ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE
(TELECONFERENCE)

Location of Meeting
Teleconference, Anchorage, Alaska

MINUTES OF MEETING
September 18, 2020
8:00 a.m.

Committee Members Present:
Jenna Hiestand, Chair, MD
Robert Carlson, MD
Vincent Greear, R.Ph.
Sarah Doran-Atchison, PharmD
Charles Ryan, MD
Claudia Phillips, MD
John Riley, PA
Ryan Ruggles, PharmD

Committee Members Absent:
Diane Liljegren, R.Ph.
Trish White, R.Ph.

Others Present:
Erin Narus, PharmD, R.Ph., State of Alaska
Charles Semling, PharmD, R.Ph.
Marti Padilla, R.Ph., Magellan Medical Administration
Umang Patel, Pharm D, R.Ph., Magellan Medical Administration
Betty Caudle, Kron Associates

1. Call to Order – Chair

Dr. Hiestand 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

There were no public comments.

4. Class Review, Discussion & Vote

4-A. Gastrointestinal: Antiemetic-Antivertigo Agents (Blue); GI Motility & Irritable Bowel Syndrome, Chronic (Red); Ulcerative Colitis (Blue); Cytokine & Cell-Adhesion Molecules (CAM) Antagonist - GI Indicated (Red)

Public Comments for Gastrointestinal: Antiemetic-Antivertigo Agents (Blue Class)

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Antiemetic-Antivertigo Agents. Chemotherapy-induced emesis and nausea can significantly impact a patient's quality of life, leading to poor compliance with future chemotherapy or radiation treatments. In addition, nausea and vomiting can lead to several adverse events, such as nutrient depletion, metabolic imbalances, erosion of self-care, and other diseases. Approximately 70% to 80% of all cancer patients receiving chemotherapy experience nausea and/or vomiting, whereas 10% to 44% experience anticipatory nausea and/or vomiting. Furthermore, more than 90% of patients using highly emetogenic chemotherapeutic agents will experience acute emesis; however, only approximately 30% of these patients will experience a vomiting episode if they receive an antiemetic prior to their highly emetogenic chemotherapeutic treatment. Motion sickness results as a conflict between the various senses in regard to motion. The overall incidence of dizziness, vertigo, and imbalance is 5% to 10%. There are multiple causes of vertigo, such as head trauma, cerebellar lesions, vestibular disease, or migraine. Symptoms include nausea, vomiting, pallor, sweating, and often a sense of impending doom. There are both non-pharmacologic and pharmacologic interventions for the prevention or management of motion sickness. None are ideal, and the medications typically cause drowsiness or similar adverse effects. Symptomatic treatment of motion sickness generally includes the use of antihistamines, benzodiazepines, or antiemetics. Vestibular rehabilitation in select patients may be used with a goal of treating the underlying cause. Morning sickness, or nausea and vomiting of pregnancy, can occur at any time of day and can affect pregnant women with varying symptoms from nausea to severe vomiting. Lifestyle changes for women with nausea and vomiting include rest, avoiding nauseating stimuli, and eating small, frequent low-fat meals that are low in spices.

Guidelines from the National Comprehensive Cancer Network were reviewed. Other guidelines, which are more than a year old, can be reviewed at the committee's leisure.

In June 2020, the FDA approved a new formulation of Metoclopramide (Gimoti), a nasal spray. It is indicated for relief of symptoms in adults with acute and recurrent diabetic gastroparesis. It is not recommended for use in pediatric patients due to the risk of tardive dyskinesia (TD) and other extrapyramidal symptoms as well as the risk of methemoglobinemia in neonates; moderate or severe hepatic impairment (Child-Pugh B or C); moderate or severe renal impairment (creatine clearance less than 60 mL/minute); and patients concurrently using strong CYP2D6 inhibitors due to the risk of increased drug exposure and adverse reaction. Avoid use in patients with depression and suicidal ideation. Tardive dyskinesia, other extrapyramidal symptoms, and neuroleptic malignant syndrome. Avoid concomitant use with other drugs known to cause tardive dyskinesia, other extrapyramidal symptoms, and neuroleptic malignant syndrome, and in patients with Parkinson's disease. If symptoms occur, discontinue use and seek immediate medical attention. Dosing recommendations were reviewed. It is available as a nasal spray.

The utilization report was reviewed, and 62% 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. RILEY. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Gastrointestinal: GI Motility & Irritable Bowel Syndrome, Chronic (Red Class)

KAREN WIN, a representative of Abbvie, discussed Viberzi and Linzess. Irritable bowel syndrome with diarrhea (IBSD) is a chronic disorder with two core symptoms, abdominal pain, and diarrhea. Viberzi is indicated in adults for the treatment of IBSD. A published relief study, which is a phase-four study, and its outcomes was reviewed. We request that Viberzi be added to the PDL as it has shown efficacy for patients with IBSD. Linzess was reviewed. In addition to the two core symptoms that most IBS patients have, patients also experience other symptoms such as abdominal bloating or discomfort which can have a profound implication on their daily life and function. Linzess is indicated for the treatment of adults with IBS with constipation or IBSC or chronic idiopathic constipation. Five new studies and their outcomes were reviewed. We request that Linzess maintain its placement on the PDL.

Dr. Umang Patel gave the Magellan presentation on GI Motility & Irritable Bowel Syndrome, Chronic. Constipation is a syndrome that is defined by bowel symptoms specific to the difficult passage of stool, infrequent passage of stool, abnormal hardness of stool, or a feeling in incomplete evacuation after a bowl movement. Though constipation can occur secondary to another disease such as Parkinson's or a spinal cord injury, idiopathic constipation occurs independent of any other underlying disorder. Chronic idiopathic constipation (CIC) is diagnosed if there are less than three spontaneous bowel movements per week with symptoms occurring for more than six months. Irritable bowel syndrome (IBS) is a functional bowel disorder that can be chronic, relapsing, and often lifelong. It occurs in up to 15% of the population and is up to 2.5 times more common in women than men. It is characterized by symptoms of abdominal pain or discomfort associated with abnormal stool frequency, consistency, stool passage, and/or bloating or abdominal distension, which may or may not be relieved by defection, at least three days per month in the past three months. It can also present with non-colonic features such as urinary and gynecologic problems, gallbladder and stomach symptoms, back pain, migraine, and depression which can lead to inappropriate patient referrals. Patients present with a combination of symptoms that are typically constipation predominant (IBS-C), diarrhea predominant (IBS-D), or mixed (IBS-M). Causes have not been fully identified, but could potentially include gut hypersensitivity, disturbed colonic motility, post-infective bowel dysfunction, or a defective anti-nociceptive system. There may also be contributing factors such as stress, food intolerance, abnormal intestinal flora that can hinder the effectiveness of treatment if left unresolved.

Guidelines from the American Gastroenterological Association were reviewed. Other guidelines, which are more than a year old, can be reviewed at the committee's leisure.

Tenapanor (Ibsrela) was approved by the FDA in September 2019 for the treatment of irritable bowel syndrome with constipation in adults. Patients may experience severe diarrhea. If severe diarrhea occurs, suspend dosing, and rehydrate patient. There is a black box warning stating it is contraindicated in patients less than 6 years of age; in young juvenile rats, it caused death presumed to be due to

dehydration. Avoid use in patients 6 years to less than 12 years of age. The safety and effectiveness have not been established in pediatric patients less than 18 years of age. Dosing recommendations were reviewed. It is available in as a tablet. In terms of renal impairment, there were no specific recommendations.

The utilization report was reviewed, and 87% 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.

Public Comments for Gastrointestinal: Ulcerative Colitis (Blue Class)

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Ulcerative Colitis. Ulcerative colitis (UC) is a chronic inflammatory disease primarily affecting the colon and rectum. It affects approximately 1 million people in the United States, and the incidence continues to increase worldwide. The CDC estimates the current prevalence is 238 adults per 100,000. It can present at any age, but onset typically peaks between 15 and 30 years of age. The disease is characterized by superficial infiltration of the bowel wall by inflammatory white cells, resulting in multiple mucosal ulcerations and crypt abscesses. The predominant symptom of UC is diarrhea, which is usually associated with blood in the stool. Additional symptoms may include pain in the lower quadrant or the rectum, along with systemic features such as fever, malaise, and weight loss. The initial attack of UC may be fulminant with bloody diarrhea, but the disease more commonly begins indolently, which is non-bloody diarrhea progressing to bloody diarrhea. UC can present initially with any extent of anatomic involvement ranging from disease confined to the rectum to the entire large intestine, which is pancolitis. Most commonly, UC follows a chronic intermittent course with long periods of quiescence interspersed with acute attacks lasting weeks to months. However, a significant percentage of patients suffer a chronic continuous course.

Guidelines from the American College of Gastroenterology and the American Gastroenterology Association were reviewed. Other guidelines, which are more than a year old, can be reviewed at the committee's leisure.

The utilization report was reviewed, and 70% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include at least one delayed-release agent, one prodrug short-acting agent, and one rectal preparation passed unanimously.

DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE DELAYED-RELEASE AGENT, ONE PRODRUG SHORT-ACTING AGENT, AND ONE RECTAL PREPARATION. SECONDED BY MR. RILEY. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Gastrointestinal: Cytokine & Cell-Adhesion Molecules (CAM) Antagonist - GI Indicated (Red Class)

DAVID GROSS, a representative of Pfizer, discussed Xeljanz. It is indicated for the treatment of adult patients with rheumatoid arthritis who have had an inadequate response to intolerance to methotrexate, for the treatment of adult patients with active psoriatic arthritis who have had inadequate response to intolerance to methotrexate, and the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response or who are intolerant to a TNF blocker. Recommended dosages for various indications were reviewed. There is a boxed warning for serious infections and malignancy. Patients treated with Xeljanz are at increased risk for developing serious infections, lymphoma, and other malignancies have been observed. The impact of Xeljanz on chronic viral hepatitis reactivation is unknown. In RA patients 50 years of age or older with at least one cardiovascular risk factor treatment with Xeljanz, 10-milligrams twice daily, which is double the recommended dose, have a higher rate of all-cause mortality compared to those treated with 5-milligrams twice daily. Thrombosis, including pulmonary embolism, DVT, and arterial thrombosis have occurred in patients treatment with Xeljanz and other JIA inhibitors. Several studies and their outcomes were reviewed. Having access to a medication with a novel mechanism of action and available for oral administration offers an additional treatment option for patients with rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis in the Alaska state Medicaid population. Based on the efficacy and long-term safety data of Xeljanz, we urge you to continue to retain Xeljanz on the PDL.

MARGARET OLMAN, a representative of Abbvie, discussed Humira. Please review the whole prescribing information at rxabbvie.com for comprehensive safety and efficacy data. Humira has 10 FDA approved indications. Today we are examining the data that supported the approval of Humira for three of those indications: the treatment of adult Crohn's disease, pediatric Crohn's disease, and ulcerative colitis. Humira is indicated to reduce the signs and symptoms, and inducing and maintaining clinical remission, in adult patients with moderately to severely active Crohn's disease who have had inadequate response to conventional therapy or if they have lost their response to or are intolerant to infliximab. Several trials and their outcomes were reviewed. With longstanding safety data, 71 global trials, 15 years of on-market experience, and over one million patients exposed, Humira has a well-defined, published benefit-to-risk database. It has sustained efficacy, published long-term safety data, and a durable response in patients with Crohn's disease and ulcerative colitis. We respectfully request you maintain the preferred status of Humira on the PDL for the people of Alaska.

Dr. Umang Patel gave the Magellan presentation on Cytokine and Cell-Adhesion Molecules (CAM) Antagonists - GI Indicated. In November 2019, the FDA approved a new indication for Ustekinumab (Stelara) for the treatment of moderately to severely active ulcerative colitis in adults. Dosing recommendations were reviewed. It is available as a subcutaneous injection or intravenous infusion.

Adalimumab-afzb (Abrilada) was approved by the FDA in November 2019. It is a biosimilar to Humira, indicated for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis, and plaque psoriasis. Dosing recommendations were reviewed. Black box warnings include an increased risk of serious infections leading to hospitalizations or death, including tuberculosis, bacterial sepsis, invasive fungal infections, and infections due to other opportunistic pathogens. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers. Post-marketing cases of hepatosplenic T-cell lymphoma, a rare T-cell lymphoma, have occurred in adolescent and

young adults with inflammatory bowel disease treated with TNF blockers. It is available in a single-dose prefilled pen, a single-dose prefilled glass syringe and a single-dose glass vial for institutional use only.

Infliximab-axxq (Avsola) was approved by the FDA in December 2019. It is a biosimilar to Remicade, indicated for the treatment of Crohn's disease in adults and pediatric patients, ulcerative colitis in adults and pediatric patients, RA in combination with methotrexate, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis. Dosing recommendations were reviewed. Black warnings include an increased risk of serious infections leading to hospitalizations or death, including tuberculosis, bacterial sepsis, invasive fungal infections, and injections due to other opportunistic pathogens. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including adalimumab products. Post-marketing cases of hepatosplenic T-cell lymphoma, a rare type of T-cell lymphoma, have occurred in adolescent and young adults with inflammatory bowel disease treated with TNF blockers including adalimumab products. It is available in a single-dose vial for intravenous infusion.

In December 2019, the FDA approved a new indication for Tofacitinib (Xeljanz, Xeljanz XR) for the treatment of adult patients with moderately to severely active ulcerative colitis who have an inadequate response or who are intolerant to TNF blockers. Use in combination with biological therapies for ulcerative colitis or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. Xeljanz was already indicated for this use. Both products were already indicated for RA and psoriatic arthritis. Dosing recommendations were reviewed. Black box warnings include an increased risk of serious infections leading to hospitalization or death, including tuberculosis, bacterial sepsis, invasive fungal infections, and injections due to other opportunistic pathogens. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including adalimumab products. Post-marketing cases of hepatosplenic T-cell lymphoma, a rare type of T-cell lymphoma, have occurred in adolescent and young adults with inflammatory bowel disease treated with TNF blockers including adalimumab products. It is available as a tablet formulation.

In January 2020, the FDA approved a new indication for Infliximab-qbtx (Ixifi) for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age or older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy. Previously, it was only indicated for adults with ulcerative colitis. Dosing and black box warnings are identical. It is available in a vial for intravenous infusion.

In July 2020, the FDA approved Adalimumab-fkjp (Hulio), a biosimilar to Humira. It is a TNF antagonist approved for the treatment of adults with moderately to severely active rheumatoid arthritis, juvenile idiopathic arthritis in patients 4 years of age or older, psoriatic arthritis in adults, active ankylosing spondylitis in adults, moderately to severely active ulcerative colitis, moderately to severely active Crohn's disease, and moderate to severe plaque psoriasis. Dosing recommendations were reviewed. Black box warnings include an increased risk of serious infections leading to hospitalization or death, including tuberculosis, bacterial sepsis, invasive fungal infections, and injections due to other opportunistic pathogens. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including adalimumab products. Post-marketing cases of hepatosplenic T-cell lymphoma, a rare type of T-cell lymphoma, have occurred in adolescent and young adults with inflammatory bowel disease treated with TNF

blockers including adalimumab products. It is available in a single-dose prefilled pen and a single-dose prefilled plastic syringe.

The utilization report was reviewed, and 78% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

In response to Dr. Hiestand, Dr. Ruggles said biosimilars were not auto substitutable. If the pharmacy wanted to make a substitution, they needed to notify the doctor and get approval. It is not the same as a generic. Dr. Umang Patel said they were current treating biosimilars as their own entities. The motion did not need to include this as it could be handled through the selection process.

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

4-B. Endocrine/Metabolic: Antihyperuricemics (Blue Class); Progestins for Cachexia (Green Class); Growth Hormone (Green Class); Androgenic Agents, Topical (Blue Class); Bone Resorption Inhibitors (Blue Class); Hypoglycemics, SGLT2 (Blue Class); Hypoglycemics, Metformin (Blue Class); Hypoglycemics, Alpha-Glucosidase (Green Class); Hypoglycemics, Meglitinides (Green Class); Hypoglycemics, Thiazolidinedione (TZD) and Combinations (Green Class); Hypoglycemics, Dipeptidyl Peptidase-4 Inhibitors (DPP-4) and Combinations (Green Class); Hypoglycemics, Glucagon-like Peptide-1 (GLP-1) and Combinations (Red Class); Rapid-Acting Insulins (Red Class); Regular Insulins (Green Class); Intermediate Insulins (Green Class); Rapid/Intermediate-Acting Combination Insulins (Blue Class); Regular/Intermediate-Acting Combination Insulins (Green Class); Long-Acting Insulins (Red Class); Phosphate Binders (Green Class)

Public Comments for Endocrine/Metabolic: Antihyperuricemics (Blue Class)

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Antihyperuricemics. Hyperuricemia can occur due to either an overproduction of uric acid, an under excretion of uric acid, or a combination of the two mechanisms. Gout is the crystal deposition of monosodium urate associated with elevated levels of uric acid. Crystals are deposited in joints, tendons, and surrounding tissues. Acute attacks of gout are painful. In over half of all cases, the metatarsophalangeal joint of the great toe is the first joint to be affected. Over time, deposition of urate masses in joints create tophi. Treatment of gout is managed in three stages: acute treatment, prophylaxis to prevent acute flares, and lowering excess stores of urate to prevent flares of gouty arthritis and prevent tissue deposition of urate crystals.

Guidelines from the American College of Rheumatology were reviewed.

The utilization report was reviewed, and 97% of prescriptions were for preferred products. At the last review, a motion of therapeutic alternatives passed unanimously.

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

Endocrine/Metabolic: Progestins for Cachexia (Green Class)

Dr. Umang Patel gave the Magellan presentation on Progestins for Cachexia. The utilization report was reviewed, and 67% of prescriptions were for preferred products. At the last review, a motion for class effect passed unanimously.

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

Endocrine/Metabolic: Growth Hormone (Green Class)

Dr. Umang Patel gave the Magellan presentation on Growth Hormone. The utilization report was reviewed, and 88% of prescriptions were for preferred products. At the last review, a motion for class effect passed unanimously.

MR. GREEAR MOVED A CLASS EFFECT. SECONDED BY MR. RILEY. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Endocrine/Metabolic: Androgenic Agents, Topical (Blue Class)

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Androgenic Agents, Topical. Male hypogonadism is caused by insufficient production of testosterone and characterized by low serum concentrations and may present as testosterone deficiency, infertility, or both. Approximately 20% of men ages 60 to 69 years old and 30% of men 70 to 79 years old have serum testosterone level below the normal range. After 30 years of age, testosterone levels in men decrease at rates up to 2% annually. Symptoms at presentation will primarily depend on the patient's age at the time of disease onset and can include impotence, decreased libido, fatigue, loss of energy, mood depression and regression of secondary sex characteristics. Potential risks due to male hypogonadism include osteoporosis, sexual dysfunction, depression, and cardiovascular disease.

Guidelines from the American College of Physicians were reviewed.

The utilization report was reviewed, and 0% was for preferred products, primarily due to the higher utilization of generics. At the last review, the motion for class effect passed unanimously.

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

Public Comments for Endocrine/Metabolic: Bone Resorption Inhibitors (Blue Class)

KERRY JOHNSON, a representative of Amgen, discussed Evenity. Evenity was approved in 2019 and is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture. It carries a box warning which states Evenity may increase the risk of MI stroke and cardiovascular death. It should not be initiated in patients who have had an MI or stroke within the preceding year. If

patient experiences an MI or stroke during therapy, Evenity should be discontinued. Please see the full prescribing information for further details. Evenity is unique in that it is the only agent for the treatment of postmenopausal osteoporosis that has a dual mechanism of action, which was described. It both increases bone formation and decrease bone resorption, resulting in rapid increases in bone mass and improvements in bone structure and strength. A patient at high risk for fracture needs rapid fracture risk reduction in the near term. Using the Evenity as initial therapy is optimal based on a pivotal study and current guidelines. Several studies and their outcomes were reviewed. Two recently updated guidelines supporting the use of Evenity were reviewed. We respect the committee consider including Evenity as an option on the PDL.

Dr. Umang Patel gave the Magellan presentation on Bone Resorption Inhibitors. Osteoporosis is characterized by the deterioration of bone tissue and low bone mass. Approximately 10 million Americans have the diagnosis of osteoporosis, and an addition 43 million have low bone mass, placing them at increased risk for this disease. As many as one in two women and one in five men are at risk for an osteoporosis-related fracture during their lifetime. Approximately one in four men in the U.S. over the age of 50 will have an osteoporosis-related fracture in his remaining lifetime. Osteoporosis is common in all racial groups but most common in Caucasians. There are three categories of osteoporosis. Postmenopausal osteoporosis affects mainly trabecular bone in the decade after menopause as estrogen deficiency increases bone resorption more than bone formation. Age-related osteoporosis results from increased bone resorption that begins shortly after peak bone mass is obtained; cortical and trabecular bone are both affected. Secondary osteoporosis is caused by medications or other diseases such as hyperthyroidism or type 1 diabetes.

Guidelines from the Endocrine Society were reviewed.

Teriparatide (Bonsity) was approved by the FDA in October 2019 as a follow-on to Forteo. It is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture; to increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture; and treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture. Dosing recommendations were reviewed. The black box warning states teriparatide has caused an increase in the incidence of osteosarcoma that was dependent on dose and treatment duration. It should not be prescribed for patients who are at increased baseline risk for osteosarcoma, including those with Pagent's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, or prior external beam or implant radiation therapy involving the skeleton. It is available in a single-patient-use pen.

For bone resorption inhibitors - IV formulation, the utilization report was reviewed, and 0% of the prescriptions were for preferred products. At the last review, a motion of therapeutic alternatives passed unanimously.

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

For bone resorption inhibitors - non-IV formulation, the utilization report was reviewed, and 95% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to

include at least one non-daily bisphosphonate and at least one parathyroid hormone analog passed unanimously.

DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE NON-DAILY BISPHOSPHONATE AND AT LEAST ONE PARATHYROID HORMONE ANALOG. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Endocrine/Metabolic: Hypoglycemics, SGLT2 (Blue Class)

SHYMAL DAS, a representative of Boehringer-Ingelheim, discussed Jardiance. For full safety and efficacy information, please reference the information on out website. Several studies and their outcomes were reviewed. We request that Jardiance be included on the PDL.

STEPHANIE YOMOMOTO, a representative of Janssen, discussed Invokana. The latest indications for Invokana include the reduction in the risk of end-stage kidney disease, doubling of serum creatinine, CV death, and hospitalization for heart failure in adults with type 2 diabetes and diabetic nephropathy with albuminuria greater than 300 milligrams per day. Effective in August 2020, the FDA conducted an independent review of the safety data and concluded that the boxed warning for lower leg amputation in the Invokana package insert has been removed. The conclusion from the FDA is that the risk no longer meets the standard for a boxed warning given the current benefit/risk profile of the treatment as more recent indication. Lower limb amputation risk remains in the warnings and precaution section. Dosage recommendations have also been updated. We strongly urge the committee to consider adding Invokana to the PDL based on the breath of indications in reducing the risk of MACE, end-stage kidney disease, and hospitalization for heart failure in adults with type 2 diabetes and diabetic nephropathy with albuminuria, as well as the established and updated safety profile of the medication.

A letter from Dr. Rosales from the Borealis Heart Institute advocating for the inclusion of Jardiance on the PDL was read into the record.

Dr. Umang Patel gave the Magellan presentation on Hypoglycemics, SGLT2. It is estimated that over 34 million Americans have diabetes mellitus. Of which, 90% to 95% have type 2 diabetes. Diabetes is responsible for increased morbidity and mortality. Adequate glycemic control is crucial to minimize chronic microvascular and macrovascular complications. Exogenous insulin supplements deficient levels of endogenous insulin, and temporarily restores the ability of the body to properly utilize carbohydrates, fats, and proteins. Multiple insulin products are available and are used as replacement therapy in the management of both type 1 and type 2 diabetes when glycemic goals are not met with oral antidiabetic agents. The sodium-glucose cotransporter 2 inhibits reduce renal glucose reabsorption in the proximal convoluted tubule, leading to increased urinary glucose excretion.

Guidelines from the Endocrine Society were reviewed.

New indications for Canagliflozin/Metformin (Invokomet, Invokamet XR) were approved by the FDA in January 2020 to reduce the risk of end-stage kidney disease, doubling of serum creatinine in cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes and diabetic nephropathy with albuminuria of 300 milligrams per day or greater. Previously, this was approved only

to reduce the risk of MACE and as an adjunct to diet and exercise to improve glycemic control in type 2 diabetes. Dosing recommendations were reviewed. It is available as a tablet.

New indications for Dapagliflozin (Farxiga) were approved by the FDA in May 2020 to reduce the risk of CV death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction categorized as class two through four. Dosing recommendations were reviewed. It is available in tablet formulation.

The utilization report was reviewed, and 72% of prescriptions were for preferred products. At the last review, a motion for class effect to include at least one medication that decreases cardiovascular risks and one that shows renal protective effect passed unanimously.

DR. RYAN MOVED A CLASS EFFECT TO INCLUDE AT LEAST ONE MEDICATION THAT DECREASES CARDIOVASCULAR RISKS AND AT LEAST ONE THAT SHOWS RENAL PROTECTIVE EFFECTS. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Endocrine/Metabolic: Hypoglycemics, Metformin (Blue Class)

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Hypoglycemics, Metformin. In September 2019, the FDA approved a new formulation (reconstituted suspension) of metformin ER (Riomet ER) as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes. Dosing recommendations were reviewed. It is available as an extended-release oral suspension and a reconstituted suspension.

The FDA provided update in June 2020 regarding their laboratory analysis of the impurity N-Nitroso dimethylamine (NDMA) in the U.S. metformin supply. While low levels of NDMA have been found in certain samples of metformin drug products, it has not been found in the metformin active pharmaceutical ingredient. Important to note that no tested samples exhibited levels of NDMA greater than the FDA's previously defined acceptable daily intake. Products tested had low to no detectable levels of the impurity. At this time, the FDA has not recalled any metformin products.

Metformin recalls as of June 2020 included Apotex, Amneal, Marksans, Teva, and Lupin due to NDMA impurities. Metformin recalls as of July 2020 included Granules Pharmaceuticals and Lupin for NDMA impurities.

The utilization report was reviewed, and 99% 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 MR. RILEY. THE MOTION PASSED UNANIMOUSLY.

Endocrine/Metabolic: Hypoglycemics, Alpha-Glucosidase (Green Class)

Dr. Umang Patel gave the Magellan presentation on Hypoglycemics, Alpha-Glucosidase. The utilization report was reviewed, and 100% of prescriptions were for preferred products. At the last review, a motion of class effect passed unanimously.

DR. RYAN MOVED A CLASS EFFECT. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Endocrine/Metabolic: Hypoglycemics, Meglitinides (Green Class)

Dr. Umang Patel gave the Magellan presentation on Hypoglycemics, Meglitinides. The utilization report was reviewed, and 0% of prescriptions were for preferred products but over the last year there were only 14 claims. At the last review, a motion of class effect passed unanimously.

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

Endocrine/Metabolic: Hypoglycemics, Thiazolidinedione (TZD) and Combinations (Green Class)

Dr. Umang Patel gave the Magellan presentation on Hypoglycemics, Thiazolidinedione (TZD) and Combinations. The utilization report was reviewed, and 95% of prescriptions were for preferred products. At the last review, a motion of class effect passed unanimously.

DR. RYAN MOVED A CLASS EFFECT. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Endocrine/Metabolic: Hypoglycemics, Dipeptidyl Peptidase-4 Inhibitors (Green Class)

Dr. Umang Patel gave the Magellan presentation on Hypoglycemics, Dipeptidyl Peptidase-4 Inhibitors. The utilization report was reviewed, and 92% of prescriptions were for preferred products. At the last review, a motion of class effect passed unanimously.

DR. RYAN MOVED A CLASS EFFECT. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Endocrine/Metabolic: Hypoglycemics, Glucagon-like Peptide-1 (GLP-1) and Combinations (Red Class)

ANTHONY HUBLER, a representative of Novo Nordisk, discussed Ozempic, a once-weekly GLP-1 receptor agonist approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Earlier this year, a label expansion for Ozempic was approved for the indication of reducing the risk of major adverse cardiovascular events including CV death, non-fatal MI, and non-fatal stroke in adults with type 2 diabetes and established cardiovascular disease. Several trials and/or studies and their outcomes were reviewed. There is a boxed warning regarding potential risk of thyroid C-cell tumors. Patients with a personal family history of MTC and patients with EM-2 should not use Ozempic. Please refer to the PI for additional safety information. We request that Ozempic be included on the PDL.

ANTHONY WHEELER, a representative of Eli Lilly, discussed Trulicity, a subcutaneous injection administered once a week and delivered using a single-dose pen device. There is no mixing or reconstitution necessary to use the device. Several trials and their outcomes were reviewed. Dosing formulation and recommendations were reviewed.

A letter from Dr. Jeffrey Medland advocating for the inclusion of Tresiba, Ozempic, and Rybelsus on the PDL was read into the record.

A letter from Dr. Russell Pierce, Goldstar Longevity and Wellness, advocating for the inclusion of Ozempic on the PDL was read into the record.

A letter from Dr. Patrick Nolan advocating for the inclusion of Tresiba, Ozempic, and Rybelsus on the PDL was read into the record.

Dr. Umang Patel gave the Magellan presentation on Hypoglycemics, Glucagon-like Peptide-1 (GLP-1) and Combinations. Semaglutide (Rybelsus) was approved by the FDA in September 2019. It is the first oral glucagon-like peptide-1 (GLP-1) receptor agonists as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. It is not recommended as first-line therapy for patients inadequately controlled on diet and exercise, it has not been studied in patients with a history of pancreatitis, and it is not indicated for use in patients with type 1 diabetes or treatment of diabetic ketoacidosis. Dosing recommendations were reviewed. There is a black box warning stating that in rodents, Rybelsus caused thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as the human relevance of Rybelsus-induced rodent thyroid C-cell tumors has not been determined. It is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). It is available in table formulation. Safety and efficacy of Rybelsus has not been established in pediatrics. If a patient is pregnant, Rybelsus should be discontinued. Rybelsus should also be discontinued in women at least two months before a planned pregnancy due to the long-out period for this medication. There are no adjustments necessary for renal or hepatic impairments.

In December 2019, the FDA approved a new formulation of Semaglutide (Ozempic), a new pen injector that incorporates a 3 mL cartridge and is designed to deliver four doses of 1 milligram of Ozempic approved. In January 2020, the FDA approved a new indication to reduce the risk of major adverse CV events (CV death, non-fatal MI, or non-fatal stroke) in adults with diabetes and established CV disease. Dosing recommendations were reviewed. Black box warnings are similar. It is available as a single-patient-use pen.

In February 2020, the FDA approved a new indication for Dulaglutide (Trulicity) for the reduction in the risk of major adverse cardiovascular events (MACE) (CV death, non-fatal MI, or non-fatal stroke) in adults with type 2 diabetes who has established CV disease or multiple CV risk factors. Dosing recommendations were reviewed. Black box warnings are similar. It is available in an injection formulation with a single-dose pen.

The utilization report was reviewed, and 49% of prescriptions were for preferred products. At the last review, a motion for class effect passed unanimously.

The committee discussed the physicians' letters submitted in support of Ozempic and Rybelsus on the PDL. Dr. Phillips said Rybelsus was the only oral formulation, but the first step of the guidelines is diet and exercise, followed by metformin, and then followed by other options that also have oral formulations. There is more than one choice for a once-weekly injection. Dr. Ryan said the numbers were pretty high for Ozempic and Rybelsus, which were not on the PDL. He questioned if a specific drug should be included in the motion. The medically necessary clause can always be utilized.

DR. PHILLIPS MOVED A CLASS EFFECT TO INCLUDE AT LEAST ONE WEEKLY INJECTION PRODUCT. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Endocrine/Metabolic: Rapid-Acting Insulins (Red Class)

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Rapid-Acting Insulins. FDA announcements were reviewed. In December 2019, the FDA published a statement regarding the pathway for approval of "chemically synthesized polypeptides." In March 2020, the majority of protein products (including all current insulin products) will have the potential for biosimilar and interchangeable products to increase competition through FDA approval under abbreviated pathways. However, products that are deemed "chemically synthesized polypeptides" are not eligible for the abbreviated approval pathways utilized for biosimilar or interchangeable products. The statement addresses how removal of this exclusion would allow for chemically synthesized follow-on insulins and other products to become approved through that abbreviated pathways as well. In March 2020, as part of Biosimilars Action Plan, the FDA announced that insulin and certain other biologic products have transitioned to a different regulatory pathway as of March 23, 2020. For Insulin Aspart, Insulin Protamine/Insulin Aspart, in September 2019, Novo Nordisk announced they will launch Novolog Mix 70/30 follow-on brands (authorized generics) in vial and pen forms on January 2, 2020. For Insulin Lispro (Insulin Lispro KwikPen), in April 2020, Lilly announced the launch of a new authorized generic for Humalog Junior KwikPen (insulin lispro injection, 100 units/mL).

In January 2020, the FDA expanded the approval for Insulin Aspart Injection (Fiasp) for improving glycemic control in patients with diabetes mellitus to include pediatric patients, including for the use of continuous SC insulin infusion. Previously, it was approved in adults only. Dosing recommendations were reviewed. Precautions and contraindications are similar to other insulins. It is available as an injection.

In June 2020, the FDA approved Insulin Lispro-aabc (Lyumjev), a rapid-acting human insulin analog indicated to provide glycemic control in adults with diabetes. Dosing recommendations were reviewed. Hypokalemia may be life-threatening. Monitor potassium levels in patients at risk of hypokalemia and treat if indicated. Never share prefilled pen between patients, even if the need has been changed. It is available as an injection.

The utilization report was reviewed, and 24% of prescriptions were for preferred products, primarily due to the high utilization generic insulin. At the last review, a motion for class effect passed unanimously.

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

Endocrine/Metabolic: Regular Insulins (Green Class)

Dr. Umang Patel gave the Magellan presentation on Regular Insulins. The utilization report was reviewed, and 0% of prescriptions were for preferred products, but it was very low utilization. At the last review, a motion for class effect passed unanimously.

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

Endocrine/Metabolic: Intermediate Insulins (Green Class)

Dr. Umang Patel gave the Magellan presentation on Intermediate Insulins. The utilization report was reviewed, and 97% 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 MR. RILEY. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Endocrine/Metabolic: Rapid/Intermediate-Acting Combination Insulins (Blue Class)

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Rapid/Intermediate-Acting Combination Insulins. In April 2020, Lilly announced the launch of a new authorized generic for Humalog Mix 75/25 KwikPen (insulin lispro protamine and insulin lispro inject table suspension, 100 units/mL).

The utilization report was reviewed, and 58% of prescriptions were for preferred products. At the last review, a motion for class effect passed unanimously.

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

Endocrine/Metabolic: Regular/Intermediate-Acting Combination Insulins (Green Class)

Dr. Umang Patel gave the Magellan presentation on Regular/Intermediate-Acting Combination Insulins. The utilization report was reviewed, and 86% of prescriptions were for preferred products. At the last review, a motion of class effect passed unanimously.

MR. RILEY MOVED A CLASS EFFECT. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Endocrine/Metabolic: Long-Acting Insulins (Red Class)

There were no public comments.

Letters from Dr. Medland and Dr. Nolan advocating for the inclusion of Tresiba on the PDL was read into the record earlier.

A letter from Dr. Rachel Kerford Lescher, Alaska Native Medical Center, advocating for the inclusion of Tresiba on the PDL was read into the record.

Dr. Umang Patel gave the Magellan presentation on Long-Acting Insulins. In December 2019, the FDA approved the expanded formulation of the addition of a modified pre-filled insulin pen that can be used with connected devices, mobile applications, or other technology (3 mL single-patient-use Basaglar Tempo Pen). It is available as an injection.

In December 2019, the FDA expanded the indication for Insulin Glargine (Tourjeo Solostar, Toujeo Max Solostar) to include pediatrics 6 to 17 years old with diabetes mellitus. Dosing, precautions, and formulations are identical.

In June 2020, the FDA approved Insulin Glargine (Semglee) under the 505(b)(2) NDA pathway and is now deemed a biologic. It is a long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes and in adults with type 2 diabetes. It is not recommended for treating diabetic ketoacidosis. Dosing recommendations were reviewed. Precautions and contraindications are the same as other insulins. It is available as a vial and a single-patient-use prefilled syringe.

The utilization report was reviewed, and 86% of prescriptions were for preferred products. At the last review, a motion of class effect to consider professional public testimony and the discussion of the committee passed unanimously.

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

Endocrine/Metabolic: Phosphate Binders (Green Class)

Dr. Umang Patel gave the Magellan presentation on Phosphate Binders. The utilization report was reviewed, and 83% 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. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

5. Review Minutes from January 2020

6. Comments from Committee Members or Chair

There were no comments from committee members.

7. Adjourn

The public portion of the meeting adjourned at 10:12 a.m. and the committee moved into executive session