ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE

Location of Meeting
Frontier Building, 3601 C Street, Room 890/896

MINUTES OF MEETING
September 20, 2019
8:00 a.m.

Committee Members Present:	**Committee Members Absent:**
Ryan Ruggles, PharmD, Acting Chair	Vincent Greear, MD
Robert Carlson, MD (telephonic)	Charles Ryan, MD
Sarah Doran-Atchison, Pharm D (telephonic)	John Riley, PA
Diane Liljegren, R.Ph. (telephonic)	Trish White, R.Ph.
Claudia Phillips, MD (telephonic)	Jeanna Hiestand, MD

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. Ruggles called the meeting to order at 8:04 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 local public/health practitioner comments.

4. Class Review, Discussion & Vote

Dr. Erin Narus gave a presentation on the new processes for developing the Alaska Medicaid Preferred Drug List (PDL). Outpatient drugs for Alaska Medicaid are defined as those that may be dispensed upon prescription and have received an NDC number from the FDA, those that are electronically listed with the FDA for which the manufacturer has obtain a new drug application, approval or an

abbreviated new drug application approval, and BLA. The definition of a covered outpatient drug is in alignment with federal regulation 42 CFR 337.502. The Medicaid formulary is considered a group rather than a list of medications. When individuals ask for drugs to be covered, they must meet the qualifications of covered outpatient drugs under federal and state regulation. Within the Medicaid program, covered outpatient drugs must participate in the Medicaid Drug Rebate Program, which is listed on the CMS website. Medicaid programs nationwide, as well as coverage programs, use utilization management or utilization review principals to manage utilization, including a PDL, to promote the utilization of clinically effective, cost beneficial drugs. The term cost beneficial is used because an inexpensive drug may not provide the outcomes we are looking for, and so it is often more beneficial to prefer a more costly drug with better patient outcomes. As part of the subcommittee of the Drug Utilization Review Committee, the Pharmacy and Therapeutics Committee (P&T Committee) uses all of the tools at its disposal to guide clinically appropriate use of medications. Utilization rules ensure appropriate usage based on FDA labeling and clinically appropriate management of medications. Criteria may also be added based on safety factors of a particular drug. The drug utilization review that guides Medicaid programs is contained under 42 USC 1396R-8.

The Support Act is based on safety edits that Congress put forward to ensure appropriate utilization and alerting prescribers, pharmacists and patients through notification of high-dose opioid prescribing regiments and drug-to-drug interactions. The PDL guides clinically appropriate, cost beneficial medication utilization within the Medicaid program and is based on the recommendations of the P&T Committee.

Historically, the PDL had to be adopted into regulation, which could take up to a year. Senate Bill 44 was signed into law on August 8, 2019. It allows for the adoption of future PDLs following committee meetings. Program staff will review the PDL, prescribing patterns, clinical literature and then consult with Magellan to determine if there are recommendations that should be brought forth to the P&T Committee. Recommendations for the current PDL will be based on the motions of the P&T Committee over the past year, as well as discussions and motions from today's meeting. After the meeting, staff will develop a proposed PDL by October 1, which will go into effect on November 1, 2019. Going forward, staff will develop a proposed PDL about a month after the P&T Committee meetings based on their recommendations, with updated PDLs taking effect the following month. Online resources, websites and email updates will be available on our website.

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

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

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Gastrointestinal: Antiemetic-Antivertigo Agents. Chemotherapy-induced vomiting and nausea can significantly impact a patient's quality of life, leading to poor compliance with future chemotherapy or radiation treatments. Nausea and vomiting can lead to several adverse events such as nutrient depletion, metabolic imbalances, erosion of self-care, anorexia, diminished performance and mental status, wound dehiscence, tears in the esophagus, and cessation of potentially useful or curative cancer treatment. Approximately 70-80% of all cancer patients receiving

chemotherapy experience nausea and/or vomiting, whereas 10-44% experience anticipatory nausea and/or vomiting. More than 90% of patient using highly emetogenic chemotherapeutic agents will experience acute emesis; however, only about 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. Overall incidence of dizziness, vertigo, and imbalance is about 5-10%. 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.

Nausea and vomiting of pregnancy, or morning sickness, can occur at any time of the day and can affect pregnant women with varying symptoms from nausea to severe vomiting. Lifestyle changes for women with nausea and vomiting of pregnancy include rest, avoiding nauseating stimuli, and eating small and frequent low-fat meals that are low in spices.

Guidelines from the American Society of Clinical Oncology (ASCO), the National Comprehensive Cancer Network (NCCN), the American Society of Anesthesiologists (ASA), and the American College of Obstetricians and Gynecologists (ACOG) were reviewed.

Updated information for Palonosetron injection was reviewed. A ready-to-administer prefilled syringe of Palonosetron was approved by the FDA. An expanded indication of Palonosetron injection was approved for the prevention of nausea and vomiting associated with cancer chemotherapy in patients ages 1 month to 17 years of age. Brand Aloxi carries this indication. Approved dosage for pediatrics is a single dose of 20 mcg/kg administered over 15 minutes approximately 30 minutes prior to start of chemotherapy. It is available in an injection formulation.

The utilization report was reviewed and 65.6% were for preferred products. At the last review, a motion of therapeutic alternatives passed unanimously.

The committee discussed the low compliance of the class. Dr. Patel noted that non-PDL could refer to nonpreferred drugs or drugs that had not yet been reviewed. In this class, there were a large number of medications that had not yet been reviewed.

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

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

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Gastrointestinal: GI Motility and Irritable Bowel Syndrome, Chronic. Constipation is defined as a syndrome by bowel symptoms specific to the difficult passage of stool, infrequent passage of stool, abnormal hardness of stool, or a feeling of incomplete evacuation after a bowel movement. Though constipation can occur secondary to another disease (such as Parkinson's or spinal cord injury), idiopathic constipation occurs independent of any underlying disorder. Chronic idiopathic constipation is diagnosed if there are less than three spontaneous bowel movements per week with symptoms occurring for greater than or equal to six months and at least wo of the previously mentioned bowel symptoms.

Irritable bowel syndrome (IBS) is a functional bowel disorder which 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, abnormal stool consistency, abnormal stool passage, and/or bloating or abdominal distension, which may or may not be relieved by defecation, at least three days per month in the last three months. It can present with non-colonic features such as functional 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), and/or alternating between both, or mixed (IBS-M). Causes have not been fully identified, but could 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, and abnormal intestinal flora, which can hinder the effectiveness of treatment if left unresolved.

Treatment guidelines by the American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA), the American Pain Society (APS), and the American Society of Interventional Pain Physicians (ASIPP) were reviewed.

Motegrity is a new medication in this class. In December 2018, the FDA approved Motegrity. It is indicated for the treatment of chronic idiopathic constipation in adults. Dosing is 2 milligrams once daily with or without food. Suicide, suicide attempts, and suicide ideation have been reported with Prucalopride; however, no causal association has been established. Patients should be monitored for persistent worsening depression or development of suicidal thoughts. It is contraindicated in patients with intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, or severe inflammatory conditions of the intestinal tract such as Crohn's disease, ulcerative colitis, or toxic megacolon. In clinical trials, severe diarrhea was reported in 1.8% of patients treated with 2 milligrams of Motegrity versus 1% in the placebo group; however, the onset and duration of diarrhea was similar in the trial. It is available in a tablet formulation.

The utilization report was reviewed and 88.3% 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. LILJEGREN. 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 Gastrointestinal: Ulcerative Colitis. Ulcerative colitis 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 to be at about 238 per 100,000 adults. This 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 is diarrhea, which is usually associated with blood in the stool. Additional symptoms may include pain in the lower quadrant or rectum along with systemic features including fever, malaise, and weight loss. The initial attack may be fulminant with bloody diarrhea, but the disease more commonly begins indolently with non-bloody diarrhea progressing to bloody diarrhea. It can present initially with any extent of anatomic involvement ranging from disease confined to the rectum to the entire large intestine. Most commonly, it 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.

Treatment guidelines from the American College of Gastroenterology (ACG), the American Gastroenterology Association (AGA), and the American Academy of Family Physicians (AAFP) were reviewed.

The utilization report was reviewed and 76.1% was 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.

The committee discussed the utilization of the class. Dr. Phillips wondered why the utilization of preferred products was not higher. Dr. Doran-Atchison questioned if there were supply issues with the drugs in this class. Dr. Semling said it was likely a brand versus generic issue where the generics came out just prior to the last PDL review.

DR. PHILLIPS 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 DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

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

MARGARET OLMON, a representative of AbbVie, discussed Humira. Please review the full prescribing information for comprehensive safety and efficacy data. Humira has 10 FDA approved indications including the treatment of adult and pediatric Crohn's disease and ulcerative colitis. It 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 with an inadequate response to conventional therapy, or if they have lost response to or are intolerant to Infliximab. Several trials and their outcomes were reviewed. With longstanding safety data, 71 global trials, 15 years of market experience, and over 1 million patients exposed, Humira has a well-defined published benefit to risk database. All TNF antagonists carry similar box warnings regarding serious infection, tuberculosis, and

malignancies. Patients starting any anti-TNF, including Humira, should be screen for TB and carefully monitored for serious events. Humira has sustained efficacy, published long-term safety, and a durable response in patients with Crohn's disease and ulcerative colitis. For these reasons, we respectfully urge the committee to maintain the preferred status of Humira on the Alaska PDL.

AARON HUWE, a representative of Merck, discussed Renflexis. Infliximab-abda, or Renflexis, is a tumor necrosis factor TNF blocker and was initially approved in 2017 as a biosimilar for Remicade, the originator of Infliximab. It includes indications for Crohn's disease, pediatric Crohn's disease, and ulcerative colitis. Renflexis received FDA approval for pediatric Crohn's disease in June 2019. At the present time, the prescribing information for Renflexis is consistent with the labeling for Remicade. The approval for Renflexis was based on evidence consistent with biosimilar development in an approval process setup by the FDA.

Dr. Umang Patel gave the Magellan presentation on Gastrointestinal: Cytokine and Cell-Adhesion Molecules (CAM) Antagonists - GI indicated. Cytokines and cell-adhesion molecules (CAMs) are chemical mediators involved in inflammatory processes throughout the body.

Cytokines are small proteins secreted in response to an immune stimulus for the purpose of mediating and regulating immunity, inflammation, and hematopoiesis. It is derived from monocytes and macrophages and induce gene expression of a number of proteins that contribute to the inflammatory response. The actions of the individual cytokines are varied and contribute to fibrosis and tissue degeneration associated with chronic inflammation, primarily by inducing the proliferation of fibroblasts and collagenase. The pro-inflammatory cytokines, tumor necrosis factors, and interleukin-1 are involved in tissue destruction in many chronic inflammatory diseases affecting various organs. TNF-alpha also has a role in Crohn's disease in stimulation of inflammation.

Cell adhesion molecules (CAMs) are cell surface proteins involved in the binding of cells, usually leukocytes, to each other, endothelial cells, or the extracellular matrix. Specific signals produced in response to wounds and infection control the expression and activation of these molecules. These are categorized into three general families of proteins: the immunoglobulin superfamily, the integrin family, and the selectin family. Other proteins that are functionally classified as CAMs are involved in strengthening the association of T cells with antigen-presenting cells or target cells, in T cell activation, and in recirculating lymphocytes back to the circulation via the lymphatic system. Different CAMs have been implicated in inflammatory, fibrotic, and autoimmune diseases.

Guidelines for the treatment of Crohn's disease from the American College of Gastroenterology (ACG) and the American Gastroenterology Association (AGA) were reviewed. Guidelines for ulcerative colitis treatment from the American Gastroenterology Association (AGA) were reviewed.

Updated information for Infliximab-adba (Renflexis) was reviewed. It is indicated to reduce signs and symptoms and inducing and maintaining clinical responses in patients 6 years of age or older with moderately to severely active Crohn's disease and ulcerative colitis. Dosages were reviewed.

Updated information for Tofacitinib (Xeljanz and Xeljanz XR) were reviewed. It is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis. The FDA had previously required REMS programs but has now determined they were no longer necessary. Dosages were reviewed.

Adalimumab-adaz (Hyrimoz) was reviewed. In November 2018, the FDA approved Hyrimoz as a biosimilar to Humira for all eligible indications of the reference product. Hyrimoz will likely not be available in the U.S. until September 30, 2023. It is indicated for adult Crohn's disease and ulcerative colitis. It also has non-GI indicated indications. Dosages were reviewed. It is available as a single-dose prefilled syringe and pen (Sensoready).

The utilization report was reviewed and 100% were for preferred products. At the last review, a motion for therapeutic alternatives with consideration to patients' previously working therapy passed unanimously.

In response to Dr. Ruggles, Dr. Patel explained that GI and non-GI medications were combined in the market basket. When they were broken out for the utilization report, the medications with no GI indications were removed, so the utilization report may need to be adjusted.

In response to Dr. Phillips, Dr. Semling noted that any drug not included on the PDL could always be prescribed utilizing the medically necessary clause to be covered.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. CARLSON. 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 (Red Class); Hypoglycemics, SGLT2 (Blue Class); Hypoglycemics, Metformin (Green Class); Hypoglycemics, Alpha-Glucosidase (Green Class); Hypoglycemics, Meglitinides (Green Class); Hypoglycemics, Thiazolidinedione (TZD) and Combinations (Green Class); Hypoglycemics, Amylin Analogues (Green Class); Hypoglycemics, Dipeptidyl Peptidase-4 Inhibitors (DPP-4) and Combinations (Green Class); Hypoglycemics, Glucagon-like Peptide-1 (GLP-1) and Combinations (Green Class); Rapid-Acting Insulins (Blue Class): Regular Insulins (Blue Class); Intermediate Insulins (Green Class); Rapid/Intermediate-Acting Combination Insulins (Green Class); Long-Acting Insulins (Green 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 Endocrine/Metabolic: Antihyperuricemics. Hyperuricemia is defined as a serum uric acid level of 6.8 milligrams per deciliter or higher. It can occur due to either an over production 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 more than half of all cases, the metatarsophalangeal joint of the big toe is the first joint to be affected. Over time, deposition of urate masses in joints creates 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 or urate crystals.

Guidelines from the American College of Rheumatology (ACR) and the American College of Physicians (ACP) were reviewed.

The American College of Foot and Ankle Surgeons (ACFAS) and the American Association of Nurse Practitioners (AANP) created a joint guideline in 2018. They recommended NSAIDs as a first-line treatment for acute gout. In addition, long-term medications, such as Allopurinol, are necessary for the treatment of recurrent gout; and when used, Allopurinol should be titrated to uric acid levels of less than 6 milligrams per deciliter.

Duzallo and Zurampic were discontinued by the manufacturer on February 1, 2019, due to business decisions. The discontinuation was not due to efficacy, safety, or clinical concerns. The products may be available until the supply is depleted.

The utilization report was reviewed and 69% 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. LILJEGREN. THE MOTION PASSED UNANIMOUSLY.

Endocrine/Metabolic: Progestins for Cachexia (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Progestins for Cachexia. The utilization report was reviewed and 34.4% were for preferred products. At the last review, a motion for class effect passed unanimously.

Dr. Ruggles noted the low utilization of the preferred products on the PDL.

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

Endocrine/Metabolic: Growth Hormone (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Growth Hormone. The utilization report was reviewed and 92% were for preferred products. At the last review, a motion for class effect passed unanimously.

In response to Dr. Carlson, Dr. Narus noted the utilization report for this particular class was based on actual dosing units due to the differential in the dosing between products in the class. From August 1, 2018 to August 1, 2019, there were 437 claims.

DR. PHILLIPS MOVED A CLASS EFFECT. SECONDED BY DR. CARLSON. 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 Endocrine/Metabolic: Androgenic Agents, Topical. This class was changed to a green class, but testimonies will still be accepted since it was initially a blue class. Hearing none, Dr. Patel resumed his presentation. The utilization report was reviewed and 7.4% were for preferred products. At the last review, a class effect passed unanimously.

In response to Dr. Ruggles, Dr. Narus said several authorized generics have come out since the last PDL update, so it is likely that the utilization report reflects a shift to generic utilization over the branded product, which staff will take into account with the new PDL coming out in November.

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

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

SYLVIA CHURCHILL, a representative of Amagen, discussed Evenity. The prescribing information and a summary of the clinical data will be provided by Dr. Patel. The full prescribing information is also available online at amagen.com. Evenity has a unique mechanism of action. Some of the agents in this class work by decreasing bone resorption, while others work by increasing bone formation. Evenity works by inhibiting sclerostin, increasing bone formation as well as decreasing bone resorption to a lesser extent. Evenity is dosed at 210 milligrams subcutaneously, once per month for 12 months. After 12 months, its anabolic effect begins to wane, so anti-resorptive agents should be considered if osteoporosis therapy is still needed. Patients should also be adequately supplemented with calcium and vitamin D during treatment with Evenity. Several studies and their outcomes were reviewed. There is a box warning indicating that Evenity may increase the risk of myocardial infarction, stroke, and cardiovascular death, so it should not be initiated in patients who have experienced an MI or stroke within the preceding year. The approval of Evenity helps to address an unmet need by providing another option for postmenopausal women with osteoporosis who are at high risk for fracture and who need to build bone within 12 months to reduce the risk of a first or a subsequent fracture.

Dr. Ruggles noted that Dr. Carlson had to leave the meeting but would try to return in an hour.

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Bone Resorption Inhibitors. Osteoporosis is characterized by the deterioration of bone tissue and low bone mass. About 10 million Americans have the diagnosis of osteoporosis, and an additional 43 million have low bone mass, placing them at increased risk for this disease. As many as 1-in-2 women and 1-in-5 men are at risk for osteoporosis-related fracture during their lifetime. Approximately 1-in-4 men in the U.S. over the age of 50 will have osteoporosis-related fractures in their remaining lifetime. Osteoporosis is common in all racial groups but is most common in Caucasians. There are three categories of osteoporosis: postmenopausal, age-related, and secondary osteoporosis.

The guidelines from the North American Menopause Society (NAMS), the National Osteoporosis Foundation (NOF), the American Association of Clinical Endocrinologists (AACE), and the American College of Endocrinology (ACE) were reviewed.

Zometa vials will be permanently discontinued by Novartis. Discontinuation of this product is not due to manufacturing, product quality, safety, or efficacy concerns. There are therapeutic equivalents available.

Evenity was FDA-approved in April 2019 for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture or multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. The dosing is 200 milligrams subcutaneously, once per month for a year, and must be administered by a health care professional. Precautions include a contraindication for patients with hypocalcemia. Usage of Evenity may result in osteonecrosis of the jaw and is usually associated with tooth extraction and/or local infection with delayed healing. Prescribers should perform a routine dental exam before starting Evenity treatment. Although causality has not been established, use of Evenity has also been associated with atypical low trauma femoral fractures. Patients should be instructed to report signs of new hip, thigh, or groin pain. Prescribers should ensure that patients receive calcium and vitamin D supplements while receiving treatment. There is a black box warning for increased risk of major adverse cardiac events including myocardial infarction, stroke, and cardiovascular death. Evenity should not be used in patients with a history of MI or stroke in the past year and should be discontinued if an MI or stroke occurs. It is available in a pre-filled syringe.

The utilization report was reviewed and 0% were for preferred products. Last year, the committee divided the bone resorption inhibitors into two subcategories, one for IV and one for oral agents. At the last review, a motion for class effect for IV bone resorption inhibitors passed unanimously.

Dr. Narus noted that the utilization within the IV class is at 0% because the drugs prescribed may not be on the PDL until it is updated.

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

Dr. Patel reviewed the utilization report for non-IV bone resorption inhibitors and 90.2% 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. PHILLIPS 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.

Dr. Ruggles suggested taking a break and rearranging the agenda to review the green classes first and the blue classes in hopes that Dr. Carlson would be back in time to discuss the blue classes. There were no objections.

Break from 9:44 a.m. to 10:06 am.

Dr. Ruggles took a roll call. Present were Dr. Liljegren (telephonic), Dr. Doran-Atchison (telephonic), Dr. Phillips (telephonic), Dr. Hiestand, and Dr. Ruggles.

Endocrine/Metabolic: Phosphate Binders (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Phosphate Binders. The utilization report was reviewed and 72.7% 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. LILJEGREN. THE MOTION PASSED UNANIMOUSLY.

Endocrine/Metabolic: Metformin (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Metformin. The utilization report was reviewed and 99.9% were for preferred products. At the last review, a motion for class effect passed unanimously.

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

Endocrine/Metabolic: Alpha-Glucosidase (Green Class)

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

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

Endocrine/Metabolic: Meglitinides (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Meglitinides. The utilization report was reviewed and 0% were for preferred products. At the last review, a motion for class effect passed unanimously.

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

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

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

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

Endocrine/Metabolic: Hypoglycemics, Amylin Analogues (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Hypoglycemics, Amylin Analogues. The utilization report was reviewed and 0% were for preferred products. At the last review, a motion for class effect passed unanimously.

Dr. Ruggles questioned if this class should be reviewed in the future since there were no prescriptions written in the last three months. Dr. Phillips suggested suspending the class and bringing it back in the future as needed.

DR. PHILLIPS MOVED A CLASS EFFECT AND TO SUSPEND REVIEW OF THIS CLASS INDEFINITELY. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

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

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Hypoglycemics, Dipeptidyl Peptidase-4 Inhibitors (DPP-4) and Combinations. The utilization report was reviewed and 90.1% were for preferred products. At the last review, a motion for class effect passed unanimously.

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

Endocrine/Metabolic: Hypoglycemics, Glucagon-like Peptide-1 (GLP-1) and Combinations (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Hypoglycemic, Glucagon-like Peptide-1 (GLP-1) and Combinations. Letters were received from Drs. Nolan, Lescher, Medland, Fenton, Abbate and Tanner advocating the inclusion of Ozempic and Tresiba on the PDL. The committee decided to postpone this class to later in the meeting when Dr. Carlson returned.

Endocrine/Metabolic: Intermediate Insulins (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Intermediate Insulins. The utilization report was reviewed and 100% were for preferred products. At the last review, a motion for class effect passed unanimously.

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

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

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Rapid/Intermediate-Acting Combination Insulins. The utilization report was reviewed and 51.8% were for preferred products. At the last review, a motion for class effect passed unanimously.

DR. PHILLIPS MOVED A CLASS EFFECT. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY. (Dr. Liljegren not responding to vote call.)

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

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Regular/Intermediate-Acting Combination Insulins. The utilization report was reviewed and 92.9% were for preferred products. At the last review, a motion for class effect passed unanimously.

DR. PHILLIPS MOVED A CLASS EFFECT. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY. (Dr. Liljegren not responding to vote call.)

Diabetes Mellitus Description and Guidelines

Dr. Umang Patel gave the Magellan presentation on the description and guidelines for diabetes mellitus. It is estimated that 30 million Americans have diabetes mellitus (DM), with nearly 95% having Type 2 diabetes. Diabetes is responsible for increased morbidity and mortality. Adequate glycemic control is crucial to minimize chronic microvascular (such as blindness and renal dysfunction) and macrovascular (such as cardiovascular disease) 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. In addition to exogenous insulin, there are several pathways by which blood glucose may be regulated in diabetic patients. The sodium-glucose cotransporter 2 (SGLT2) inhibitors reduce renal glucose reabsorption in the proximal convoluted tubule, leading to increased urinary glucose excretion. Studies evaluating the impact of SGLT2 inhibitors on macrovascular complications (such as cardiovascular outcomes) include the EMPA-REG OUTCOME and CANVAS/CANVAS-R, which were reviewed.

The guidelines from the American Diabetic Association (ADA), the European Association for the Study of Diabetes (EASD), the American Academy of Clinical Endocrinologists (AACE), the American College of Endocrinology (ACE), the American College of Physicians (ACP), and the World Health Organization (WHO) were reviewed.

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

Dr. Umang Patel read a letter from Dr. Robert Skala, True North Medicine, advocating for the inclusion of Jardiance and Synjardy XR on the PDL.

MAE KWONG, a representative of Janssen, discussed Invokamet. It is an SGLT2 inhibitor indicated for glycemic control in adults with Type 2 diabetes and to reduce the risk of major adverse cardiovascular events in adults with Type 2 diabetes and established cardiovascular disease. It is the only SGLT2 inhibitor approved with three-point needs to reduce the risk of cardiovascular death, MI

and stroke. Several studies and their outcomes were reviewed. We request that Invokamet be added to the PDL because of its differentiated clinical benefits from the other SGLT2 inhibitors and not a class effect. Invokamet is the only SGLT2 inhibitor with three-point needs benefits and the only medication in 17 years to achieve positive results from a randomized controlled dedicated renal outcomes trials in patients with Type 2 diabetes and chronic kidney disease. We anticipate hearing from the FDA on the renal indication by the end of the month.

JULIE MCDAVITT, a representative of Boehringer Ingelheim, discussed Jardiance. It is an SGLT2 inhibitor also known as Empagliflozin. Jardiance is the first and only SGLT2 inhibitor proven to scientifically reduce the risk of cardiovascular death in adults with established cardiovascular disease and Type 2 diabetes. Several trials and their outcomes were reviewed. Jardiance has been embraced by associations such as the American Diabetes Association, the American Association of Clinical Endocrinologists, and most recently the American College of Cardiology. Empagliflozin is currently the preferred SGLT2 inhibitor in the American College of Cardiology Expert Consensus Decision Pathway. In June, the FDA granted a fast-track designation to Empagliflozin for the reduction of the risk of cardiovascular death and hospitalization for heart failure in people with chronic heart failure disease. More information will be released in the coming months. Based on the current evidence, we respectfully ask the committee to continue to maintain the status of Jardiance on the PDL.

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Hypoglycemic, SGLT2. A new MedWatch safety alert for SGLT2 inhibitors for diabetes was reviewed. The FDA is warning that cases of necrotizing fasciitis of the perineum (known as Fournier's gangrene) have been reported with SGLT2 inhibitors based on results of a case series. Between March 2013 and May 2018, 12 cases of Fournier's gangrene were found in patients taking an SGLT2 inhibitor, resulting in significant medical care needed and one death. A new warning will be added to the prescribing information of all SGLT2 inhibitors regarding this risk. Health care practitioners should assess patients for Fournier's gangrene if they present with symptoms consistent with this diagnosis. Patients should be treated accordingly immediately.

The utilization report was reviewed and 68.3% were for preferred products. At the last review, a motion for class effect passed unanimously.

Dr. Liljegren suggested preferring at least one drug that decreases cardiovascular risk and one that decreases renal progression.

DR. LILJEGREN MOVED A CLASS EFFECT TO INCLUDE AT LEAST ONE MEDICATION THAT DECREASES CARDIOVASCULAR RISKS AND ONE THAT SHOWS A RENAL PROTECTIVE EFFECT. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

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

COURTNEY WALKER, a representative of Novo Nordisk, discussed Fiasp. Fiasp is a rapid-acting human insulin analog indicated to improve glycemic control in adults with Type 1 or Type 2 diabetes. We have submitted to the FDA regarding children and adolescents. Fiasp is insulin aspart, the same insulin analog molecule as Novolog, but with two excipients added to increase the initial absorption and add in stabilization. The excipients include niacinamide (vitamin B3), which increases the speed of

initial absorption. The onset of action for Fiasp in circulation is about 2.5 minutes. After administration, the maximum concentration was reached at about 63 minutes after administration. It can be administered by subcutaneous injection at the start of a meal or within 20 minutes after starting a meal, allowing for post-meal dosing. IV administration information is included in the prescribing information as well. When converting from another meal-time insulin to Fiasp, the conversion can be made on a unit-to-unit basis with education to the patient on the difference in insulin dose timing. Several studies and their outcomes were reviewed. Hypoglycemia is the most common adverse reaction of all insulin therapies including Fiasp. Please refer to the prescribing information for further details. Once in use, both the vial and pen are stable at room temperature or in the refrigerator for 28 days. We request that Fiasp be included on the PDL.

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Rapid-Acting Insulins. Guidelines from the American Diabetes Association (ADA) were reviewed.

In November 2018, the FDA eliminated the REMS requirement for Afrezza since it met its goals. Risk of bronchospasm is added to post-marketing experience and correction of the histopathological diagnosis of lung cancer due to lung blastoma.

The utilization report was reviewed and 68.7% was for preferred products. At the last review, a motion of class effect passed unanimously.

Dr. Carlson returned to the meeting.

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

Public Comments for Endocrine/Metabolic: Regular Insulins (Blue Class)

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Regular Insulins. The FDA Safety Communication, 2019, was reviewed. It warned patients not to use devices for diabetes management that are not authorized for sale in the U.S., stating they have not been evaluated and approved by the FDA to ensure they provide reasonable safety and efficacy for their intended use. Use of agents that may not be reliable could result in inaccurate glucose readings and unsafe insulin dosing, possibly leading to clinically significant injury or death.

The Humalog (Insulin Lispro) Authorized Generic, 2019, was reviewed. Eli Lilly announced plans to launch an authorized generic for Humalog, 100 units per milliliter, through their subsidiary ImClone Systems.

The utilization report was reviewed and 6 claims were for non-preferred products. At the last review, a motion for class effect passed unanimously.

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

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

There were no public comments.

Dr. Umang Patel read six letters into the record. Dr. Samuel Abbate, Adonai Diabetes and Endocrinology Center in Wasilla, advocated for the inclusion of Tresiba on the PDL. Dr. Patrick Nolan, Endocrinology/Internal Medicine in Anchorage, advocated for the inclusion of Ozempic and Tresiba on the PDL. Dr. Jeffrey Medland, Anchorage, advocated for the inclusion of Tresiba and Ozempic on the PDL. Dr. Cydney Fenton, Independence Park Medical Services in Anchorage, advocated for the inclusion of Tresiba on the PDL. Dr. J. Ross Tanner, Diabetic and Lipid Clinic in Anchorage, advocated for the inclusion of Tresiba, Jardiance, Ozempic, and Trulicity on the PDL. Dr. Rachel Lescher, Alaska Native Medical Center in Anchorage, advocated for the inclusion of Tresiba on the PDL.

The utilization report was reviewed and 86.4% were for preferred products. At the last review, a motion for class effect to consider professional public testimony and the discussion of the committee passed unanimously.

Dr. Liljegren felt that Tresiba should be a preferred agent on the PDL based on the compelling letters from the pediatric endocrinologists. Dr. Phillips felt Tresiba would be especially useful for diabetic patients that lived in the villages.

DR. LILJEGREN MOVED A CLASS EFFECT TO INCLUDE TRESIBA FOR PEDIATRIC PATIENTS.

The committee discussed using the medically necessary clause to prescribe Tresiba. Dr. Liljegren felt it might be too time consuming to use the medically necessary clause considering the number of prescriptions written for Tresiba and the severity of diabetes. Dr. Narus noted that Tresiba would be recommended by staff for the PDL that would go into effect after the meeting, based on clinical evidence and the discussions of the P&T Committee last year, unless it was opposed by the committee.

DR. LILJEGREN WITHDREW HER MOTION.

DR. PHILLIPS MOVED A CLASS EFFECT TO CONSIDER PROFESSIONAL PUBLIC TESTIMONY AND THE DISCUSSION OF THE COMMITTEE. SECONDED BY DR. LILJEGREN. THE MOTION PASSED UNANIMOUSLY.

Dr. Doran-Atchison left the meeting.

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

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Hypoglycemics, Glucagon-like Peptide-1 (GLP-1) and Combinations. The utilization report was reviewed and 91.5% were for preferred products. At the last review, a motion for class effect passed unanimously.

Dr. Patel noted that two of the physician letters read earlier in the meeting advocated for Ozempic on the PDL, which is a part of this class.

Dr. Liljegren suggested including a once daily and once weekly formulation in the motion. Some patients prefer the once daily formulation, because they forget to take the medication if it is only once weekly. Dr. Ruggles said the Bydureon pen was a once weekly formulation but was not a preferred product. Bydureon BCise and Ozempic both have easy-to-use devices. An oral gel GLP-1 formulation is scheduled to come out later in the month but is not included in this year's basket.

DR. LILJEGREN MOVED A CLASS EFFECT TO INCLUDE AT LEAST ONE DAILY AND ONE WEEKLY FORMULATION. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Dr. Erin Narus thanked everyone for their participation in the meeting and noted that the next meeting would be November 15, 2019. The committee moved into a closed session.

5. Review Minutes from April 2018.

6. Comments from Committee Members or Chair

7. Adjourn

The public portion of the meeting adjourned at 11:30 a.m.