ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE

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

MINUTES OF MEETING
September 21, 2018
8:00 a.m.

Committee Members Present:
Jeffrey Demain, MD, Chair
Robert Carlson, MD (telephonic)
Vincent Greear, MD (attended 1 hour)
Jenna Hiestand, MD
Claudia Phillips, MD (telephonic)
John Riley, PA (telephonic)
Ryan Ruggles, PharmD
Trish White, MD (telephonic)

Committee Members Absent:
Diane Liljegren, MD (excused)
Charles Ryan, MD

Others Present:
Erin Narus, PharmD, State of Alaska
Chuck Semling, PharmD, State of Alaska
Elaine Edwards, RPh, Magellan Medicaid Administration
Umang Patel, PharmD, RPh, Magellan Medicaid Administration
Colette Grower, Kron Associates

1. Call to Order – Chair

Dr. Demain called the meeting to order at 8:03 a.m. and reviewed the rules of the meeting. Public comments are limited to three minutes. Industry comments will be taken on red and blue classes only and are limited to three minutes. No testimony will be taken on the green classes, as there are no new indications for these classes.

Erin Narus welcomed Dr. Chuck Semling, PharmD, to the Pharmacy and Ancillary Services Unit as the coordinator for the P&T and DUR Committees.

2. Roll Call

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

3. Public Comments - Local Public/Health Practitioners

DR. PAT NOLAN distributed a handout and discussed the insulin Degludec (Tresiba) for diabetic patients. Pediatric endocrinologists like this insulin, especially for patients above the age of one. It is also very helpful for patients who forget to take their insulin. We request that Degludec remain on the Alaska Medicaid PDL for the reasons outlined on the handout. With Degludec, we see a noticeable decline in hypoglycemic episodes, particularly nocturnally.

In response to Dr. Demain, Dr. Nolan said Degludec is a basal insulin. From his experience, there is a definite decrease in hypoglycemic episodes and paramedic calls from patients using Degludec.

Dr. Nolan discussed continuous glucose monitoring, which he believes is a game-changer for diabetic patients who are pregnant. Every pregnant patient with diabetes, whether they have Type 1, Type 2 or gestational diabetes, should have a continuous glucose monitor. There are only a few on the market, which were reviewed, but they are extremely important for improving outcomes, reducing costs, and monitoring insulin. The monitors will result in a decrease of pregnant patients and/or newborns who need intensive care. He requested that Medicaid develop a mechanism for expediting the approval of monitoring systems for pregnant diabetic patients.

Dr. Semling said the DUR Committee has discussed continuous glucose monitors. The delay in approving the monitors appear to be around billing, not approval of the monitors themselves. The Call Center has been notified that requests for continuous glucose monitors should an escalated issue.

The committee discussed several continuous glucose monitors currently in the marketplace, both with and without alarms.

4. Class Review, Discussion & Vote

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

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

There were no public testimonies.

Dr. Umang Patel gave the Magellan presentation on Gastrointestinal: Antiemetic-Antivertigo Agents. Chemotherapy-induced vomiting, also known as 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, anorexia, diminished performance and mental status, wound dehiscence, and numerous other events. Approximately 70-80 percent of all cancer patients receiving chemotherapy experience nausea and/or vomiting, whereas 10-44 percent experience anticipatory nausea and/or vomiting. More than 90 percent of patients using highly emetogenic chemotherapeutic agents experience acute emesis; however, only about 30 percent experience vomiting episodes if an antiemetic is received prior to their highly emetogenic chemotherapeutic treatment.

Motion sickness is a result of conflict between the various senses in regard to motion. The overall incidence of dizziness, vertigo and imbalance is 5-10 percent. There 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, also known as morning sickness, can occur at any time of day and can affect pregnant women with varying symptoms. Lifestyle changes include rest; avoiding nauseating stimuli; and eating small, frequent, low-fat meals that are low in spice.

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

New medications in the class were reviewed. Aprepitant (Cinvanti) is indicated in combination with other antiemetic agents for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high-dose cisplatin, as well as nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy. Cinvanti has not been studied for treatment of established N/V. It has not been studied in patients with severe hepatic impairment or patients less than 18 years of age. It should be used with caution with other medications that are primarily metabolized by CYP3A4. Dosage recommendations were reviewed. It is available as an injectable emulsion.

Updated information for drugs in the class were reviewed. Akynzeo (Fosnetupitant/Palonosetron) is indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Dosage recommendations were reviewed. It is available as capsules or an injection formulation. Varubi (Rolapitant) is indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy including, but not limited to, highly emetogenic chemotherapy. Dosing recommendations were reviewed. It is available as a tablet or an injectable emulsion.

Utilization for the antiemetic/antivertigo agents were reviewed. In a three-month period, there were 6,529 claims with 64 percent being for drugs on the PDL. At the last review, a motion for therapeutic alternatives passed unanimously.

In response to Dr. Demain, Dr. Patel said there were no drastic changes in the guidelines from 2013/2014 to 2018, so the current PDL should be within the guidelines.

DR. RUGGLES MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. (UNIDENTIFIED). THE MOTION PASSED UNANIMOUSLY.

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

There were no public testimonies.

Dr. Umang Patel gave the Magellan presentation on Gastrointestinal: 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 of incomplete evacuation after a bowel movement. Through constipation can occur secondarily to another disease, idiopathic constipation occurs independent of any other underlying disorder. Chronic idiopathic constipation, or CIC, is diagnosed if there are less than three spontaneous bowel movements per week with symptoms occurring for six months or greater and at least two 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 percent 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 past three months. It can also present with non-colonic features that can lead to inappropriate patient referrals. Patients present with a combination of symptoms that are typically constipation predominant, diarrhea predominant, and/or alternating between both or mixed. 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 be contributing factors such as stress, food intolerance, abnormal intestinal flora that can hinder the effectiveness of treatment if left unresolved.

Treatment guidelines from the American College of Gastroenterology (ACG), the American Gastroenterology Association (AGA), the American Pain Society (APS), and the American Academy of Pain Medicine (AAPM) were reviewed.

Updated information for drugs in the class were reviewed. Plecanatide (Trulance) is indicated for the treatment of chronic idiopathic constipation in adult patients and treatment of irritable bowel syndrome with constipation. Dosing recommendations were reviewed. Trulance is contraindicated in patients with known or suspected mechanical GI obstruction. Use in children less than 6 years of age is contraindicated and carried a boxed warning. Trulance should be avoided in children less than 18 years of age. No studies are listed for patients with renal or hepatic impairment. It is available in a 3-milligram tablet.

Utilization for the class was reviewed. In a three-month period, there were 344 claims with 93.9 percent being for drugs on the PDL. At the last review, a motion for therapeutic alternatives to include one formulation for diarrhea and one for constipation passed with one abstention.

In response to Dr. Demain, Dr. Patel said the use of Trulance was not outlined in the guidelines, but the guidelines are older than the new indication for Trulance. He suggested prescribing Trulance only if the patient was intolerance or there was treatment failure using the other drugs in the class.

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

Gastrointestinal: Ulcerative Colitis (Green Class)

Dr. Umang Patel gave the Magellan presentation on Gastrointestinal: Ulcerative Colitis. Ulcerative colitis (UC) is a chronic inflammatory disease primarily affecting the colon and rectum. It affects approximately 500,000 people in the United States, accounts for 250 million annual physician visits, and 30,000 hospitalizations. The onset of UC is commonly between 15 and 40 years of age, with a second peak between 50 and 80 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 rectum, along with systemic features such fever, malaise, and weight loss. The initial attack of UC may be fulminant with bloody diarrhea, but the disease more commonly begins indolently, with 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. Most commonly, UC follows a chronic intermittent course with long period 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 Academy of Family Physicians (AAFP), the American College of Gastroenterology (ACG), and the American Gastroenterological Association (AGA) were reviewed. Guideline updates are currently underway.

Utilization for the class was reviewed. In a three-month period, there were 285 claims with 81.2 percent being for drugs on the PDL. 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. RUGGLES 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 DR. HIESTAND. THE MOTION PASSED UNANIMOUSLY.

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

Dr. Patel read letters from two local practitioners. Richard Blake, a certified physician's assistant at Cottonwood Creek Clinic, advocated for the inclusion of Xeljanz on the PDL. Dr. John Boston advocated for the inclusion of Xeljanz (a pill) on the PDL as it is medically necessary for some patients due to their medical and living conditions.

DR. DAVID GROSS, a representative of Pfizer, discussed Xeljanz. It is an oral medication indicated for the treatment of adult patients with rheumatoid arthritis with inadequate response or intolerance to Methotrexate. Dosage recommendations is 5-milligrams, twice daily; or 11-milligrams of the XR formulation, once daily, as monotherapy or in combination of with nonbiologic DMARDs. Xeljanz is also indicated for adults with active psoriatic arthritis. Dosage recommendations is the same as those

with rheumatoid arthritis. In May, Xeljanz was approved for the treatment of adult patients with moderately to severely active ulcerative colitis. Dosage recommendations is 10-milligrams, twice daily, for at least eight weeks, followed by either 5- or 10-milligrams, twice daily, depending on the patient's therapeutic response. Xeljanz has a boxed warning for serious infections and malignancy. Patients treated with Xeljanz are at increased risk for developing serious infections that may lead to hospitalization or death. Lymphoma and other malignancies have also been observed in patients treated with Xeljanz. Please refer to the package insert for more details. Several studies and their outcomes were reviewed. Xeljanz is a useful option to have available due to its unique mechanism of action, its established safety and efficacy, and the fact that it is available in an oral dosage formulation.

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, but today we will only review those for the treatment of adult Crohn's Disease, pediatric Crohn's Disease, and ulcerative colitis. Humira is indicated to reduce the signs and symptoms in inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's Disease who with an inadequate response to conventional therapy, or if they lost response to or are intolerant to Infliximab. Several trials and/or studies and their outcomes were reviewed. All TNF antagonists carry similar boxed warnings regarding serious infections, tuberculosis, and malignancies. Patients starting on any anti-TNF, including Humira, should be screened for tuberculosis and carefully monitored for serious events. Humira has demonstrated sustained efficacy, long-term safety, and a durable response in patients with Crohn's Disease and ulcerative colitis. For these reasons, we request that Humira maintain its status as a preferred agent on the PDL.

CHROMA EZENDUKA, a representative of UCB, discussed Cimzia. Cimzia is a unique anti-TNF biologic that is the only pegylated and FC-free molecule. It is FDA-approved for the treatment of moderate to severe Crohn's Disease, as well as the extra intestinal manifestations that many patients experience. In May, Cimzia receive an additional indication for psoriasis. Cimzia carries a boxed warning for increased risk of injection such as TB, but please refer to the package insert for a complete list of warnings and precautions. Studies have shown that Crohn's Disease affects women in their peak reproductive years with about 50 percent of patients being under 35 years of age at time of diagnosis. Women often feel the need to choose between treating Crohn's Disease and starting a family due to potential effects. The FDA enacted the Pregnancy and Lactation Labeling Rule, which requires the replacement of pregnancy letter categories with scientific date by 2020. UCB is the first pharmaceutical company to sponsor studies assessing placental and breastmilk transfer in infants born to mothers taking Cimzia. The studies showed negligible to low levels of Cimzia in the infant's blood and the mother's breastmilk, and no serious adverse events occurred in the infants. These results reflect Cimzia's unique structure, which was reviewed. The FDA recognized the impact of this data and approved an update of Cimzia's package insert to include the results of this study in March 2018. Cimzia is currently a non-preferred agent on the PDL, but we request it be added on behalf of women between the ages of 18 and 45 who are planning to start a family.

Dr. Umang Patel gave the Magellan presentation on Gastrointestinal: Cytokine & Cell-Adhesion Molecules (CAM) Antagonists - GI Indicated. Cytokines and cell-adhesion molecules (CAMs) are chemical mediators involved in inflammatory processes throughout the body. Cytokine 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 widely 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 factor (TNF), and interleukin-1 are involved in tissue destruction in many chronic inflammatory diseases affecting various organs.

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. Most CAMs are characterized 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 system, and in recirculating lymphocytes back to the circulation via the lymphatic system. Different CAMs have been implicated in inflammatory, fibrotic, and autoimmune diseases.

Treatment guidelines from the American College of Gastroenterology (AGC) and the American Gastroenterology Association (AGA) for Crohn's Disease was reviewed. The guidelines from the American College of Gastroenterology (ACG) for ulcerative colitis were reviewed.

Updated information for drugs in the class were reviewed. Infliximab-abda (Renflexis) is indicated to reduce signs and symptoms in patients 6 years of age and older with moderately to severely active Crohn's Disease and ulcerative colitis. There is no available data for pregnancy. Dosage recommendations were reviewed. It is available in a single dose vial. Adalimumab-adbm (Cyltezo) is indicated for Crohn's Disease in patients with an inadequate response to conventional therapy, ulcerative colitis, rheumatoid arthritis, ankylosis spondylitis, juvenile idiopathic arthritis, plaque psoriasis, and psoriatic arthritis. There is no available date for pregnancy. Dosage recommendations were reviewed. It is available in a single dose pre-filled glass syringe. Tofacitinib (Xeljanz, Xeljanz XR) is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis, rheumatoid arthritis, and psoriatic arthritis. Limitations include a risk of injection with increasing degrees of lymphopenia. Consideration should be given to lymphocyte counts when assessing individual patient's risk of injection. Caution should be used in patients with a history of chronic lung disease, those who develop interstitial lung disease, and those with increasing degrees of lymphopenia as they might be prone to infection. Lymphoma and other malignancies have been reported including melanoma, prostate cancer, and pancreatic cancer. Dosage recommendations were reviewed. It is available in a 5-milligram or 11-milligram oral tablet.

Utilization for the class was reviewed. In a three-month period, there were 566 claims with 98.5 percent being for drugs on the PDL. At the last review, a motion for therapeutic alternatives passed unanimously.

In response to Dr. Demain, Dr. Patel said there were pregnancy category B and C drugs within the class.

Dr. Narus clarified that Cimzia, which the speaker said was not on the PDL, was on the proposed PDL that was still going through the regulatory process.

In response to Dr. Demain, Dr. Patel said the guidelines state that whatever drug induces remission should be the drug the patient uses for continued remission. If that drug's effectiveness begins to wane

and better results are achieved with a new drug, then that becomes the preferred product for that patient. Dr. Demain warned against changing a patient's drug simply because a different drug is approved on the new PDL.

Dr. Demain pointed out there was strong support for an oral agent, which was included on the PDL currently being reviewed.

DR. (UNIDENTIFIED) MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES WITH CONSIDERATION TO PATIENTS' PREVIOUS WORKING THERAPY. SECONDED BY DR. (UNIDENTIFIED).

In response to Dr. Riley, Dr. Demain said an oral agent is on the proposed PDL that is undergoing approval, but the current motion does not guarantee that an oral agent will remain on the PDL. However, the motion guarantees that if a patient is doing well on a medication then they will stay on that medication.

THE MOTION PASSED UNANIMOUSLY.

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

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

There were no public testimonies.

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Antihyperuricemics. Hyperuricemia is defined as serum uric acid greater than 6.8 milligrams per deciliter. It can occur due to either an overproduction or uric acid, an under excretion or uric acid, or a combination of the two. 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 the cases, the metatarsophalangeal joint of the great 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 or urate to prevent flares of gouty arthritis and prevent tissue deposition or urate crystals.

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

Updated information for drugs in the class were reviewed. Lesinurad/Allopurinal (Duzallo) is indicated for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a medically appropriate daily dose of Allopurinol alone. Dosing recommendations were reviewed. This drug requires refrigeration before and after reconstituting. Dose reduction or alternatives should be considered in patients with severe renal or hepatic impairment. Do not use in combination with Lesinurad (Zurampic) since it is one of the active ingredients. Duzallo is available in a tablet formulation.

Utilization for the class was reviewed. In a three-month period, there were 1,075 claims with 89.6 percent being for drugs on the PDL. At the last review, a motion for therapeutic alternatives passed unanimously.

In response to Dr. Demain, Dr. Patel said he did not know the reason for the increased risk of cardiac events within this class.

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

Endocrine/Metabolic: Progestins for Cachexia (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Progestins for Cachexia. Cachexia is a complex syndrome that includes weight loss, lipolysis, loss of muscle, visceral protein, anorexia, chronic nausea, and weakness. It is defined as a loss of greater than 5 percent of an individual's baseline body weight. It occurs with, but not limited to, a number of diseases such as advanced cancer, chronic obstructive pulmonary disease, AIDS, Crohn's disease, and renal failure. It is estimated that more than 80 percent of patients with advanced cancer or AIDS will develop cachexia before death.

The treatment for cachexia was reviewed. In addition to nutritional interventions, corticosteroids, and progestational drugs, are medications that have been used for the management of cachexia. For this review, only the progestational drugs Megace and Megace ES will be included. Both formulations are solely indicated for the treatment of anorexia, cachexia or an unexplained, significant weight loss in patients with AIDS.

Utilization for the class was reviewed. In a three-month period, there were 35 claims with 17 percent being for drugs on the PDL. The committee discussed the low utilization of drugs on the PDL. It appears that tablet formulations were preferred over suspension formulations. At the last review, a motion for class effect passed unanimously.

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

Public Comments for Endocrine/Metabolic: Growth Hormones (Blue Class)

DR. ANTHONY HOOVLER, a representative of Novo Nordisk, discussed Norditropin. Growth hormone deficiency is a chronic condition for which daily injections are required for many years. This

therapy is difficult for patients, families, and providers. There are several growth hormone products, all of which contain the Somatropin molecule. Norditropin was approved in 1987 and has six approved pediatric indications, which were reviewed. In December 2016, two warnings and precautions were added to the Norditropin label, as well as those of other growth hormone products. These include possible hypersensitivity reactions and hypoadrenalism. The active ingredient in all approved growth hormone therapies is Somatropin. However, excipients may differ. The recommending dosages for all indications are outlined in the PI. Growing hormone therapy for children is usually a weight-based dosing regimen. Norditropin is available in four prefilled multi-dose flexpro pens with single doses as small as 0.25 milligrams or as large as 8 milligrams that can be delivered via a single injection. Several studies and their outcomes were reviewed. Novo Nordisk offers a training and education service program called NordiCare.

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Growth Hormone Agents. Growth hormone deficiency (GHD) results from inadequate production of growth hormone and can produce various medical conditions dependent on age. Adults with GHD may have diminished lean body mass, poor bone density, and a number of physical and psychological manifestations. It can be congenital or acquired in childhood or adult life, in addition to being partial or complete. The condition is usually permanent and may be an isolated deficiency or occur in association with deficiencies of other pituitary hormones. In most cases, the diagnosis should be based on result of provocative tests as recommended by the Pediatric Endocrine Society. The 2009 American Association of Clinical Endocrinologists Guidelines for Clinical Practice indicates no evidence exists to support any specific growth hormone product over another.

Prader-Willi Syndrome (PWS) is a genetic disorder in which several genes on chromosome 15 are missing or unexpressed on the paternal chromosome. It is characterized by hyperphagia and food preoccupations, as well as small stature and mental retardation. The major manifestations are neurobehavioral and endocrine abnormalities, hypothalamic obesity, hypotonia, short stature, developmental delay, and aspects of hypothalamic endocrine dysfunction and pubertal delay or absence. In some cases, the impaired GH secretion, which can persist into adulthood, may be the result of hypothalamic dysfunction. Daily growth hormone injections support linear growth, increased muscle mass, and may lessen food preoccupation and weight gain in patients.

Children with chronic renal insufficiency (CRI) may have difficulty attaining a normal height and weight for several reasons including malnutrition, renal osteodystrophy, electrolyte, calcium and vitamin D imbalances, inadequate use of protein by the body, and abnormalities in the growth hormone-insulin-like growth factor axis.

Babies born small for gestational age (SGA) is defined as babies with birth weights that fall below the tenth percentile for that gestational age. Typically, intrauterine growth retardation is the causative factor. Although the majority of these children catch up during the first two years of their life, approximately 10 percent do not. Growth hormone levels in these children may be low or within normal range. Decreased growth may be due to insensitivity to growth hormone as well as low IGF-1 levels. It is thought that administering exogenous GH may overcome GH insensitivity.

Short stature homeobox gene (SHOX) is a gene on the X and Y chromosomes that control the formation of many body structures including the growth and maturation of bones in the arms and legs. Patients with this deficiency may present with a broad phenotypic spectrum ranging from isolated short

stature with no distinguishing clinical features to short stature with moderate to severe skeletal dysplasia. Approximately 2-3 percent of patients with clinical features consistent with idiopathic short stature may test positive for SHOX deficiency.

In patients with Turner Syndrome (TS), female sexual characteristics are present but are underdeveloped due to chromosomal abnormalities. At least 95 percent of all patients with TS have short stature, which is characterized by mild intrauterine growth retardation, slow growth during infancy, delayed onset of the childhood component of growth, and growth failure. These factors lead to a diminished final height, which can be positively affected by growth hormone therapy.

Idiopathic short stature (ISS) is a condition in which the height of an individual is more than a 2 standard deviation score below the corresponding mean height for a given age, sex, and population group without evidence of systematic, endocrine, nutritional, or chromosomal abnormalities. ISS is defined as height standard deviation of less than or equal to -2.25. Children with ISS have normal birth weights and are GH sufficient.

Short bowel syndrome (SBS) is a malabsorption disorder caused by either the surgical removal of the small intestine or the loss of its absorptive function due to various diseases. Intestinal mucosa contains receptors for growth hormone and for the IGF-1, which is known to mediate many of the cellular actions of growth hormone. In human clinical studies, the administration of growth hormone enhanced the transmucosal transport of water, electrolytes, and nutrients. Zorbtive is indicated for the treatment of SBS in patients receiving specialized nutritional support.

Noonan Syndrome (NS) is a congenital disorder that includes heart malformation, short stature, indentation of the chest, learning disabilities, impaired blood clotting, and a certain configuration of facial features. Short stature is present in as many as 80 percent of patients. Growth hormone has been used successfully to correct short stature associated with the disorder.

Updated information for drugs in the class were reviewed. Somatropin (Zomacton) is indicated as replacement of endogenous growth hormone in adults and pediatric patients with GH deficiency. Treatment of pediatric patients with growth failure due to idiopathic short stature, short stature homeobox-containing gene, Turner syndrome, and small for gestational age with no catch-up growth by 2 to 4 years of age. Recommended dosing was reviewed. This requires refrigeration before and after reconstituting. Zomacton is available in vials. Somatropin (Norditropin Flexpro/Nordiflex) is indicated for pediatric patients with idiopathic short stature and growth failure due to Prader-Willi syndrome. Dosing recommendations were reviewed. Norditropin requires refrigeration. It is available in prefilled pens of varying dosages.

Utilization for the class was reviewed. In a three-month period, there were 3,893 dosing-unit claims with 91.7 percent being for drugs on the PDL. At the last review, a motion for class effect passed unanimously.

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

The committee took a 10-minute break

Dr. Demain called the meeting back to order and noted that he has completed his second three-year term as chairman of the Alaska Medicaid Pharmacy & Therapeutics Committee. This will be his last meeting as the chair, but he looked forward to the growth of the committee.

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

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

There were no public testimonies.

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Androgenic Agents, Topical. Male hypogonadism is caused by insufficient production of testosterone and characterized by low serum concentrations. It may present as testosterone deficiency, infertility, or both. Approximately 20 percent of men ages 60 to 69 years old and 30 percent of men 70 to 79 years old have serum testosterone levels below the normal range. 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.

Treatment guidelines from the American Urological Association (AUA) and the Endocrine Society were reviewed.

Utilization for the class was reviewed. In a three-month period, there were 77 claims with 49.4 percent being for drugs on the PDL. At the last review, a motion for class effect passed unanimously.

DR. (UNIDENTIFIED) MOVED A CLASS EFFECT. SECONDED BY DR. (UNIDENTIFIED). THE MOTION PASSED UNANIMOUSLY.

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

There were no public testimonies.

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. Osteoporosis affects approximately 10 million Americans with an additional 43 million having low bone mass, placing them at increased risk. As many as one in two women and one in five men are at risk for an

osteoporosis-related fracture during their lifetime. One in four men in the U.S. over the age of 50 will have an osteoporosis-related fracture. Osteoporosis is common in all racial groups, but it is most common in Caucasians. There are three categories of osteoporosis: postmenopausal, age-related, and secondary osteoporosis. Secondary osteoporosis is caused by medications or specific disease states.

Treatment guidelines from the North American Menopause Society (NAMS), the National Osteoporosis Foundation (NOF), the American Association of Clinical Endocrinologists (ACE), and the American College of Endocrinology (ACE) were reviewed. Updated guidelines from the U.S. Preventative Services Task Force (USPSTF), the American College of Physicians (ACP), and the International Osteoporosis Foundation (IOF) were reviewed.

Updated information for drugs in the class were reviewed. Denosumab (Prolia) is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture or multiple risk factors for fracture or in patients who have failed or are intolerant to other osteoporosis therapies. It is indicated for the treatment of osteoporosis associated with newly initiated or sustained systemic glucocorticoid therapy in men and women at high risk for fractures. It is also indicated for the treatment of bone loss in men with prostate cancer on androgen deprivation therapy, bone loss in women undergoing breast cancer therapy with adjuvant aromatase therapy, and for increased bone mass in men diagnosed with osteoporosis and a high fracture risk who have failed or are intolerant to other potential therapies. Dosing recommendations were reviewed. Limitations include its pregnancy category X, an active REMS program to mitigate the risk of hypocalcemia, osteonecrosis of the jaw, atypical femoral fractures, serious infections, and dermatologic reactions. It is available in a prefilled syringe formulation.

In response to Dr. Demain, Dr. Patel said the guidelines do not prefer one medication over another when treating osteonecrosis of the jaw.

Dr. Patel noted that this class had been previously grouped with the oral bisphosphonates. At the last review, a motion for therapeutic alternatives to include one non-daily bisphosphonate and one parathyroid hormone analog passed unanimously.

The committee discussed potential motions as the class was different than at the last review. The first group is IV formulations, which has not been previously reviewed. The second group includes oral bisphosphonates and sub-Q injectable preparations.

DR. HIESTAND MOVED A CLASS EFFECT FOR IV, BONE RESORPTION INHIBITORS. SECONDED BY DR. RUGGLES. THE MOTION PASSED UNANIMOUSLY.

DR. RUGGLES MOVED THE DRUGS IN THE BONE RESORPTION SUPPRESSION AND RELATED AGENTS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE NON-DAILY BISPHOSPHONATE AND AT LEAST ONE PARATHYROID HORMONE ANALOG. SECONDED BY DR. RILEY. THE MOTION PASSED UNANIMOUSLY.

Endocrine/Metabolic: Hypoglycemics, Metformin (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Hypoglycemics, Metformin. It is estimated that 30 million Americans have diabetes, of which nearly 95 percent have Type 2.

Diabetes is responsible for an increased risk of 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.

Treatment guidelines from the American Diabetes Association (ADA), the American Academy of Clinical Endocrinologists (AACE), the American College of Endocrinologists (ACE), and the American College of Physicians (ACP) were reviewed.

Utilization for the class was reviewed. In a three-month period, there were 4,473 claims with 99.8 percent being for drugs on the PDL. At the last review, a motion for class effect passed unanimously.

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

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

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Alpha-Glucosidase. Utilization for the class was reviewed. In a three-month period, there were 11 claims with 100 percent being for drugs on the PDL. At the last review, a motion for class effect passed unanimously.

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

Public comments for Endocrine/Metabolic: Hypoglycemics, SGLT2 (Red Class)

MAE QUANG (ph), a representative of Janssen, discussed Canagliflozin (Invokamet). We request that Invokamet be added to the PDL due to its positive glycemic, blood pressure, weight, cardiovascular and renal benefits seen in clinical trials. Several trials and their outcomes were reviewed. The guidelines position SGLT2 inhibitors as second in line therapy, after Metformin, for diabetic patients. With the totality of evidence and support of a positive risk benefit profile for Canagliflozin, we request that the committee consider adding it to the PDL as a preferred agent.

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Hypoglycemics, SGLT2. A new MedWatch Safety Alert was issued in August 2018 for SGLT2 inhibitors for diabetes. The FDA is warning that cases of rare but serious infection of the genitals and area around the genitals have been reported with the class of Type 2 diabetes and patients taking SGLT2 inhibitors. Patients should seek medical attention immediately if they experience symptoms of tenderness, redness, or swelling of the genitals or the area from the genitals back to the rectum and have a fever above 100.4 degrees Fahrenheit. Health care professionals should assess patients for Fournier's gangrene if they present with the symptoms described. If Fournier's gangrene is suspected, physicians should start treatment immediately with broad-spectrum antibiotics and surgical debridement if necessary. They should also discontinue the SGLT2 inhibitor, closely monitor blood glucose levels, and provide appropriate alternative therapy for glycemic control. Both patients and health care professionals are encouraged to

report adverse events or side effects to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

There are three new medications in the class. Ertugliflozin (Steglatro) is indicated as adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes. Ertugliflozin/Metformin (Segluromet) is indicated as adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes who are not adequately controlled on a regimen containing Ertugliflozin or Metformin, or in patients who are already treated with both Ertugliflozin and Metformin. Ertugliflozin is not recommended in patients with moderate renal impairment and is contraindicated in patients with Ertugliflozin/Metformin in patients with eGFR greater than 30 milliliters. Erugliflozin/Sitagliptin (Steglujan) is indicated as adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes who are not adequately controlled. It is not recommended for use in pregnancy during the second and third trimesters. No information is available regarding safety and efficacy in patients under 18 years of age. Ertugliflozin is not recommended in patients with moderate renal impairment.

Utilization for the class was reviewed. In a three-month period, there were 347 claims with 58.2 percent being for drugs on the PDL. At the last review, a motion for class effect passed unanimously.

DR. RUGGLES MOVED A CLASS EFFECT. SECONDED BY DR. HIESTAND.

In response to Dr. Riley, Dr. Narus said Invokamet was currently a non-preferred agent on the PDL. The other two products are available via the interim prior authorization process. Drugs that are FDA approved and have an NEC on file with the FDA and that have FDA approval either through an ANDA, an NDA or a BLA and participate in the National Drug Rebate/Medicaid Drug Rebate Program are available through the program. New drugs that have not yet been placed on the PDL are generally available through the prior authorization process. Products that are preferred on the PDL generally do not have as many utilization edits. Non-preferred products on the PDL are generally available through the medically necessary clause. However, there are some products, due to review by the Drug Utilization Review Committee, that do apply specific clinical criteria.

THE MOTION PASSED UNANIMOUSLY.

Endocrine/Metabolic: Hypoglycemics, Meglitinides (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Hypoglycemics, Meglitinides. Utilization for the class was reviewed. In a three-month period, there were 4 claims with none being for drugs on the PDL. At the last review, a motion for class effect passed unanimously.

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

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

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Thiazolidinedione (TZD) and Combinations. Utilization for the class was reviewed. In a three-month period, there were 317 claims with 95.9 percent being for drugs on the PDL. At the last review, a motion for class effect passed unanimously.

DR. HIESTAND MOVED A CLASS EFFECT. SECONDED BY DR. RUGGLES. THE MOTION PASSED UNANIMOUSLY.

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

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Amylin Analogues. Utilization for the class was reviewed. In a three-month period, there were 891 claims with 91.8 percent being for drugs on the PDL. At the last review, a motion for class effect passed unanimously.

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

Public comments on Endocrine/Metabolic: Hypoglycemics, Dipeptidyl Peptidase-4 Inhibitors (DPP-4) and Combinations (Red Class)

There were no public testimonies.

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Hypoglycemics, Dipeptidyl Peptidase-4 Inhibitors (DPP-4) and Combinations. The new medication in this class is Saxagliptin/Dapaglifozin (Qtern). It is indicated as adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes with inadequate control with Dapagliflozin or who are already treated with Dapagliflozin and Saxagliptin. This drug should only be administered in patients who tolerate Dapagliflozin 10-milligram. Dosing recommendations were reviewed. Qtern is contraindicated in patients with moderate to severe renal impairment, end-stage renal disease, or dialysis due to the SGLT2 inhibitor component. Patients should be monitored for UTIs and treated promptly. Fatal cases of ketoacidosis have been reported in patients taking Dapagliflozin. Discontinue use if ketoacidosis is suspected and promptly assess and provide treatment. Prior to starting Saxagliptin/Dapagliflozin (Qtern) consider predisposing factors for ketoacidosis such as pancreatic insulin deficiency, caloric restriction, and alcohol abuse. Qtern should not be used in patients with active bladder cancer and it is not recommended for pregnant women during their second and third trimester.

Utilization for the class was reviewed. In a three-month period, there were 1,167 claims with 91.3 percent being for drugs on the PDL. At the last review, a motion for class effect passed unanimously.

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

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

DR. ANTHONY HOOVLER, a representative of Novo Nordisk, discussed Ozempic. It is the newest once-weekly GLP-1 receptor agonist and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes. Similar to other longer-acting GLP-1 receptor agonists, there is a boxed warning regarding a potential risk of thyroid C-cell tumors. Patients with personal or family histories of medullary thyroid pancreatitis in patients with MN2 should not use Ozempic. As with all GLP-1 receptor agonists, the Ozempic label includes warnings and precautions

regarding pancreatitis. Discontinue Ozempic if pancreatitis is suspected and do not restart if confirmed. GI side effects were the most commonly reported adverse events with Ozempic. Please refer to the PI for complete safety information. The safety and efficacy of Ozempic has been established in the Sustain Clinical Development Program, which is a comprehensive program enrolling more than 8,000 adults with Type 2 diabetes. Several studies and their outcomes were reviewed. Cardiovascular safety information is included in the label with data from the Sustain 6 Trial. Ozempic is available in a one-pen carton for initial titration and a 0.5-milligram to 1-milligram weekly dose in a two-pen carton for maintenance. Needles are included in the packaging so there is no need for an additional prescription. We request that Ozempic be added to the PDL.

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Hypoglycemics, Glucagon-like Peptide-1 (GLP-1) and Combinations. The new medication in this class is Ozempic. It is indicated as adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes. Dosing recommendations were reviewed. Ozempic has not been studied in patients with a history of pancreatitis. It is contraindicated in patients with a personal or family history of medullary thyroid carcinoma and in patients with multiple endocrine neoplasia syndrome Type 2. Ozempic is available in prefilled multidose pens.

Utilization for the class was reviewed. In a three-month period, there were 891 claims with 91.8 percent being for drugs on the PDL. At the last review, for class effect passed unanimously.

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

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

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Rapid-Acting Insulins. Utilization for the class was reviewed. In a three-month period, there were 1,596 claims with 69.2 percent being for drugs on the PDL. At the last review, a motion for class effect passed unanimously.

Dr. Demain pointed out that in previous reviews, the insulins were combined and not broken out. Also in the past, consideration was given to hospital protocols for sliding scales to ensure the same medications were available when patients transitioned out of the hospital. The committee discussed the grandfathering clause and the medically necessary clause.

DR. (UNIDENTIFIED) MOVED A CLASS EFFECT. SECONDED BY DR. RUGGLES. THE MOTION PASSED UNANIMOUSLY.

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

There were no public testimonies.

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Regular Insulins. The new drug in the class is Insulin Human (Humulin R). It is indicated to improve glycemic control in adults and children with diabetes mellitus. It is for use in patients requiring daily doses of less than 200 units. Dosing recommendations were reviewed. Humulin R should be administered 30 minutes prior to mealtime. It is available in three strengths in vials and a prefilled pen.

Utilization for the class was reviewed. In a three-month period, there were 13 claims with none being for drugs on the PDL.

DR. RUGGLES MOVED A CLASS EFFECT. SECONDED BY DR. HIESTAND. THE MOTION PASSED UNANIMOUSLY.

Endocrine/Metabolic: Intermediate Insulins (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Intermediate Insulins. Utilization for the class was reviewed. In a three-month period, there were 123 claims with 100 percent being for drugs on the PDL.

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

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

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Regular/Intermediate-Acting Combination Insulins. Utilization for the class was reviewed. In a three-month period, there were 52 claims with 73.1 percent being for drugs on the PDL.

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

Public comments for Endocrine/Metabolic: Regular/Intermediate-Acting Combination (Green Class)

There were no public testimonies.

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Regular/Intermediate-Acting Combination Insulins. Utilization for the class was reviewed. In a three-month period, there were 86 claims with 100 percent being for drugs on the PDL.

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

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

DR. ANTHONY HOOVLER, a representative of Novo Nordisk, discussed Tresiba, a long-acting basal insulin analogue indicated to improve glycemic control in adults and children with diabetes. Earlier this year, the Tresiba label was updated to include the DEVOTE trial. The primary objective of the trial was to evaluate cardiovascular safety. The primary endpoint was achieved as the incidence of major adverse cardiovascular events in patients treated with Tresiba was similar to that of those treated with glargine U100. The DEVOTE trial and its outcomes was further reviewed. For additional safety information, please refer to the PI. Earlier in the meeting, Dr. Demain had a question regarding the health economics of Tresiba. As the product is relatively new to the market, there is not a lot of real-

world data in U.S. populations. However, there was a publication by Weatherall and Current Medical Research and Opinion from last year that is an impact model for commercially-insured patients with Type 1 and Type 2 diabetes comparing Tresiba with glargine. Overall, there was a 3.5 percent cost savings with Tresiba versus glargine. However, the model was based on a commercially-insured population and adults only. The challenges of doing studies for Medicaid-patient populations was discussed. However, Tresiba has the greatest breadth of approved indications in adults and children.

Dr. Demain noted that there were several letters submitted in support of including Tresiba on the PDL.

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Long-Acting Insulins. The updated formulation for Toujeo Solostar was reviewed. It is indicated to improve glycemic control in adults and children with diabetes. It is available in 1.5-milliliter and 3-milliliter prefilled SoloStar pens. The 3-milliliter prefilled SolorStar pen is recommended for patients requiring at least 20 units per day. Patients with visual impairments that rely on audible clicks should use caution when using this formulation.

Utilization for the class was reviewed. In a three-month period, there were 2,725 claims with 95.4 percent being for drugs on the PDL. At the last review, a motion for class effect to include a pen for the rapid-acting insulins passed unanimously.

Dr. Ruggles said there was discussion at the last review about including Tresiba on the PDL due to its pediatric outreach. Dr. Erin Narus said the state considered that discretion in light of the motion. Dr. Demain said endocrinologists have endorsed Tresiba because they believe it improves patient quality of life and reduces hospitalization and hypoglycemic events. If Tresiba is currently on the PDL, but if the committee specifically wants it to remain on the PDL then it must be included in the motion.

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

Public comments for Endocrine/Metabolic: Phosphate Binders (Blue Class)

There were no public testimonies.

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Phosphate Binders. Chronic kidney disease (CKD) affects approximately 30 million American in the U.S. As kidney function deteriorates, the ability to eliminate phosphorus declines, resulting in hyperphosphatemia. Elevated levels of phosphorus inhibit the conversion of 24-hydroxyvitamin D to 1,25- hydroxyvitamin D (calcitriol). The reduction in calcitriol decreases intestinal absorption of calcium and eventually leads to hypocalcemia. In end stage renal disease, patients are at risk for several complications of hyperphosphatemia, including the development of renal bone disease, extraosseous calcifications of soft tissue, and vasculature. Hyperphosphatemia is also associated with increased risk of death. Direct stimulators of parathyroid hormone (PTH) secretion include hypocalcemia, low levels of calcitriol, and hyperphosphatemia. Secondary hyperparathyroidism contributes to abnormal bone metabolism. Management of renal osteodystrophy includes maintenance of calcium and phosphate balance, vitamin D supplementation, reduction of patient exposure to aluminum, and, in some cases, parathyroidectomy.

Treatment guidelines from the National Kidney Foundation and the Kidney Disease: Improving Global Outcomes Foundation were reviewed.

Updated information for Ferric Citrate (Auryxia) was reviewed. It has a new indication for iron replacement product for the treatment of iron deficiency anemia in adults with chronic kidney disease and not on dialysis.

Utilization for the class was reviewed. In a three-month period, there were 150 claims with 64 percent being for drugs on the PDL. At the last review, a motion for therapeutic alternatives passed unanimously.

DR. RUGGLES MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. HIESTAND. THE MOTION PASSED UNANIMOUSLY.

5. Review of Minutes from January 2018 Meeting

This item was not addressed.

6. Comments from Committee Members or Chair

Dr. Demain thanked everyone for their participation in the meeting. The next meeting will be in November 16, 2018.

Dr. Erin Narus thanked Dr. Demain for his service on the Alaska Medicaid Pharmacy and Therapeutics Committee and hoped that he would continue to be available for consultation on Medicaid-related issues in the future. Under Dr. Demain's leadership, we have continued to maintain fiscal responsibility and provided access to a wide variety of medications through the management and recommendations of the Pharmacy & Therapeutics Committee.

Dr. Demain thanked Dr. Erin Narus for her kind remarks, as well as everyone who has participated in the meetings over his tenure as chairman of the Alaska Medicaid Pharmacy and Therapeutics Committee.

7. Adjournment

The next meeting is scheduled for November 16, 2018.

The meeting moved into executive session.