxa was discontinued in May 2020 in 40 milligram and 80 milligram strengths.

Warfarin was discontinued in June 2020 in all strengths of Coumadin due to unexpected manufacturing issues that could not be resolved expeditiously.

In February 2021, Apotex voluntarily recalled two batches of Enoxaparin Sodium injection. Some syringe barrels contain 150 milligram/milliliter markings instead of 100 milligram/milliliter markings 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 of a dose could lead to bleeding complications. No adverse events have been reported.

The utilization report was reviewed and 99.7% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include one oral agent, one injectable agent, one DOAC that can be used for PE and CV prophylaxis, and Warfarin passed unanimously.

**MR. GREEAR MOVED THE PRODUCTS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE INJECTABLE, ONE DOAC THAT CAN BE USE FOR PE AND CV PROPHYLAXIS, AND WARFARIN. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.**

Dr. Ryan joined the meeting.

***Cardiovascular: Beta-Blockers (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Cardiovascular: Beta-Blockers.

The utilization report was reviewed and 88.6% of prescriptions were for preferred products. At the last review, a motion for class effect to include both Carvedilol and Metoprolol Succinate passed unanimously.

**DR. RYAN MOVED A CLASS EFFECT TO INCLUDE BOTH CARVEDILOL AND METOPROLOL SUCCINATE. SECONDED BY MR. RILEY. THE MOTION PASSED UNANIMOUSLY.**

***Public Comments for Cardiovascular: Calcium Channel Blockers (Blue Class)***

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Cardiovascular: Calcium Channel Blockers. The background was previously reviewed with ACE-Inhibitors. In December 2020, the FDA approved a new formulation of Nymalize of 6 milligrams/milliliters and a 5-milliliter and 10-milliliter unit-dose prefilled syringes. Previously, it was only 3 milligram/milliliter concentration. The indications, warnings, precautions, and dosing remain the same.

The utilization report was reviewed and 98.7% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include at least one short-acting agent, one extended-release agent, and one non-dihydropyridine agent passed unanimously.

**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. CARLSON. THE MOTION PASSED UNANIMOUSLY.**

***Public Comments for Cardiovascular: Erythropoiesis Stimulating Agents (Blue Class)***

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Cardiovascular: Erythropoiesis Stimulating Agents. Anemia is a frequent complication affecting over 3 million Americans. It is associated with serious diseases such as chronic kidney disease, diabetes, h eat disease, and cancer, as well as chronic inflammatory conditions like rheumatoid arthritis or inflammatory bowel disease. Erythropoietin is a glycoprotein produced in the kidneys that stimulates RBC production from bone marrow. It acts on the erythroid progenitor cells in the bone marrow to cause late differentiation and maturity of the RBCs. Endogenous production of erythropoietin by the kidney is normally regulated by the level of tissue oxygenation. Hypoxia and anemia generally increase the production of erythropoietin, which in turn stimulates erythropoiesis. In normal subjects, plasma erythropoietin levels range from 0.01 to 0.03 units/milliliter and may increase 100- to 1,000-fold during hypoxia or anemia. However, patients with CKD have impaired production of erythropoietin, which is the primary cause of their anemia.

Beta thalassemia is a rare inherited blood disorder marked by the reduction of functional hemoglobin levels. It has an incidence of approximately 1 in 100,000 individuals in the general population. There are three subtypes that are characterized by the severity of symptoms: minor, intermediate, and major. Individuals with beta thalassemia major require regular blood transfusion, as often as every two to four weeks and are dependent on medical care for survival. Treatment is highly dependent on type, progression and severity of disease, and the presence or absence of certain symptoms. Treatment

options may include regular blood transfusions, chelation therapy, folic acid treatment, removal of the spleen and/or gallbladder, and possibly bone marrow transplant. Reblozyl was the first FDA-approved erythroid maturation agent, which reduces patient transfusion burden by regulating late-stage RBC maturation. It is approved for the treatment of anemia in adult patients with beta thalassemia who require red blood cell transfusions.

In April 2020, the FDA approved a new indication for Reblozyl for the treatment of anemia failing an erythropoiesis stimulating agent and requiring two or more red blood cell units over eight weeks in adult patients with low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts or with myelodysplastic/myeloproliferate neoplasms with ring sideroblasts and thrombocytosis. For thrombosis/thromboembolism, there is an increased risk in patients with beta thalassemia. Physicians should monitor patients for signs and symptoms of thromboembolic events and institute treatment promptly. For hypertension, physicians should monitor blood pressure during treatment and initiate anti-hypertensive treatment, as necessary. For embryo-fetal toxicity, Reblozyl may cause fetal harm. Female patients should be advised of potential risk to the fetus and use of effective contraception. Dosing recommendations were reviewed. It is available as an injection.

The  utilization report was reviewed and 80% of prescriptions were for preferred products. At the last review, a motion of therapeutic alternatives passed unanimously.

**MR. GREEAR MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.**

***Public Comments for Cardiovascular: Lipotropics, Other (Red Class)***

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Cardiovascular: Lipotropics, Other. The National Health and Nutrition Examination Survey reported that in 2015 to 2018, approximately 11.4% of adults had high total cholesterol and 18.4% had low HDL-C. There is a higher prevalence in women compared to men. Many clinical trials have demonstrated that a high serum concentration of LDL-C and low levels of HDL-C are major risk factors for coronary heart disease.

Recommendations from the American Association of Clinical Endocrinologists and the American College of Endocrinology were reviewed.

In February 2020, the FDA approved Nexletol, an adenosine triphosphate-citrate lyase (ACL) inhibitor, as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering or LDL-C. Elevations in serum uric acid have occurred. Assess uric acid levels periodically as clinically indicated. Monitor for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate. Avoid concomitant use of Nexlizet with Simvastatin greater than 20 milligrams and Pravastatin greater than 40 milligrams. Nexletol may cause fetal harm based on its mechanism of action. Dosing recommendations were reviewed. It is available as a tablet.

In February 2020, the FDA approved Nexlizet, an ACL inhibitor and cholesterol absorption inhibitor, indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C. Elevations in serum uric acid have occurred. Assess uric acid levels periodically as clinically indicated. Monitor for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate. Avoid concomitant use of Nexlizet with Simvastatin greater than 20 milligrams and Pravastatin greater than 40 milligrams. Nexlizet may cause fetal harm based on its mechanism of action. Dosing recommendations were reviewed. It is available as a tablet.

In February 2021, the FDA approved Evkeeze, which is indicated as an adjunct to other LDL-C lowering treatments for adults and pediatric patients 12 years of age and older with homozygous familial hypercholesterolemia. The safety and effectiveness of Evkeeze has not been established in patients with other causes of hypercholesterolemia, including those with heterozygous familial hypercholesterolemia. The effects on cardiovascular morbidity and mortality have not been determined. There can be embryo fetal toxicity, and it may cause fetal harm based on animal studies. Patients should be advised of potential risks to a fetus. Consider obtaining a pregnancy test prior to initiating treatment. Advise patients who may become pregnant to use contraception during treatment and for at least five months following the last dose. Dosing recommendations were reviewed. It is available as an injection.

The utilization report was reviewed and 43.1% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

In response to Dr. Phillips, Dr. Umang Patel said the low utilization rate was primarily due to a large number of prescriptions being for non-reviewed medications.

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

***Cardiovascular: PCSK-9 Inhibitors (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Cardiovascular: PCSK-9 Inhibitors.

The utilization report was reviewed and 0% of prescriptions were for preferred products. At the last review, a motion for class effect passed unanimously.

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

***Public Comments for Cardiovascular: Platelet Aggregation Inhibitors (Blue Class)***

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Cardiovascular: Platelet Aggregation Inhibitors. The 2018 Herat Disease and Stroke Statistics update cites cardiovascular (CV) disease as the leading

cause of all deaths in the U.S. in 2015, with coronary heart disease being the leading cause of CV death, followed by stroke, among CV deaths. Stroke also causes significant morbidity and mortality in the U.S. and is the fifth leading cause of death behind heart disease, cancer, chronic lower respiratory disease, and accidents. Inhibitory effects on platelet aggregation have led to a significant decrease in the rate of vascular events for both heart primary and secondary CV prevention trials. A small percentage of patients with CV disease have aspirin resistance and may be at higher risk for CV events. The definition of aspirin resistance is quite variable in the literature and has been described as the failure to prevent a thrombotic event, the inability to inhibit platelet thromboxane formation, or the inability to cause prolongation of bleeding time. Other antithrombotic drugs have been developed to improve the platelet aggregation inhibition and to improve the safety profile of platelet aggregation inhibitor therapy.

In November 2020, the FDA approved a new indication for Brilinta to reduce the risk of the first MI or stroke in patients with coronary artery disease at high risk for such events. While use is not limited to this setting, the efficacy of Brilinta was established in a population with type 2 diabetes. Warnings, dosage, and formulations remain the same.

In May 2020, Boehringer Ingelheim made a business decision to discontinue brand-name Aggrenox after June 1, 2020.

The utilization report was reviewed and 98.3% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include at least Clopidogrel passed unanimously.

**DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDES AT LEAST CLOPIDOGREL. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.**

***Public Comments for Cardiovascular: Pulmonary Arterial Hypertension (Blue Class)***

**SOPHIA YUN,** a representative of Janssen, discussed Uptravi, an oral prostacyclin receptor agonist indicated for the treatment of pulmonary hypertension WHO Group 1 to delay disease progression and reduce the risk of hospitalization for PAH. PAH is a rare, progressive, chronic disease that often affects working age patients. It also significantly restricts daily function and may lead to death in a few years. The goal of treatment for PAH is to achieve a low-risk status. Several studies and their outcomes were reviewed. Adverse reactions include headache, diarrhea, jaw pain, nausea, myalgia, vomiting, pain in extremity, and flushing. The 2015 European Society of Cardiology and European Registry Society Guidelines listed Uptravi as class 1-B recommendation for a sequential combination in functional class 2 and functional class 3. Based on the clinical data, we respectfully request the committee to consider adding Uptravi on the Alaska PDL.

Dr. Umang Patel gave the Magellan presentation on Cardiovascular: Pulmonary Arterial Hypertension (PAH). The prevalence of PAH varies substantially depending on the type, etiology, and underlying condition; estimated to be about 15 per million people. It is characterized by an increase in pulmonary arterial pressure and secondary right ventricular failure. This is defined as a resting mean pulmonary arterial pressure of about 25 millimeters of mercury or greater. Symptoms include dyspnea, dizziness, syncope, fatigue, 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. Management should be limited to specialized centers where clinicians are experienced in the evaluation and treatment of patients with PH. 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 PAH including idiopathic or underlying disease and hereditary causes. Cellular changes in the walls of 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, thromboembolism, or heart disease. The World Health Organization classifies PH patients into five groups based on etiology. Group I refers to pulmonary arterial hypertension. Group II refers to PH due to left heart disease. Group III refers to PH due to lung disease. Group IV refers to PH due to blood clots in the lungs. Group V refers to PH due to blood and other rare disorders. In 2013, clinical classifications were updated to provide the same PH classifications for adult and pediatric patients. In addition, the individual categorization of the persistent PH of neonates was included.

In December 2020, Sildenafil was voluntarily recalled for one lot of Sildenafil 100 milligram tablets and one lot of Trazodone 100 milligram tablets to the consumer level due to a product mix-up resulting in the agents inadvertently packaged together during bottling at a third-party facility. To date, no adverse events related to the recall have been reported.

REMS updates were reviewed. In April 2020, the FDA established a single shared system REMS for Opsumit and corresponding generics, called the Macitentan REMS Program. This new program will replace the original REMS once the first generic for Macitentan is approved. In December 2020, updates to the approved Ambristentan REMS, including modifications to the prescriber and pharmacy guide were made for Letairis. On the REMS website, updates were made to the inpatient pharmacy requirements for enrolled patients who are continuing therapy in the inpatient setting and are already being cared for by a certified prescriber to correspond with the current inpatient pharmacy requirements in the approved REMS. A provision now allows prescribers to grant greater than a 30-day supply for females of reproductive potential due to travel or personal extenuating circumstances. Certified outpatient pharmacy listings and links to Spanish materials on the REMS website were also added as a new office contact portal.

The utilization report was reviewed and 48.1% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include one from each class plus one inhaled product passed unanimously.

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

**4-C. Anti-Infective:** Antifungals, Oral (Green); Antifungals, Topical (Blue); Antivirals, Influenza (Blue); Fluoroquinolones, Oral (Green); Hepatitis B Agents (Green); Hepatitis C Agents (Blue); Otic Antibiotics (Green)

***Anti-Infective: Antifungals, Oral (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Anti-Infective: Oral.

The utilization report was reviewed and 98.5% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include at least one Fluconazole tablet, one oral Terbinafine preparation, and one pediatric preparation passed unanimously.

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

***Public Comment for Anti-Infective: Antifungals, Topical (Blue Class)***

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Anti-Infective: Antifungals, Topical. Onychomycosis is a fungal infection of the nails that causes thickening, discoloration, and separation from the nail beds. It occurs in 10% of the general population, 20% in persons 60 years of age and older and 50% in those over 70 years of age. It is most often caused by dermatophytes. Recurrence rate of onychomycosis is 10% to 50%.

In May 2020, the FDA expanded the indication for Jublia to include patients 6 years of age and older for the topical treatment of onychomycosis of the toenails due to Trichophyton rubrum and Trichophyton mentagrophytes. Previously, it was only indicated in adults. Warnings, precautions, dosage, and availability remain the same.

The utilization report was reviewed and 86.4% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include at least one solution, one shampoo, and one topical cream ointment passed unanimously.

**DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE SOLUTION, ONE SHAMPOO, AND ONE TOPICAL CREAM OINTMENT. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.**

***Public Comment for Anti-Infective: Antivirals, Influenza (Blue Class)***

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Anti-Infective: Antivirals, Influenza. This is a common illness affecting most people at least once in their lifetime. Uncomplicated illness typically resolves after 3 to 7 days. It is often self-limiting. Persons at higher risk for influenza complications are those less than 2 years of age, those greater than 65 years of age, immunocompromised patients, pregnant/postpartum patients, patients less than 19 years of age but on long-term aspirin therapy, American Indians/Alaska Natives, extremely obese patients, nursing homes/other chronic care facility patients, and patients with specific chronic disease states. Influenza vaccination is the primary method

of prevention. Inactive influenza vaccines are available in quadrivalent and trivalent formulations, while recombinant influenza vaccine and LAIV4 are available in quadrivalent formulations. There is also a high-dose inactivated influenza vaccine and adjuvanted inactivated influenza vaccine available in trivalent formulations. For the 2020-2021 season, inactivated influenza vaccines, recombinant influenza vaccine, and live attenuated influenza vaccine are available. Virus strains included in the 2020-2021 U.S. egg-based trivalent influenza vaccines contain hemagglutinin derived from an influenza A/Guangdong-Maonan/SWL1536/2019(H1N1)pdm09-like virus, an A/Hong Kong/2671/2019 (H3N2)-like virus, and a B/Washington/02/2019 (Victoria lineage)-like virus Quadrivalent influenza vaccines contain HA derived from the three viruses contained in the trivalent vaccine plus a B/Phuket/3037/2013-like virus (Yamagata lineage). Cell culture-based inactivated (ccIIV4) and recombinant (RIV4) influenza vaccines contain HA derived from an A/Hawaii/70/2019 (H1N1)pdm09-like virus, an A/Hong Kong/45/2019 (H3N2)-like virus, a B/Washington/02/2019 (Victoria lineage)-like virus, and a B/Phuket/3037/2013 (Yamagata lineage)-like virus.

Treatment guidelines from the Centers for Disease Control and Prevention were reviewed.

In December 2020, the FDA approved an expanded indication for Xofluza tablets to include post-exposure prophylaxis of influenza in adults and pediatric patients 12 years of age and older of a 40 milligram/20 milliliter oral suspension for constitution to a final concentration of 2 milligrams/milliliters. Warmings, precautions, and dosage remain the same.

In February 2021, the FDA approved an expanded indication for Rapivab for the treatment of acute uncomplicated influenza in patients 6 months of age and older, previously it had been 2 years of age and older, who have been symptomatic for two days or less. Warnings, precautions, dosage, and availability remain the same.

The utilization report was reviewed and 99.5% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include Oseltamivir passed unanimously.

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

***Anti-Infective: Fluoroquinolones, Oral (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Fluoroquinolones, Oral.

The utilization report was reviewed and 98.6% of prescriptions were for preferred products. At the last review, a motion of class effect passed unanimously.

**MR. GREEAR MOVED A CLASS EFFECT. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.**

***Anti-Infective: Hepatitis B Agents (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Anti-Infective: Hepatitis B Agents.

The utilization report was reviewed and 88.7% of prescriptions were for preferred products. At the last review, a motion of therapeutic alternatives passed unanimously.

**MR. GREEAR MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.**

***Public Comment for Anti-Infective: Hepatitis C Agents (Blue Class)***

**MARGARET OLMON,** a representative of Abbvie, thanked the committee for including Mavyret on the Alaska PDL and requested that it continue to be available for Alaska's Medicaid patients. Mavyret is the only once-daily pan-genotypic ribavirin-free regiment FDA-approved to treat patients 12 years of age and older with chronic hepatitis C virus across all genotypes 1 through 6. This includes those who do and do not have cirrhosis, have treatment experience, have HIV or chronic kidney disease. Mavyret can also be administered to patients after a kidney or liver transplant, regardless of baseline renal disease. Up to 95% of patients with HCV can be treated with Mavyret. The vast majority of patients awaiting treatment in Alaska are eligible for an eight-week course of therapy. Mavyret carries a boxed warning regarding the risk of hepatitis B reactivation in patients co-infected with HCV and HBV, as do all direct acting antivirals. Mavyret also has two contraindications: one for patients with moderate or severe hepatitis impairment and patients taking Atazanavir or Rifampin. The most common adverse reactions were headache and fatigue. Mavyret requires no liver monitoring or baseline resistance testing. No dosage or duration adjustments are needed for patients with HIV co-injection or any level of renal impairment including dialysis. For complete safety and full prescribing information, please visit rxabbvie.com. We request that Mavyret remain on the Alaska PDL.

Dr. Umang Patel gave the Magellan presentation on Anti-Infective: Hepatitis C Agents. Hepatitis C virus (HCV) is the most common chronic blood-born infection in the U.S. In approximately 15% to 25% of patients who become infected with hepatitis C, the virus is eliminated during the acute phase of the injection by T cell-mediated antiviral mechanisms; however, in the other 75% to 85%, the infection can persist for decades. An estimated 23,000 to 46,000 children in the U.S. have HCV. Approximately 2.7 million people in the U.S. are chronically infected, although it is estimated that nearly 75% of those people may be unaware of their infection due to the insidious progression of the disease. HCV accounts for 40% of chronic liver disease in the U.S. In patients with chronic HCV infection followed for 20 years, disease progression to cirrhosis occurs in about 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% per year will develop hepatocellular carcinoma. HCV infection is the most common reason for liver transplantation and results in an estimated 8,000 to 10,000 deaths per year in the U.S. The most important risk for HCV infection is injection-drug use, which accounts for at least 60% of acute HCV infections in the U.S. Other modes of transmission include mother-to-infant, receiving a blood or organ donation prior to 1992, occupational exposures, chronic hemodialysis, and contaminated devices shared for non-injection drug use such as intranasal illicit drug use. Sexual transmission also occurs but generally seems to be inefficient except among HIV-infected men who have unprotected six with men. Other risk factors include incarceration and receiving a tattoo in unregulated settings. It is estimated that 29% of incarcerated persons in North America are anti-HCV positive. Hepatitis C viral genotype is an important factor in selecting the optimal treatment planning, dictating drug selection, dose, and

duration of treatment. There are six HCV genotypes and more than 50 subtypes, and the distribution of HCV genotypes varies across the world. Genotype 1 is the most common worldwide and accounts for about 70% to 75% of U.S. infections. Genotypes 2 and 3 account for the majority of the other approximate 25% to 30% HCV infections in the U.S. Genotype 4 is predominate in Egypt. Genotype 5 is localized to South Africa. Genotype 6 to localized to Hong Kong and South Asia.

Guidelines from the U.S. Preventative Services Task Force and the Centers for Disease Control and Prevention were reviewed.

In July 2020, the FDA approved Epclusa for the treatment of HCV genotypes 1, 2, 3, 4, 5 and 6 in pediatric patients 6 years of age and older or weighing 17 kilograms or more. It was previously only indicated in adults. In March 2020, the FDA approved a new 200/50 mg tablet. All other information remains the same.

The utilization report was reviewed and 92.6% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

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

***Anti-Infective: Otic Antibiotics (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Anti-Infective: Otic Antibiotics.

The utilization report was reviewed and 74.6% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include one Otic Glucocorticoid Combination passed unanimously.

**DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE OPTIC GLUCOCORTICOID COMBINATION. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.**

**4-D. Genitourinary:** Benign Prostatic Hyperplasia (BPH) Agents (Green); Bladder Relaxant Preparations (Red); Vaginal Antibiotics (Blue)

***Genitourinary: Benign Prostatic Hyperplasia (BPH) Agents (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Genitourinary: Benign Prostatic Hyperplasia (BPH) Agents.

The utilization report was reviewed and 97.4% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include one alpha blocker and one androgen hormone inhibitor passed unanimously.

**DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE ALPHA BLOCKER AND ONE ANDROGEN HORMONE INHIBITORS. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.**

***Public Comment for Genitourinary: Bladder Relaxant Preparations (Red Class)***

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Genitourinary: Bladder Relaxant Preparations. Overactive bladder (OAB) is a chronic and debilitating syndrome that is characterized by urinary urgency with or without urge incontinence, usually in combination with urinary frequency (8 or more voiding episodes per 24 hours) or nocturia (awakening one or more times per night to void). Prevalences is about 16% in men and 17% in women, as well as 20% of those older than 60 years of age. First line therapy is behavioral therapy. Second line treatment is oral antimuscarinics including Darifenacin, Fesoterodine, Oxybutynin, Solifenacin, Tolterodine, or Trospium. Surgery is reserved for patients with severe refractory OAB symptoms or who are not candidates for oral therapy.

In May 2020, the FDA approved a new formulation of Vasicare LS, an oral suspension formulation of Solifenacin Succinate. Indications, warnings, precautions, and dosage remain the same.

In June 2020, Enablex was discontinued. Allergan made a business decision to permanently discontinue all strengths of Enablex. Generic versions are available.

In December 2020, the FDA approved Gemtesa, a beta-3 adrenergic agonist indicated for the treatment of OAB with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults. Monitor for urinary retention, especially in patients with bladder outlet obstruction and in patients taking muscarinic antagonist medications for OAB, in whom the risk or urinary retention may be greater. If urinary retention develops, discontinue treatment. Safety and effectiveness in pediatric patients have not been established. It is not recommended for patients with end-stage renal disease with or without hemodialysis. It is not recommended for patients with severe hepatic impairment. Dosing recommendations were reviewed. It is available as a tablet.

The utilization report was reviewed and 75.8% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

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

***Public Comment for Genitourinary: Vaginal Antibiotics (Blue Class)***

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Genitourinary: Vaginal Antibiotics. Bacterial vaginosis is a polymicrobial clinical syndrome resulting from Lactobacillus species with anaerobic bacteria and numerous fastidious or uncultivated anaerobes. Symptoms include vaginal discharge,

pain, itching, or malodor and can be asymptotic. It is associated with STDs and other female genital tract infections. A diagnosis requires three of four Amsel's criteria, which can be abnormal gray discharge, vaginal pH of greater than 4.5, or greater than 20% of the epithelial cells being clue cells. The Nugent score is considered the standard for 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.

In 2020, the U.S. Preventative Services Task Force issued a final recommendation on screening for bacterial vaginosis in pregnant persons to prevent preterm delivery. Based on available evidence, the committee recommends against screening for bacterial vaginosis in pregnant persons who are not at increased risk for preterm delivery. Additionally, they concluded the current evidence is inadequate to evaluate the benefits versus harms of screening for bacterial vaginosis in pregnant persons who are at increased risk for preterm delivery. Furthermore, the committee issued a final recommendation in August 2020 recommending behavioral counseling for all sexually active adolescents and adults who are at increased risk for sexually transmitted infections.

In February 2021, the Vandazole PI was expanded to remove indication language excluding pregnant women. Previously, the indication read for the treatment of bacterial vaginosis in non-pregnant women. It now reads for the treatment of bacterial vaginosis in post-monarchal females. The contraindications, dosage, and formulation remain the same.

The utilization report was reviewed and 89.7% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

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

**5. Break as Needed - 15 Minutes**

The meeting moved into closed session. The public telephone lines were disconnected.

**6. Review Minutes from January 2021**

The meeting minutes from January 15, 2021, were reviewed. There were no changes.

**DR. PHILLIPS MOVED TO APPROVE THE MEETING MINUTES OF JANUARY 15, 2021. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.**

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

Mr. Riley was thanked for chairing the meeting. Mr. Greear was thanked for his service as this will be his last meeting. The next meeting will be held September 17, 2021.

**8. Adjourn**

The meeting adjourned at 9:53 a.m.