ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE
(ZOOM MEETING)

Location of Meeting
Teleconference, Anchorage, Alaska

MINUTES OF MEETING
November 20, 2020
8:00 a.m.

Committee Members Present:
Jenna Hiestand, Chair, MD
Robert Carlson, MD
Jonathan Harrison, PharmD
Diane Liljegren, R.Ph.
Claudia Phillips, MD
John Riley, PA
Trish White R.Ph.

Committee Members Absent:
Vincent Greear, R.Ph.
Sarah Dorah-Atchison, PharmD
Charles Ryan, MD

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

1. Call to Order – Chair

Dr. Semling introduced new committee member Dr. Jonathan Harrison, the pharmacy manager at Anchorage Neighborhood Health.

Dr. Hiestand called the meeting to order at 8:06 a.m.

2. Roll Call

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

3. Public Comments - Local Public/Health Practitioners

There were no public comments.

4. Class Review, Discussion & Vote

4-A. Cystic Fibrosis: CFTR Potentiator Agents (Blue); Antibiotics, Inhaled (Green); Pancreatic Enzymes (Green)

Public Comments for Cystic Fibrosis: CFTR Potentiator Agents (Blue Class)

LISA ALLEN, a representative of Vertex Pharmaceuticals, discussed Trikafta and Kalydeco. On November 18, the FDA approved a label update for Trikafta for use in patients with moderate hepatic impairment. Use is not recommended in patients with moderate hepatic impairment and should only be considered when there is a clear medical need, and the benefits exceed the risks. Trikafta should be used with caution and at a reduced dose as described in the USPI. Liver function tests should be closely monitored in patients with mild and moderate hepatic impairment. Please see Section 2.3, 8.7, and 12.3 of the Trikafta USPI to review these label changes. On September 25, the FDA expanded the indication of Kalydeco to include patients with CF ages 4 to less than 6 months who have one mutation in the CFTR gene that was responsive to Ivacaftor based on clinical and/or in vitro assay data. Kalydeco was generally well tolerated, and the safety profile was similar to that seen in older patients. The effectiveness of Kalydeco in patients between 4 to 6 months was reviewed. There are less than 50 patients with CF between the ages of 4 to 6 months in the U.S. estimated to carry one of these approved CFTR mutations. The committee was encouraged to review all of the data provided on the four CFTR modulators. Several studies and their outcomes were reviewed. We request the committee update the education and clinical policy for Kalydeco to include the newly eligible members from ages 4 to less than 6 months old, and to maintain the CFTR modulators on the PDL in accordance with their FDA approved indications.

Dr. Umang Patel gave the Magellan presentation on Cystic Fibrosis: CFTR Potentiator Agents. Cystic Fibrosis (CF) is a serious autosomal recessive multiorgan disorder. It affects about 30,775 children and adults in the U.S. and is the most common fatal genetic disease in Caucasians. The median survival in patients with CF is 47.4 years with 80% of patients reaching adulthood. In 2018, adults comprised approximately 55% of the CF population; while in 1988, they comprised approximately 31%. Mutations lead to the disease of the exocrine gland function, resulting in the formation of thick mucus that builds up in the lungs, GI tract, and other parts of the body. CF transmembrane conductance regulator (CFTR) functions as a chloride channel, and mutations in it can result in abnormalities of chloride transport across epithelial cells on mucosal surfaces. Primary treatment goals include maintaining lung function by controlling infection and clearing mucus in the airway; maintaining appropriate growth by providing nutritional support; and managing disease complications.

Guidelines for cystic fibrosis from the Cystic Fibrosis Foundation, 2013, and the Clinical Pharmacogenetics Implementation Consortium, 2014 were provided.

In August 2020, the FDA expanded indications for Kalydeco for the treatment of cystic fibrosis in patients ages 4 to less than 6 months of age and weighing more than 5 kilograms or more who have more than one mutation in the CFTR gene that is responsive to Ivacaftor based on clinical and/or in vitro assay data. Previously, it was only approved in patients 6 months of age or older. Dosage recommendations were reviewed. This medication is pregnancy category B. There is no dose adjustment recommended for mild to moderate renal impairment. There are no studies for moderate to severe renal impairment. It is available as tablets and oral granules in unit-dose packets.

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

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO BE USED APPROPRIATELY. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

Cystic Fibrosis: Antibiotics, Inhaled (Green Class)

Dr. Umang Patel gave the Magellan presentation on Cystic Fibrosis: Antibiotics, Inhaled. The utilization report was reviewed, and 0% of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

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

Cystic Fibrosis: Pancreatic Enzymes (Green Class)

Dr. Umang Patel gave the Magellan presentation on Cystic Fibrosis: Pancreatic Enzymes. The utilization report was reviewed, and 94.7% of the prescriptions were for preferred products. At the last review, a motion for class effect passed unanimously.

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

4-B. Central Nervous System: Multiple Sclerosis Agents (Red); Stimulants & Related Agents (Green); Sedative Hypnotics (Red); Anticonvulsants (Red); Antipsychotics - Atypical (Red); Antidepressants (Red); Alzheimer's Agents (Green)

Public Comments for Central Nervous System: Multiple Sclerosis (Red Class)

SHIRLEY QUACH, a representative of Novartis, discussed Kesimpta, which was approved by the FDA in August 2020 for the treatment of relapsing forms of MS, or RMS, to include clinically isolated syndromes, relapsing-remitting disease, and active secondary progressive disease in adults. It is the first fully human anti-CD20 monoclonal antibody for targeted B cell therapy in RMS and offers the advantage of being self-administered as compared to other anti-CD20 monoclonal antibodies that are administered by IV infusion. Despite multiple disease modifying therapies available for the treatment of MS, there remains no standard treatment guidelines and providers tend to make trade-offs between efficacy and safety when choosing which agent to use. Kesimpta offers providers a highly efficacious MS agent with a favorable safety profile via a monthly self-administered injection. Several trials and their outcomes were reviewed. Kesimpta has the power, precision, and flexibility to help MS patients control their disease and offers a highly efficacious self-administered B cell therapy with a good safety profile. We request that Kesimpta be added to the PDL.

LYNDA FINCH, a representative of Biogen, discussed Vumerity (Diroximel Fumarate). It was approved by the FDA on October 30, 2019, for the treatment of relapsing forms of MS to include clinically isolated syndrome, relapsing-remitting MS, and active secondary progressive MS in adults. Its distinct chemical structure was reviewed. Due to its bioequivalence to Tecfidera, we can expect to see the same efficacy and safety profile as Tecfidera. It also carries the same warnings and precautions on its label. However, Vumerity has demonstrated an improved GI tolerability profile compared to Tecfidera in a study published in January 2020. Several studies and their outcomes were reviewed. While Tecfidera had only a 4% discontinuation rate in clinical studies, we see rates of 20% in the real-work settings. While GI events resolve in the first month or two for most patients, there are patients who suffer prolonged GI intolerability. This is a progressive illness, and it is important to have access to medications that are both efficacious and tolerable to maintain adherence and prevent relapses in disability progression. We request that you consider adding Vumerity to the PDL as an option for your patients with relapsing forms of MS.

KYLE DOWNEY, a representative of Genentech, discussed Ocrevus, which has been reviewed by the committee in the past. Ocrevus is indicated for both the treatment of relapsing-remitting and primary progressive MS. It is the first and only therapy to be approved for PPMS. Several trials and their outcomes were reviewed. We request that Ocrevus be added to the PDL because it is the only agent to be approved for both PPMS and RMS, the open line extension studies have demonstrated that patients started on Ocrevus had less disability and annualized relapse rates, and real-world data has demonstrated that patients have better adherence and persistency overall when using Ocrevus.

Dr. Hiestand asked if Ocrevus had been associated with PML. Kyle Downey said there was a warning box for PML and referred the committee to the data submitted and the USPI. He would also be happy to follow-up with the committee regarding the PML patient population.

WENDY BIBEAU, a representative of BMS, discussed Zeposia, a once-daily S1P receptor modulator. Zeposia was approved in the U.S. in March 2020 for the treatment of relapsing forms of MS including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults. Several studies and their outcomes were reviewed. Additional information is reported in corresponding peer-reviewed publications and the PI. Zeposia is a once-daily oral capsule. It is the only S1P modulator that does not have a first dose observation. In addition, it does not require generic testing prior to initiation. Based on the clinical evidence and the key attributes described, we request that Zeposia be added to the PDL.

Dr. Umang Patel gave the Magellan presentation on Central Nervous System: Multiple Sclerosis. Multiple sclerosis (MS) is a complex human autoimmune-type inflammatory disease of the central nervous system. More than 2.3 million people worldwide have MS, 1 million of which are in the U.S. Multiple sclerosis occurs most commonly in Caucasians, with rare cases in African-Americans and Asian-Americans. Although the etiology is predominantly unknown, it is characterized pathologically by demyelination and subsequent axonal degeneration. The nerve degeneration associated with MS can result in a wide variety of symptoms, including sensory disturbances in the limbs, optic nerve dysfunction, ataxia, fatigue, as well as bladder, bowel, and sexual dysfunction. Severe cases may result in partial or complete paralysis. While cognitive impairment occurs in approximately 50% of people with MS, only 10% experience serious intellectual deterioration. MS can be categorized as either relapsing-remitting MS (observed in 85% to 90% of patients) or primary progressive MS (observed in

10% of patients). Relapses or "attacks" typically present sub acutely, with symptoms developing over hours to several days, persisting for several days or weeks, and then gradually dissipating.

MS can fall into one of the following categories, with the potential to progress from less severe to more serious types. Clinically isolated syndromes (CIS) are the first episode of neurologic symptoms due to inflammation or demyelination lasting at least 24 hours. Patients with MRI-detected brain lesions consistent with MS are at high risk of developing MS. Relapsing-remitting MS (RRMS) is clearly defined, self-limited attacks of neurologic dysfunction, followed by periods of remission without disease progression. Most patients experience a recovery of function that is often, but not always, complete. Primary progressive MS (PPMS) with a nearly continuous worsening of disease not interrupted by distinct relapses. Some of these individuals have occasional plateaus and temporary minor improvements. Lastly, secondary progressive MS (SPMS) is a relapsing-remitting disease course at onset, followed by progression with or without occasional relapses, minor remissions, and plateaus. Most patients eventually convert to progressive MS.

The American Academy of Neurology, 2019, issued updates to their guidelines related to vaccinations, which were reviewed.

In December 2019, Fingolimod was approved by the FDA in 0.5 milligram capsules as a first-time generic of Gilenya. The launch is not expected due to litigation. Biocon and Sun have agreed not to launch their generic capsules until decisions by the patent office or the court. HEC's launch is currently blocked to an injunction.

In November 2019, Vumerity was approved by the FDA for the treatment of relapsing forms of MS to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults. For patients with lymphopenia, obtain a CBC including lymphocyte count before initiating, after six months, and every six to 12 months thereafter. Consider interruption if lymphocyte count is less than .5 X 10^9 per liter and persists for more than six months. For patients with anaphylaxis and angioedema, discontinue and do not restart treatment. For patients with liver injury, obtain serum aminotransferase, alkaline phosphatase, and total bilirubin levels before initiating and during treatment as clinically indicated. Discontinue if clinically significant liver injury induced by treatment is suspected. Dosing recommendations were reviewed. It is available as a delayed-release capsule.

In March 2020, Zeposia was approved by the FDA, an S1P receptor modulator for the treatment of relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults. Use of Zeposia may increase the risk of infections. Obtain a complete CBC before initiation of treatment. Monitor for infection during treatment and for three months after discontinuation. Do not start in patients with active injections. For patients with liver injury, discontinue if significant liver injury is confirmed. Obtain liver function tests before initiating treatment. For patients with fetal risk, women of childbearing potential should use effective contraception during treatment and for three months after stopping treatment. For patients with increased blood pressure, monitor blood pressure during treatment. Dosing recommendations were reviewed. It is available as a capsule.

In April 2020, Bafiertam was approved by the FDA for the treatment of relapsing forms of MS to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults. It is contraindicated if co-administered with Dimethyl Fumarate or Diroximel

Fumarate. For patients with anaphylaxis and angioedema, discontinue and do not restart treatment. For patients with progressive multifocal leukoencephalopathy (PML), without treatment at the first sign or symptom suggestive of PML. For patients with herpes zoster and other serious opportunistic infections, consider withholding treatment in cases of serious infection until the injection has resolved. For patients with lymphopenia, obtain a CBC including lymphocyte count before initiating treatment, after six months, and every six to 12 months thereafter. Dosing recommendations were reviewed. It is available in a delayed-release capsule.

In August 2020, the FDA approved the first generic for Biogen's Tecfidera for Mylan, which is Dimethyl Fumarate. It is indicated for the treatment of relapsing forms of MS to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults. Limitations include anaphylaxis and angioedema, PML, herpes zosters and other serious opportunistic injections. Dosing recommendations were reviewed. It is available as a delayed-release capsule.

In August 2020, the FDA approved a new indication for Kesimpta. It also got a new brand name to correspond with the new use. It is indicated for the treatment of relapsing forms of MS to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults. For patients with infections, delay treatment administration until the injection has resolved. Vaccination with live-attenuated or live vaccines is not recommended during treatment. For patients with injection-related reactions, management depends on the type and severity of the reaction. For patients with reduction in immunoglobulins, monitor the level at the beginning, during, and after discontinuation of treatment until B-cell repletion. Consider discontinuing if patient develops a serious opportunistic injection or recurrent injections if immunoglobulin levels indicate immune compromise. Kesimpta may cause fetal harm based on animal data. Advise females of reproductive potential of the potential risk to a fetus and to use an effective method of contraception during treatment and for six months after stopping treatment. Dosing recommendations were reviewed. It is available as injection solution in a single-dose prefilled pen or syringe.

The utilization report was reviewed and 65.4% of prescriptions were for preferred products. At the last review, a motion of therapeutic alternatives passed unanimously.

Dr. Hiestand wondered if the medication indicated for primary progressive MS should be included in the motion. Dr. Liljegren said primary progressive MS was rare. Physicians can use the medically necessary clause or go through the DUR Committee.

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

Central Nervous System: Stimulants and Related Agents (Green Class)

Dr. Umang Patel gave the Magellan presentation on Central Nervous System: Stimulants and Related Agents. The utilization report was reviewed and 98% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include at least one oral preparation, one extended-release preparation, one non-stimulant preparation, one alpha agonists, and one orally disintegrating preparation or liquid passed unanimously.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE ORAL PREPARATION, ONE EXTENDED-RELEASE PREPARATION, ONE NON-STIMULANT PREPARATION, ONE ALPHA AGONIST, AND ONE ORALLY DISINTEGRATING PREPARATION OR LIQUID. SECONDED BY MR. RILEY. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Central Nervous System: Sedative Hypnotics (Red Class)

There were no public testimonies.

Dr. Umang Patel gave the Magellan presentation on Central Nervous System: Sedative Hypnotics. Insomnia is a complex symptom that comprises difficulties falling asleep, staying asleep, or non-refreshing sleep in combination with daytime dysfunction or distress. The symptom complex can be an independent disorder (primary insomnia) or the result of another condition (secondary insomnia). Insomnia is commonly divided into three types based on duration. Transient insomnia lasts up to one week and is often referred to as adjustment sleep disorder because it is caused most often by an acute situational stress, such as a test or deadline. It is often recurrent with the same or similar stresses. Short-term insomnia, by definition, lasts 1 to 6 months and is usually associated with more persistent stressful situational (death or illness) or environmental (noise) factors. Chronic insomnia is insomnia lasting more than 6 months. The incidence of insomnia in children ranges from 1-6%. In children with neurodevelopmental or psychiatric comorbidities, the incidence is as high as 50-75%. Insomnia in children may result in irritability, restlessness, lack of concentration, suicide risk, and poor memory.

Guidelines from the National Organization for Rare Disorders, 2017, and the U.S. Department of Veterans Affairs and Department of Defense, 2020, were reviewed.

In December 2019, the FDA approved Dayvigo, which is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. Dayvigo impairs alertness and motor coordination including morning impairment. Risk increases with dose and use of other central nervous system depressants. For patients taking Dayvigo, 10 milligrams, caution against next day driving and other activities requiring complete mental alertness. Sleep paralysis, hypnogogic/hypnopompic hallucinations, and cataplexy-like symptoms may occur. Behaviors including sleepwalking, sleep driving, and engaging in other activities while not fully awake may occur. Discontinue immediately if a complex sleep behavior occurs. Effects on respiratory function should be considered. Dosing recommendations were reviewed. It is available as a tablet.

The utilization report was reviewed, and 70% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

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

Public Comments for Central Nervous System: Anticonvulsants (Red Class)

DEBBIE SHEPPE, a representative of Neurelis, discussed Valtoco, which is diazepam nasal spray, was approved by the FDA in January 2020. Valtoco is indicated for the emergency rescue treatment of

episodes of frequent seizure, also known as seizure clusters, or acute or intermittent seizures. It is the first and only internasal rescue treatment for epilepsy in patients 6 years of age and older. Its efficacy was based on the relative bioavailability compared to Diastat, and Diastat's efficacy has been well established in seizure clusters. Seizure clusters affect approximately 170,000 people in the U.S., but only 20% of patients took medication in response to seizure clusters. Instead, they used more expensive treatments like emergency rooms. In Alaska, the population with seizure clusters is approximately 360 patients. People live with the burden of now knowing when their seizure clusters will occur, so the goal of rescue medication is to treat and hopefully terminate the cluster once recognized. In a recent analysis of patient diaries, the majority of seizure events within the cluster can occur 6-24 hours after the presenting seizure. Valtoco has the half-life of 49 hours, which would allow coverage within the expected 24-hour timeframe of the seizure cluster. Valtoco's proprietary formulation is called Intravail, and it increases the drug absorption across the nasal mucosa resulting in 97% bioavailability relative to IV Diazepam. There are four doses available based on the patient's age and weight. Several studies and their outcomes were reviewed. Valtoco will provide a non-invasive, on-hand rescue treatment for seizure emergencies. It is the only nasal spray indicated in patient from ages 6 years and older. In the middle of a seizure event, the FDA indicated that Valtoco provided substantial advancement to patient care. We request that Valtoco be placed on the PDL.

RAJ SANDHAR, a representative of USB, discussed Nyzilam, the first FDA-approved midazolam intranasal spray indicated for seizure clusters. Seizure clusters are acute episodes of consecutive seizures that occur with short interictal periods. Real-world evidence studies have shown that individuals suffering from seizure clusters had a five times higher rates of hospitalization, which is not related to status epilepticus, and a three-and-a-half times higher mortality risk compared to individuals with non-clustering seizures. Additionally, 30-40% of this population utilized the emergency room over a one-year period. Seizure cluster emergencies require rapid intervention to break the cluster and prevent progression to prolonged seizures or SE. Until 2019, the only FDA-approved treatment for seizure clusters was Diazepam rectal gel that less than 10% of patients reported using. Underutilization of rescue therapy can lead to potentially preventable increased use of emergency care. Using a seizure rescue therapy may also help decrease or prevent neurological damage and improve the quality of life for the patient and potentially their caregivers as well. Nayzilam nasal spray CIV is the first nasal spray indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern in patients with epilepsy, 12 years of age and older. It is the only Midazolam-based option approved for the treatment of seizure clusters. Several studies and their outcomes were reviewed. Nayzilam has a boxed warning on the risk from concomitant use with opioids, as well as other important warnings and precautions including cardiorespiratory adverse reactions, central nervous system depression from concomitant use with other CNS depressants, or moderate or strong CYP3A4 inhibitors, suicidal behavior and ideation, impaired cognitive function and glaucoma. It is contraindicated in patients with acute narrow-angle glaucoma or a hypersensitivity to Midazolam. The most common adverse reactions are somnolence, headache, nasal discomfort, throat irritation, and rhinorrhea. Epilepsy patients need open, unrestricted open access to epilepsy medications for the benefit of themselves as well as their caregivers. We request that you add Nayzilam to the PDL.

SIBIN STEPHEN, a representative of Zogenix, discussed Fintepla. Fintepla oral solution was approved by the FDA on June 25, 2020. It is indicated for the treatment of seizures associated with Dravet syndrome in patients 3 years of age and older. The tablet can be taken with or without food. Dosing recommendations, which are based on weight and taken twice daily, were reviewed. Fintepla is

available only through a restricted program called Fintepla REM Program. Several trials and their outcomes were reviewed. We request that Fintepla be included on the PDL.

Dr. Umang Patel read a letter dated November 17, 2021 from the Epilepsy Foundation of America, advocating for open access to all seizure rescue medications on the PDL because epilepsy medications are not interchangeable, and treatment of epilepsy is highly individualized.

Dr. Umang Patel gave the Magellan presentation on Central Nervous System: Anticonvulsants. Epilepsy is one of the most common disorders of the central nervous system (CNS). It is defined when a person has two or more seizures. It affects approximately 2.2 million Americans, with 150,000 new cases diagnosed each year. The risk is estimated to be 1% from birth to 20 years of age, and 3% at 75 years of age. Isolated seizures may also occur during a febrile illness, after head trauma, or as a result of withdrawal from alcohol or sedative/hypnotics. A seizure is traceable to an unstable cell membrane or cluster of cells. Excessive excitability spreads either locally (partial seizure) or more widely (generalized seizure). Partial seizures begin in one hemisphere of the brain. Unless they become secondarily generalized, they can cause alterations in motor functioning, sensory symptoms, or automatisms. If there is no loss of consciousness, they are called simple partial. If there is loss or impairment of consciousness, they are called complex partial. About 70% of patients with epilepsy can be maintained on one drug. Noncompliance and evolving refractory epilepsy are common reasons for treatment failure. If control is not achieved with one drug, an alternative medication should be attempted before others are added to current therapy.

Lennox-Gastaut Syndrome is one of the most severe forms of childhood epilepsy and is one of the hardest forms to treat. It is characterized by mental retardation and multiple seizure types. Patients have seizures daily, sometimes experiencing several seizures a day. They may also experience “drop attacks,” which are defined as a loss of muscle control causing the patient to fall abruptly to the floor.

Infantile spasm primarily consists of a sudden bending forward of the body with stiffening of the arms and legs. West Syndrome is characterized by infantile spasms, developmental regression, and a specific pattern on EEG testing called hypsarrhythmia, which is chaotic brain waves. The onset is usually in the first year of life, typically between 4 and 8 months and usually stops by 5 years of age but it may be replaced by other seizure types.

Dravet Syndrome is a rare, catastrophic form if epilepsy that presents in the first year of life and is characterized by frequent, prolonged seizures. Patients may experience multiple seizure types during their lifetime. Infants with Dravet syndrome often experience multiple comorbidities over their lifetime related to the persistent seizure activity, including behavioral and developmental delay. It is also associated with a 15-20% mortality rate due to Sudden Unexpected Death in Epilepsy (SUDEP).

Goals for treating epilepsy are to reduce the frequency of seizure occurrence along with providing the best possible quality of life for the patient. Treatment will depend on the type of seizure. Many classes of drugs are available to treat different forms of seizures. Some patients will require more than one drug to control their seizures.

In October 2019, the FDA expanded indications for Keppra and Keppra XR to include the treatment of partial onset seizures in patients 1 month of age or older as monotherapy. Previously, it was approved in this population for adjunctive use only.

In November 2019, the FDA approved Xcopri for the treatment of partial onset-seizures in adults. Discontinue if no alternate etiology. Use caution when administering Xcopri with other drugs that shorten the QT interval. Monitor patients for suicidal behavior and ideation. Monitor for somnolence and fatigue and advise patients not to drive or operate machinery until they have gained sufficient experience on Xcopri. Concomitant use with other CNS depressants or alcohol may have additive effects. Xcopri is a DEA designated Schedule V controlled substance. Dosage recommendations were reviewed. It is available as a tablet. Based on animal data, there can be fetal harm with Xcopri. There is a dose reduction for hepatic impairment and renal impairment. It should not be used in patients with end-stage renal disease who rare undergoing dialysis.

In December 2019, there was a voluntary recall of Levetiracetam oral solution by Lannett Company due to contamination with Bacillus subtilis. In January 2020, Taro issued a voluntary recall of one lot of Lamotrigine tablets due to cross contamination with another drug, Enalapril. In February 2020, Taro issued a voluntary recall of two lots of Phenytoin oral suspension that may not re-suspend properly upon being shaken. This is a required step in the administration process and failure of the product to properly re-suspend can lead to over or under dosing. In infants and young children, an inaccurate dose could result in serious adverse outcomes such as intoxication or breakthrough seizures. In a small portion of patients, changes in Phenytoin levels resulting in severe breakthrough seizures, may experience status epilepticus, which can be life-threatening.

In January 2020, the FDA approved Valtoco, a Diazepam nasal spray. It is a benzodiazepine for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity, such as seizure clusters and acute repetitive seizures, that are distinct from a patient's usual seizure pattern, for use in patients with epilepsy 6 years of age and older. Black warnings include concomitant use of benzodiazepines are opioids may result in profound sedation, respiratory depression, coma, and death. Dosage recommendations were reviewed. Based on animal data, Valtoco can cause fetal harm. It is available as a nose spray.

In February 2020, the FDA expanded indications for Sabril for use in patients as young as 2 years of age for refractory complex partial seizures. Previously, it was only approved in patients 10 years of age and older. It is indicated for adjunctive therapy in patients 2 years of age and older who have responded inadequately to several alternative treatments. Sabril is not indicated as a first line therapy. It is available as a tablet.

In June 2020, the FDA approved Fintepla for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older. There is an association between serotonergic drugs with 5-HT2B receptor agonist activity, including fenfluramine, and valvular heart disease and pulmonary arterial hypertension. Echocardiogram assessments are required before, during, and after treatment. It is only available through a restricted program called the Fintepla REMS Program. Dosage recommendations were reviewed. It is available as an oral solution.

In August 2020, the FDA expanded indications for Epidiolex for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex to include in patients 1 year of age or older. Previously, it was only indicated in children 2 years of age and older, and for only Lennox-Gastaut and Dravet syndromes. It is available as an oral solution.

The utilization report was reviewed, and 95% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

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

Public Comments for Central Nervous System: Antipsychotics - Atypical (Red Class)

PAUL THOMPSON, a representative of Alkermes, discussed Aristada and Aristada INITIO. There is a black boxed warning for increased mortality in elderly patients with dementia-related psychosis. Aristada is an extended-release intramuscular injectable atypical antipsychotic indicated for the treatment of schizophrenia. Aristada INITIO, in combination with a 30-milligram dose of oral Aripiprazole, is indicated for the initiation of Aristada when used for the treatment schizophrenia in adults. Dosing recommendations were reviewed. ALPINE, a new clinical study published in the Journal of Clinical Psychiatry in May 2020, and its outcomes were reviewed. The motion common adverse events with Aristada and Aristada INITIO is akathisia, with other common side effects being insomnia, headache, and injection site pain. We request that Aristada and Aristada INITIO be maintained on the PDL.

JOSH BISHOP, a representative of Abbvie, discussed Vraylar. It is a once-daily oral second-generation atypical antipsychotic. It is approved for the treatment of schizophrenia in adults, manic or mixed episodes of bipolar I disorder in adults. There is published head-to-head data showing superiority of Vraylar over Risperidone in schizophrenia patients with predominate negative symptoms. Vraylar has boxed warnings for suicidal thoughts and behaviors, and increased mortality in elderly patients with dementia-related psychosis. It also has some of the same warnings and precautions that other atypicals have. Common adverse effects include akathisia and others. Vraylar has several characteristics that distinguish it from other drugs in the class, four of which were described and include a unique pharmacologic profile, a long half-life, its metabolic profile, and it is approved for treatment of the full spectrum of bipolar I disorder including manic, mixed, and depressive episodes. We request that Vraylar be included on the PDL.

STEPHANIE YAMAMOTO, a representative of Janssen, discussed Invega Sustenna, a long-acting injectable for the treatment of schizophrenia and schizoaffective disorder. It is administered monthly and contains paliperidone palmitate, as does its three-month counterpart, Invega Trinza. There was an update to the American Psychiatric Association Guidelines this year. Notably, the recommendation for use of a long-acting injectable is not restricted to those with a history of non-adherence, but also when patients prefer it. When we consider the cost of managing schizophrenia in Medicaid patients, studies reveal a heavy cost burden driven by relapses. Over five and half years, Medicaid patients will relapse nine times on average, with a mean pool of healthcare costs per episode of over $35,000. These costs are largely driven by institutional costs including in-patient and ER visits, as well as long-term care admission. To that point, Sustenna is the only long-acting injectable antipsychotic shown to delay relapse versus oral antipsychotics in a randomized, comparative setting. Several studies and their outcomes were reviewed. We thank you for maintaining access to a comprehensive selection of effective options for Alaskans, including Invega Sustenna and Trinza.

BILL ROWE, a representative of Intra-Cellular, discussed Caplyta, an atypical antipsychotic indicated for the treatment of schizophrenia in adults. Schizophrenia is a serious illness. Several trials

and their outcomes were reviewed. Dosing recommendations were reviewed. It should be taken with food. Short-term studies have proven its efficacy with low rates of adverse events. Like other drugs in the class, it has a boxed warning for dementia in elderly patients. Please see the full prescribing information. We request that Caplyta be considered for the PDL.

Dr. Phillips said she could only find one year-long study on Caplyta looking metabolic processes. The study started out with 602 people and ended with 239 people. She questioned why two-thirds of the people quit the study. Bill Rowe said he could provide the committee with the numbers on the long-term study. The drop-out rate was comparable to other long-term open label studies. Most of the patients who dropped out withdrew their consent, not for adverse events or other issues. Information on why patients withdrew their consent could be provided to the committee.

Dr. Phillips asked if they were planning any head-to-head trials for Caplyta and other atypical drugs. Bill Rowe said there was a comparison with Risperidone in the short-term studies. He did not know of any definitive plans for head-to-head trials in schizophrenia with adults. Dr. Phillips said it would be interesting to see how Caplyta compared to Latuda, which is supposed to have a good metabolic profile. Further information can be sent directly to Magellan.

AITEN PATADIA, a representative of Otuska, discussed Abilify Mycite, an extended-release injectable suspension that is indicated for the treatment of schizophrenia and maintenance monotherapy treatment of bipolar I disorder. It was approved by the FDA as the first once-monthly, long-acting injectable for the maintenance monotherapy of bipolar I disorder in adults. Abilify Mycite is an intramuscular injection into the deltoids or gluteal and is to be administered by a healthcare professional. Several studies and their outcomes were reviewed. We request that Abilify Mycite be included on the PDL.

JOSH GETTY, a representative of Indivior, discussed Perseris, a Risperidone extended-release injectable suspension for subcutaneous use. It is indicated for the treatment of schizophrenia in adults. It is to be administered in the abdominal subcutaneous injection only and should not be administered by any other route. Each injection must be administered by a healthcare professional using the pre-packaged syringe and safety needle provided. For patients who have taken Risperidone, tolerability should be established with oral Risperidone prior to starting Perseris. Dosing recommendations were reviewed. Patients who stable on oral Risperidone doses lower than 3 milligrams a day or higher than 4 milligrams a day may not be candidates for Perseris. A loading dose of Risperidone is not needed prior to Perseris injection if the patient has already been known to tolerate Risperidone. Most common adverse reactions in clinical trials were increased weight, sedation or somnolence, and muscular skeletal pain. Several studies and their outcomes were reviewed. We request that you consider increasing access to Perseris as a way to provide prescribers additional solutions for the treatment of schizophrenia in adults.

Dr. Umang Patel gave the Magellan presentation on Central Nervous System: Antipsychotics - Atypical. Schizophrenia is the most common psychotic illness, which affects 1% of the population. Between 25% to 50% of schizophrenic patients attempt suicide, and 10% of patients succeed in their attempt. Symptoms include delusions, hallucinations, disorganized speech, disorganized or catatonic behavior, and negative symptoms, and at least 1 of these should be delusions, hallucinations, or disorganized speech.

Lifelong prevalence estimates of bipolar disorder range from 0.9% to 2.1% of the population. It is characterized by episodes of mania, depression, or a mixed state. Criterion used to diagnose bipolar I disorder is the presence of a manic episode, which is defined as persistent elevated, expansive, or irritable mood for at least one week with increased energy or activity, or a mixture feature specifier, which is rapidly alternating polarity of mood, sadness, irritability, and mania for at least one week, and three or more other characteristic symptoms. These symptoms can be inflated self-esteem or grandiosity, decreased need for sleep, more talkative than usual, pressured speech, like of ideas or feelings of racing thoughts, distractibility, increased in goal-directed activity or psychomotor agitation and excessive involvement in risky pleasurable activities.

The prevalence of Tourette's disorder is unknown, but observational studies have suggested a prevalence of 1% in school-aged children. It is a genetic tic disorder characterized by motor and vocal tics. Generally, individuals have repetitive, stereotyped movements of vocalizations such as sniffing, muscle tension, and blinking. DSM-5 criteria for Tourette's state multiple motor and at least one vocal tic is present during the illness, not necessarily simultaneously, and have been present for one year or longer, although they may wax and wane in frequency. The onset of these symptoms must occur prior to 18 years of age to be considered Tourette's disorder. Peak tic severity typically occurs between the ages of 10 and 12 years of age. Tics usually improve during adolescence, with 18% of those older than 16 years of age experiencing no tics at all, and 60% having minimal or mild tics six years after initial examination.

Guidelines from the American Academy of Child and Adolescent Psychiatry, 2013; the American Psychiatric Association, 2002; and the American Academy of Neurology, 2019, were reviewed.

In August 2019, the FDA approved Secuado as a new medication for the treatment of adults with bipolar I disorder. There is a black boxed warning of elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. It is not approved for the treatment of patients with dementia-related psychosis. It is contraindicated in patients with severe hepatic impairment. There is an increased incidence of cerebrovascular adverse reactions such as stroke and transient ischemic attacks. For patients with neuroleptic malignant syndrome, manage with immediate discontinuation and close monitoring. For patients with tardive dyskinesia, discontinue if clinically appropriate. Secuado may cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure. Dosage recommendations were reviewed. It is available in a transdermal patch.

In February 2020, the FDA approved Caplyta as an atypical antipsychotic indicated for the treatment of schizophrenia in adults. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Dosing recommendations were reviewed. It is available as a capsule. It is contraindicated for patients with hepatic impairment.

In December 2019, Fazaclo was discontinued. Based on a commercial decision, Jazz Pharmaceuticals is discontinuing all NDCs for Fazaclo, except one. In July 2020, Eli Lilly discontinued Symbyax 6/50 milligram and 12/50 milligram capsules. Distribution will continue until the end of December 2020.

Ziprasidone was approved by the FDA as the first generic for Geodon IM from Gland in January 2020. Geodon IM is no longer protected by any patent or regulatory exclusivities.

In April 2020, the FDA issued a Drug Safety Communication strengthening a warning regarding bowel concerns in patients taking Clozapine. Constipation that may occur with Clozapine can, uncommonly, progress to serious bowel complications. The FDA is advising healthcare practitioners evaluate bowel and function prior to starting Clozapine, avoid prescribing it with anticholinergics, counsel patients on the risk, evaluate bowel habits through treatment, monitor for symptoms associated with complications, and consider prophylactic laxative treatment if the patient has a history of constipation or bowel obstruction.

The utilization report was reviewed, and 90.9% of prescriptions were for preferred products. At the last review, a motion of therapeutic alternatives to include at least one oral preparation, one intramuscular injection, and two long-acting intramuscular injectables, one of which has a duration of at least four weeks, passed unanimously.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE ORAL PREPARATION, ONE INTRAMUSCULAR INJECTION, AND TWO LONG-ACTING INTRAMUSCULAR INJECTABLES, ONE OF WHICH HAS A DURATION OF AT LEAST FOUR WEEKS. SECONDED BY MR. RILEY. THE MOTION PASSED WITH DR. HARRISON NOT RESPONDING.

Break from 10:00 a.m. to 10:11 a.m.

Chairman Jenna Hiestand called the meeting back to order at 10:11 a.m. A roll call was done, and all participants were present.

Public Comments for Central Nervous System: Antidepressants (Red Class)

It was noted that Stephanie Yamamoto was having technical issues and would call back into the meeting.

Dr. Umang Patel gave the Magellan presentation on Central Nervous System: Antidepressants. Prevalence of 12-month and lifetime major depressive disorder (MDD) is approximately 17.3 million American adults or 7.3% of the U.S. population. Women experience depression more often than men. In addition, the prevalence of depression in 2017 was estimated at 3.2 million adolescents (ages 12 to 17 years). With appropriate therapy, 70-80% of patients experiencing MDD achieve response. However, as many as one-half of all patients do not experience sufficient symptom improvement with initial treatment. Among patients who remit, residual symptoms are common and associated with impaired psychosocial functioning and increased relapse rates. Until recently, known differences among antidepressant drugs were generally limited to safety and tolerability issues. However, over the past handful of years, a number of studies have emerged to evaluate possible differences among antidepressant classes in their ability to resolve specific symptoms of depression. Each of the groups of drugs in this class has a potential role in the treatment of MDD, primarily as a result of their heterogeneous spectrums of activity. As with many psychotropic drugs, patients failing to respond to one type of antidepressants may respond to a switch to, or augmentation with, an antidepressant with another mechanism of action.

Generalized Anxiety Disorder (GAD) affects about 2.7% of the adult U.S. population annually, and women are 60% more likely to be affected by anxiety over their lifetime. The disorder develops gradually and can begin across the life cycle, though the risk is highest between childhood and middle age. GAD is diagnosed when a person worries excessively about a variety of everyday problems for at least six month and are unable to get rid of their concerns, even though they usually realize that their anxiety is more intense than the situation. Physical symptoms that often accompany the anxiety include fatigue, headaches, muscle tension, muscle aches, difficulty swallowing, trembling, twitching, irritability, sweating, nausea, and hot flashes.

Social Anxiety Disorder (SAD) is the most common anxiety disorder in the U.S., affecting approximately 5.3 million people per year. It is the third most common psychiatric disorder after depression and alcohol abuse. It is characterized by a marked and persistent fear of social or performance situations in which embarrassment may occur. Women and men are equally likely to develop the disorder, which usually begins in childhood or early adolescence. Social anxiety disorder is often accompanied by other anxiety disorders or depression, and substance abuse may develop if people try to self-medicate their anxiety.

Panic Disorder is a severe, chronic anxiety disorder characterized by recurrent episodes of panic and the development of fear or anxiety regarding the possibility of future panic attacks. Incidences range between 3 to 6 million people per year with one-half to two-thirds of those affected being female. Up to 15% of the general population experiences isolated panic attacks, whereas up to 3.5% develop full panic disorder during their lifetime.

Vasomotor Symptoms (VMS) associated with menopause, such as hot flashes and night sweats, often are considered the most bothersome symptoms of menopause and affect approximately 75% of women over the age of 50 years. The Endocrine Society recommends SSRIs, SNRIs, gabapentin, or pregabalin for moderate to severe vasomotor symptoms in patients with contraindications to hormone therapy or who choose not to use hormone therapy. Paroxetine mesylate, or Brisdelle, is the only SSRI approved to treat VMS. The American Association of Clinical Endocrinologists state that therapeutic trials of nonhormonal medications may be considered for the relief of menopausal symptoms in women with no contraindications. The American College of Obstetricians and Gynecologists state SSRIs, SNRIs, clonidine, and gabapentin are effective alternatives to hormone therapy for the treatment of VKS related to menopause.

Guidelines for GAD, SAD, Panic Disorder, OCD, and PTSD were reviewed.

In October 2019, the FDA expanded the indications for Fetzima for the maintenance treatment in patients with major depressive disorder, including use beyond eight weeks. It is available as an extended-release capsule.

In August 2020, the FDA approved Spravato for depressive symptoms in adults with major depressive disorder with acute suicidal ideation or behavior. Previously, it was approved only for treatment-resistant depression in adults. It is indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression in adults. There can be depressive symptoms in adults with major depressive disorder with acute suicidal ideation or behavior. There is an increased risk of suicidal thoughts and behavior in pediatric and young adult patients taking antidepressants. Closely monitor all anti-depressant treated patients for clinical worsening and emergence of suicidal thoughts

and behaviors. There is a risk for sedation and dissociation after administration. Monitor patients for at least two hours after administration. There is a potential for abuse and misuse. Consider the risks and benefits of prescribing Spravato prior to use in patients at higher risk of abuse. Monitor patients for signs and symptoms of abuse and misuse. It is a Schedule III controlled substance under the Controlled Substance Act. Assess blood pressure prior to and after administration. Evidence of therapeutic benefit should be evaluated at the end of the four-week induction phase to determine need for continued treatment. Evidence of therapeutic benefit should be evaluated after four weeks to determine need for continued treatment. Treatment beyond four weeks has not been systematically evaluated.

In August 2020, the FDA approved Cymbalta for the treatment of fibromyalgia in pediatric patients 13 years of age and older. Previously, it was approved for fibromyalgia in adults only. It is indicated for the treatment of major depressive disorder in adults, generalized anxiety disorder in adults and pediatrics 7 years of age and older, diabetic peripheral neuropathic pain in adults, fibromyalgia in adults and pediatric patients 13 years of age and older, and chronic musculoskeletal pain in adults. There is an increased risk of suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants. Monitor for worsening or emergence of suicidal thoughts and behaviors. Dosing recommendations were reviewed. It is available as a delayed-release capsule.

Mirtazapine was recalled in January 2020. Aurobindo issued a voluntary recall of one lot of Mirtazapine tablets to the consumer level due to a label error on declared strength. The higher dose may increase risk of adverse events.

The utilization report was reviewed, and 96.4% of prescriptions for Antidepressants, SSRIs, were for preferred products; and 91.5 percent of prescriptions for Antidepressants, Others, were for preferred products.

STEPHANIE YAMAMOTO, a representative of Janssen, discussed Spravato, a nasal spray available through the Spravato REMS Program. It is a controlled substance with a novel mechanism of action involving the NMDA receptor. Spravato has two indications. The first is in conjunction with an oral antidepressant for the treatment of treatment-resistant depression in adults. The second indication is for the treatment of depressive symptoms in adults with major depressive disorder with acute suicidal ideation or behavior. This psychiatric emergency is not easily researched or studied, and no other treatment for this high-risk patient population. Major depressive disorder is the second leading cause of disability in the U.S. The overall economic, clinical, and social burden of major depressive disorder is greater than that of cancer or diabetes. Several studies and their outcomes were reviewed. Dosing recommendations were reviewed. Patients with MDD miss an estimated 21 workdays per year, compared to average employees who miss an average of six workdays per year. We request that Spravato be added to the PDL.

Dr. Umang Patel continued the Magellan presentation on Central Nervous System: Antidepressants. At the last review, a motion for class effect for Antidepressants, SSRIs, was made. A friendly amendment was offered to grandfather successfully managed patients. The motion, as amended, passed unanimously.

Dr. Phillips pointed out that patients could not get Spravato at their local pharmacy because it required two hours of observation and monitoring when administered. She questioned how the drug was billed.

Dr. Erin Narus said Spravato was billed through the medical billing as a separate line item. The administration time was billed separately for the encounter.

ANTIDEPRESSANTS, SSRIs. DR. LILJEGREN MOVED A CLASS EFFECT. SECONDED BY MS. WHITE. THE MOTION PASSED UNANIMOUSLY.

Dr. Umang Patel said a motion for therapeutic alternatives for Antidepressants, Others, passed unanimously.

ANTIDEPRESSANTS, OTHER: DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY MR. RILEY. THE MOTION PASSED UNANIMOUSLY.

Central Nervous System: Alzheimer's Agents (Green Class)

Dr. Umang Patel gave the Magellan presentation on Central Nervous System: Alzheimer's Agents. The utilization report was reviewed, and 90% of prescriptions were for preferred products. At the last review, a motion of therapeutic alternatives passed unanimously.

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

4-C. Analgesics: NSAIDs (Red); Analgesics, Opioid - Short Acting (Red); Analgesics, Opioid - Long-Acting (Blue); Neuropathic Pain (Blue); Antimigraine Agents (Red); Skeletal Muscle Relaxants (Blue); Restless Leg Syndrome (RLS) (Green)

Public Comments for Analgesics: NSAIDS (Red Class)

There were no public testimonies.

Dr. Umang Patel gave the Magellan presentation for Analgesics, NSAIDs. Nonsteroidal anti-inflammatory drugs (NSAIDs) are commonly used to treat rheumatoid arthritis (RA), osteoarthritis (OA), and pain from various etiologies. NSAIDs are the most widely used drugs in the United States with approximately 80 million prescriptions being filled yearly, which accounts for about 4.5% of all prescriptions. It is estimated that over the counter NSAIDs are used five to seven times more often than prescription NSAIDs. Most oral NSAIDs are now available as generics and are generally considered to be safe and effective. NSAIDs are associated with adverse effects including gastrointestinal bleeding, peptic ulcer disease hypertension, edema, and renal disease. In addition, NSAIDs have been linked to an increased risk of myocardial infarction, which is reflected in the boxed warning for all NSAIDs.

In July 2015, the FDA issued a Safety Alert strengthening the existing warning on the increased risk of heart attack and stroke risk associated with NSAIDs.

Guidelines from the American College of Rheumatology, 2019 and 2020; and the American College of Physicians and American Academy of Family Physicians, 2020, were reviewed.

In February 2020, the FDA approved Anjeso as an injection for the management of moderate to severe pain, alone or in combination with non-NSAID analgesics in adults. Due to the delayed onset of analgesia, use alone is not recommended when rapid onset of analgesia is required. NSAIDs cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use. Anjeso is contraindicated in the setting of coronary artery bypass graft surgery. NSAIDs cause an increased risk of serious GI adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. Dosage recommendations were reviewed. It is available as a single-dose injection.

In February 2020, the FDA approved Advil Dual Action as an over-the-counter combination product for temporary relief of minor aches and pains due to headache, toothache, backache, menstrual cramps, muscular aches, and minor pain of arthritis in adults and children 12 years of age or older. It has the same black boxed warnings. Use of NSAIDs during a third trimester pregnancy increases the risk of premature closure of the fetal ductus arteriosus. Avoid use after 30 weeks of gestation. Dosage recommendations were reviewed. It is available as a tablet.

In March 2020, the FDA approved a full prescription to over-the-counter switch of Diclofenac Sodium Gel, 1%, for the temporary relief of arthritis pain only in the hands, wrists, elbows (upper body areas) and feet, ankles, knees (lower body areas). Availability of the over-the-counter version is expected in the spring of 2020 and the prescription version will be discontinued by GlaxoSmithKline.

In March 2020, the first generic for Vimovo was approved from Dr. Reddys.

In April 2020, Fresenius Kabi USA voluntarily recalled 13 lots of Ketoralac Tromethamine injections. The recall is due to the presence of particulate matter, which contains carbon, silicon, oxygen, and polyamides found in eight reserve sample vials. Administration of products containing particulate matter could result in local irritation of blood vessels, injection-site swelling, inflamed or infected tissue mass, blood clots, scarring of lung tissues, and allergic reactions.

The utilization report was reviewed, and 98.7% of prescriptions were for preferred products. At the last review, a motion for class effect passed unanimously.

MR. RILEY MOVED A CLASS EFFECT TO INCLUDE A TOPICAL PREPARATION. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Analgesics: Opioid - Short-Acting (Red Class)

There were no public comments.

Dr. Umang Patel gave the Magellan presentation for Analgesics, Opioid - Short Acting. While definitions vary, chronic pain is generally defined as pain lasting greater than 3 months or past the time required for normal tissue healing. It has various etiologies, including injury, inflammation, and underlying medical conditions. Approximately 11.2% of adults report daily pain, which is greatly misunderstood. Historically, data have suggested that pain may be undertreated, but newer estimates imply that opioid treatment for pain may be overutilized. An estimated 20% of patients presenting to outpatient providers with noncancer pain or pain-related diagnoses, whether acute or chronic, receive

an opioid prescription. Likewise, per capita opioid prescriptions increased by 7.3% from 2007 to 2012, with prescribers writing 66.5 opioid prescription for every 100 Americans in 2016. Approximately 165,000 people have died from overdoses related to opioid pain medications in the U.S. from 1999 to 2014. Likewise, drug related deaths have tripled from 1999 to 2015. During 2015 alone, 33,091 persons in the U.S. died from opioid related overdoses. Opioid related overdose was higher among males (13.7%) in comparison to females (7.1%). Despite this, persistent pain that is uncontrolled may have clinical, psychological, and social consequences; thus, it is critical to weigh the risks and benefits of opioid use and reevaluate patients routinely for appropriate dose, duration, and treatment choice, including both pharmacologic and non-pharmacologic modalities.

In 2019, the FDA announce changes to the Transmucosal Immediate-Release Fentanyl (TIRF) REMS program. Changes include requiring prescribers to document a patient's opioid tolerance concurrently with each prescription of the TIRF medicine for outpatient use. It requires inpatient pharmacies to develop internal policy and procedures to verify opioid tolerance in hospitalized patients requiring TIRF medicines. TIRF meds for outpatient use must have evidence or other documentation of safe use conditions, including concurrent documentation of opioid tolerance; and requiring the development of a new patient registry to monitor for serious adverse events including overdose, both fatal and non-fatal.

In 2019, the CDC clarified that their guidelines on opioid prescribing are not intended to deny opioid therapy for pain management for any patients with chronic pain, particularly in patients with sickle cell disease, undergoing cancer treatment, and cancer survivors with chronic pain. It aims to ensure that clinicians and patients consider all safe and effective treatment options.

In October 2019, the Department of Health and Human Services published a new guideline for clinicians on dosage reduction or discontinuation of long-term opioid analgesics. This guidance discusses the risks of opioid taper and advises that opioids should not be quickly tapered or discontinued abruptly due to the potential for opioid withdrawal which can result in acute withdrawal symptoms, pain exacerbation, psychological distress, and suicidal ideation in patients who are physiologically dependent. Except for life-threatening circumstances, it is not recommended to abruptly reduce an opioid dose or discontinue. Guidance details situations when it may be appropriate to taper to a reduced dosage. Other key recommendations include referring patients with serious mental illness, high suicide risk, or suicidal ideation to a behavioral health provider prior to taper; assessing patients for opioid use disorder if they show signs of opioid misuse and offering medication-assisted treatment if appropriate; advising patients of risks for overdose if they abruptly return to the higher dose; tapering by 5-20% every four weeks is common, but longer tapering schedules may be required; and considering transition to Buprenorphine for patients on high doses and unable to taper.

Guidelines from the American College of Physicians and the American Academy of Family Physicians, 2020, were reviewed.

In April 2020, the FDA reported Janssen's Ultram tablets will be permanently discontinued as a business decision. The FDA recommends the product remain on the formularies until September 30, 2022, when the last batch expires. Only the brand-name product will be discontinued. In April 2002, the FDA reported Janssen's Ultracet will be permanently discontinued as a business decision. It will remain on formularies until October 31, 2022, when the last batch of drug expires. Only the brand-name product will be discontinued. In September 2020, the FDA posted that Ingenus Pharmaceuticals

will discontinue the Carisoprodol/Aspirin/Codeine Phosphate combination. No active NDCs for this combination are available.

In April 2020, the DEA published their 2020 edition of Drugs of Abuse Resource Guide. It includes information on a drug's origin, street names, mode of abuse, its effects, and legal status in the U.S. It now also includes information on vaping, as well as updated information on Fentanyl, marijuana, and stimulants.

In September 2020, the FDA issued warning letters to 17 website owners for the illegal sale of unapproved and misbranded opioids. This includes those sold without a prescription and products without adequate directions for use.

In August 2020, the FDA approved Olinvyk for use in adults for the management of acute pain severe enough to require an IV opioid analgesic and for whom alternative treatments are inadequate. It is indicated for short-term use in hospitals, and other controlled clinical settings. There are limitations of use because of the risk of addiction, abuse, and misuse with opioids, even at recommended doses. It is recommended to reserve for use in patients for whom alternative treatment options such as non-opioid analgesics or opioid combination products have not been tolerated or are not expected to be tolerated, have not provided adequate analgesia or are not expected to provide adequate analgesia. There are black boxed warnings. This medication exposes patients and other users to risk of opioid addiction, abuse, and misuse, which can lead to overdose and death. Serious, life-threatening, or fatal respiratory depression may occur. Monitor for respiratory depression, especially during initiation or following a dose increase. Prolonged use of Olinvyk during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. Dosing recommendations were reviewed. It is available as a single-dose injection.

In September 2020, the FDA approved Ololo as a new formulation of Tramadol oral solution for the use in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Limitations of use are similar. There are numerous black boxed warnings, which can be reviewed on the PI or the PTR on the web portal. Dosing recommendations were reviewed. It is available as an oral solution.

The utilization report was reviewed, and 47.3% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

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

Public Comments for Analgesics: Opioids - Long-Acting (Blue Class)

There were no public comments.

Dr. Umang Patel gave the Magellan presentation for Analgesics, Opioids - Long-Acting. The FDA released a drug safety communication and MedWatch for opioid pain relievers and opioid use disorder agents recommending healthcare practitioners discuss and consider Naloxone use with all patients at the time of prescribing. The FDA is requiring manufacturers for all opioid pain relievers and OUD treatments add recommendations on Naloxone to the product labeling for healthcare practitioners to

consider and discuss prescribing Naloxone. When these meds are prescribed or renewed, the FDA is recommending the potential need for a Naloxone prescription to be evaluated. Corresponding updates will also be made to the Med Guides. In addition, for patients that are not receiving a prescription for an opioid analgesic or OUD treatment, consideration should be given to prescribing Naloxone for them if they are at a higher risk of opioid overdose. The FDA also recommends healthcare practitioners consider prescribing Naloxone when a patient has household members who may be at risk for accidental ingestion or opioid overdose.

Pfizer will discontinue manufacture and distribution of all strengths of Embeda capsules. The stop sales date was November 15, 2019, with the anticipated unavailability timeframe in early 2020. The FDA reported Janssen's Duragesic will be permanently discontinued as a business decision. Only the brand-name will be discontinued. The FDA is recommending the product remain on formularies until July 31, 2021, when the last batch expires. The first generic for hydrocodone extended-release formulation, Alvogen, was approved by the FDA in January 2020.

The utilization report was reviewed, and 61.9% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include at least one oral preparation, one transdermal preparation, and at least one abuse-deterrent preparation passed unanimously.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE ORAL PREPARATION, ONE TRANSDERMAL PREPARATION, AND AT LEAST ONE ABUSE-DETERRENT PREPARATION. SECONDED BY MS. WHITE. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Analgesics: Neuropathic Pain (Blue Class)

There were no public comments.

Dr. Umang Patel gave the Magellan presentation for Analgesics: Neuropathic Pain. Neuropathic pain has recently been defined as the pain that evolves as a result of direct injury or disease to the nervous system, specifically the somatosensory system. It can be caused by a number of different diseases such as diabetes mellitus, herpes zoster, human immunodeficiency virus (HIV) infection.

In December 2019, the FDA issues a drug safety communication regarding serious breathing difficulties using Gabapentin or Pregabalin, in patients who also have other respiratory risk factors such as opioid pain medications, other CNS depressant drugs, COPD or elderly patients. The FDA is planning to continue monitoring the safety of these medications.

There were no updates to the guidelines.

In July 2020, the FDA approved a new indication for Qutenza for the treatment of neuropathic pain associated with diabetic peripheral neuropathy of the feet. Previously, it was approved for the management of neuropathic pain associated with postherpetic neuralgia. Dosage recommendation were reviewed. It is available as a patch.

The utilization report was reviewed, and 99% of prescriptions were for preferred products.
At the last review, a motion for therapeutic alternatives passed unanimously.

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

The committee verified the motion for Analgesics, Opioid - Long-Acting. The motion should read therapeutic alternatives to include at least one oral preparation, one transdermal preparation, and at least one abuse-deterrent preparation. Dr. Liljegren said it would probably be a good idea to restate the previous motion when making a new motion to prevent confusion.

Public Comments for Analgesics: Antimigraine Agents (Red Class)

JENNIFER SHEAR, a representative of Teva, discussed Ajovy, which is indicated for the preventative treatment of migraine in adult patients. It may be administered by healthcare professionals, patients, and/or caregivers. The Ajovy autoinjector became available in April 2020. Ajovy is the only long-acting self-administered subcutaneous anti-CGRP with the option of monthly or quarterly dosing, allowing it to be dosed as few as four times per year either with the autoinjector or the pre-filled syringe. The FOCUS study and its outcomes were reviewed. Several trials and their outcomes were reviewed.

CARRIE JOHNSON, a representative of Amgen, discussed Aimovig. It is indicated for the preventative treatment of migraine in adults. It can be self-administered using the SureClick autoinjector that comes in two dosing options. Of the injectable products, Aimovig is the only one that specifically targets the CRP receptor. It has an established safety and tolerability profile. The most common adverse reactions were injection site reactions and constipation. Warnings and precautions were reviewed. Please see the full prescribing information for further details. Several studies and their outcomes were reviewed. Aimovig has demonstrated long-term safety and efficacy, has a unique mechanism of action, and comes in two different dosing options that can be self-administered.

CHELSEA LEROUE, a representative of Biohaven, discussed Nurtec ODT and its four key features that differentiate it from other acute migraine treatments. First, ease of use for physicians and patients. It is available in one dosage form, one dosage strength, and one package size of eight tablets. It is the only orally disintegrating tablet formulation that dissolves rapidly within seconds without the need for water, making it convenient for patients to take Nurtec ODT up to once daily, as needed, whenever or wherever a migraine occurs. Second, favorable safety profile. The most common adverse reactions were nausea. Nurtec ODT is not associated with addiction potential. It is not contraindicated in patients with cardiovascular disease or risk factors. It has been studied in patients taking preventive migraine medications. Third, sustained benefits of a single dose. A migraine attack, by definition, can last up to 72 hours. Medications with longer half-life have been shown to correlate with lower rates of headache. Nurtec ODT has a half-life of approximately 11 hours, which is longer than that of many triptans and roughly twice that of the other commercially available drugs. Pain relief, pain freedom, and ability to function normally were sustained through 48 hours with a single dose of Nurtec ODT. Less than 15% of Nurtec ODT treated patients took additional rescue medication. Only one tablet of Nurtec ODT is needed to treat a migraine, which may lead to less utilization than other acute medications. Fourth, restores patient's ability to function normally. After taking a single dose of Nurtec ODT, patients reported functioning normally as soon as 15 minutes, and this is sustained through 48 hours. These benefits may favorably impact healthcare costs, workplace productivity, and migraine patient wellbeing. We request that Nurtec ODT as a preferred agent on the PDL.

Dr. Umang Patel gave the Magellan presentation for Analgesics, Antimigraine Agents. Migraine headaches account for 10-20% of all headaches in adults and affects over 39 million men, women, and children in the U.S. Headache is one of the most common complaints by patients when presenting to a physician. Approximately 85% of patients with migraine headaches suffer less than three to four attacks per month. Migraine headache must be differentiated from tension-type headaches. Key criteria for the diagnosis include an episodic headache lasting from four to 72 hours with at least two of the following symptoms: unilateral pain, throbbing, aggravated by routine physical activity, and pain of moderate to severe intensity. During a headache, at least one of the following are present: nausea and/or vomiting or photophobia and phonophobia.

Cluster headaches (CH) is a severe, primary headache disorder characterized by extreme pain on one side of the head and autonomic symptoms. CH periods can persist for weeks to months with daily or more frequent attacks of 15 to 180 minutes in duration. The estimated lifetime prevalence of CH is more than one in 1,000 and can be either episodic or chronic in nature.

Guidelines from the American Headache Society, 2019; and the American Academy of Neurology and American Headache Society, 2019, were reviewed.

In October 2019, the FDA approved Reyvow, a serotonin 1F receptor agonist indicated for the acute treatment of migraine with or without aura in adults. Advise patients not to drive or operate machinery until at least eight hours after taking each dose. It may cause CNS depression and should be used with caution if used in combination with alcohol or other CNS depressants. Reactions consistent with serotonin syndrome were reported in patients treated with Reyvow. Discontinue if symptoms occur. Dosing recommendations were reviewed. It is available as a tablet.

In January 2020, the FDA approve Ajovy as a new formulation of a 225 mg/1.4 mL autoinjector. It was already approved in this strength as a prefilled syringe, and both are approved for the preventative treatment of migraine in adults and can be self-administered subcutaneously following training. Dosing recommendations were reviewed. It is available as a prefilled autoinjector or prefilled syringe.

In February 2020, the FDA approved Nurtec ODT for the acute treatment of migraine with or without aura in adults. It is not indicated for the preventative treatment of migraine. If a serious hypersensitivity reaction occurs, discontinue treatment and initiate appropriate therapy. Severe hypersensitivity reactions have included dyspnea and rash, which can occur days after administration. Nurtec ODT should be avoided in patients with severe hepatic impairment. Dosage recommendations were reviewed. It is available as an orally disintegrating tablet.

In February 2020, the FDA approved Vyepti for the preventative treatment of migraine in adults. Reactions have included angioedema, urticaria, facial flushing, and rash. If a hypersensitivity reaction occurs, consider discontinuing treatment and initiate appropriate therapy. Dosing recommendations were reviewed. It is available as a single-dose vial solution.

In April 2020, the FDA reported that GSK made a business decision to discontinue manufacturing Imitrex, 6 milligram, single-dose vials. Distribution of the product is expected to conclude in August 2020. Only brand-name product will be discontinued. In July 2020, Sandoz reported to the FDA the discontinuation of Cafergot manufacturing.

Dr. Erin Narus noted that lines had been muted and an industry representative had not been able to speak earlier.

JOSH BISHOP, a representative of Abbvie, discussed Ubrelvy for the acute treatment of migraine. It was approved by the FDA in late 2019. We believe that triptans will continue to be the standard of care for the acute treatment of migraine attacks. However, there are patients with other conditions that account for 25% of the migraine population. We believe those patients should have first line access. We have robust data confirming that many patients prescribed oral triptans have side effects that lead to discontinuation, and approximately 30% of patients on triptans have an insufficient clinical response. Multiple studies have confirmed that nearly half of patients never refill their triptan and very few move to a second triptan. For those who have an inadequate response to triptan, approximately 53% of those patients end up doing opioids and barbiturates. When patients do not respond to triptan, they end up using other healthcare resources, which has an estimated cost to payers of an additional $6,000 per patient per year. Ubrelvy has differentiated itself from the newer agents, as well as the triptans, for the cardiovascular and insufficient responder populations. It has been proven to be safe and effective. It has a tolerability profile similar to placebo. There are no warnings and no precautions. The most common adverse events were nausea and somnolence. Several studies and their outcomes were reviewed. We request that Ubrelvy be included on the PDL.

Dr. Umang Patel continued the Magellan presentation for Analgesics, Antimigraine Agents. The utilization report was reviewed, and 96.1% of prescriptions for Antimigraine Agents, Triptans, were for preferred products. At the last review, a motion for therapeutic alternatives for Antimigraine Agents, Triptans, passed unanimously.

Dr. Liljegren wondered if the motion should include at least one medication that was available by a non-oral route. Dr. Semling said the PDL included nasal and injectable triptans. Dr. Liljegren said those medications may not remain on the PDL after going through the next bidding process. Dr. Semling said it was more than likely that those medications would remain on the PDL.

DR. LILJEGREN MOVED THE TRIPTANS BE CONSIDERED CLASS EFFECT, TO INCLUDE AT LEAST ONE NON-ORAL PREPARATION. SECONDED BY MR. RILEY. THE MOTION PASSED UNANIMOUSLY.

The utilization report was reviewed, and 58.8% of prescriptions for Antimigraine Agents, Other, were for preferred products. At the last review, a second motion for therapeutic alternatives to both treatment and prevention of migraines for Antimigraine Agents, Other, passed unanimously.

In response to Dr. Hiestand, Dr. Umang Patel said the lower utilization rate was due to non-reviewed use of the agents Ubrelvy at 20% and Ajovy at 15%.

DR. LILJEGREN MOVED THE ANTIMIGRAINE AGENTS, OTHERS, BE CONSIDERED THERAPEUTIC ALTERNATIVES, TO INCLUDE AT LEAST ONE DRUG FOR PROPHYLACTIC TREATMENT AND AT LEAST ONE DRUG FOR ACUTE TREATMENT OF MIGRAINE. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Analgesics: Skeletal Muscle Relaxants (Blue Class)

Dr. Umang Patel gave the Magellan presentation for Analgesics, Skeletal Muscle Relaxants. Spasticity is a condition in which muscles are continuously contracted causing stiffness or tightness which may interfere with movement and speech. It is usually caused by damage to the portion of the brain or spinal cord that controls voluntary movement. A major health concern, it can be associated with a number of disease entities such as spinal cord injury, multiple sclerosis, traumatic brain injury, cerebral palsy, and stroke. Symptoms may include hypertonicity, clonus, exaggerated deep tendon reflexes, muscle spasms, scissoring, and fixed joints. The degree of spasticity varies from mild muscle stiffness to severe, painful, and uncontrollable muscle spasms. Skeletal muscle relaxants are FDA-approved to treat two different types of conditions: Muscular pain or spasms from peripheral musculoskeletal conditions, and spasticity from upper motor neuron syndromes. Both conditions affect patients' mobility and affect independence in activities of daily living and work.

In September 2019, the FDA approved Ozobax as a new formulation of 5 milligram per 5 milliliter solution for the treatment of spasticity related to MS, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscle rigidity. Otherwise, all information for this medication is the same. The indications, limitations, and dosage remain identical. It is available as an oral solution.

The utilization report was reviewed, and 98.2% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

Dr. Liljegren felt Carisoprodol should be excluded from the PDL because it is a habit-forming medication and there are multiple medications to choose from that are non-habit forming.

DR. LILJEGREN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, EXCLUDING CARISOPRODOL FROM THE PDL. SECONDED BY MS. WHITE. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Analgesics: Restless Leg Syndrome (RLS) (Green Class)

Dr. Umang Patel gave the Magellan presentation for Analgesics: Restless Leg Syndrome (RLS).
The utilization report was reviewed, and 0% of prescriptions were for preferred products, but the entire class was non-reviewed. 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.

4-D. Substance Dependence: Smoking Cessation Products (Blue); Opioid Dependance (Blue); Opioid Reversal Agents (Green)

Public Comments for Substance Dependence: Smoking Cessation Products (Blue Class)

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Substance Dependence: Smoking Cessation Products. In April 2020, the U.S. Preventative Services Task Force issued a recommendation for

school-aged children and adolescents who have not started to use tobacco stating that primary care clinicians are recommended to provide interventions such as education or brief counseling in order to prevent tobacco use initiation in these individuals. However, for school-age children and adolescents who use tobacco, it was concluded the current evidence is inadequate to determine the benefits versus risks of primary care-feasibility interventions regarding tobacco cessation.

Guidelines from the U.S. Preventative Services Task Force, 2020; and the American Thoracic Society, 2020, were reviewed.

The utilization report was reviewed, and 98.1% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

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

Public Comments for Substance Dependence: Opioid Dependence (Blue Class)

JOSH GETTY, a representative of Indivior, thanked the committee for the access that Alaskans have to Sublocade and asked to have that continue. The FDA recently approved a label update. Sublocade is started with a 300-milligram injection, a second 300-milligram injection the following month, and then monthly injections of 100 milligrams. If a patient is maintaining on 100 milligram dosing but is planning to be away for a vacation and may miss their next injection, we can offer a 300-milligram injection as a one-time maintenance bridge and then pick up with the 100-milligram monthly dosing two months after the 300-milligram dose.

PAUL THOMPSON, a representative of Alkermes, discussed Vivitrol. Vivitrol contains Naltrexone, which is an opioid antagonist indicated for the prevention of relapse to opioid dependence following opioid detoxification. Dosing recommendations were reviewed. It is administered by a healthcare professional using the provided components. Several studies and their outcomes were reviewed. In some cases, injection site reaction can be severe. Patients need to be opioid free before starting Vivitrol for a minimum of 7 to 10 days to avoid precipitation of opioid withdrawal. We request that Vivitrol continue to be maintained on the PDL.

Dr. Umang Patel gave the Magellan presentation on Substance Dependence: Opioid Dependence. There is an estimated 31.9 million Americans ages 12 years and older who were current (in past month) illicit drug users. There were approximately 10.3 million people aged 12 or older in the U.S. who misused opioids in the past year. Approximately 20.3 million people aged 12 or older in 2018 were considered to have a substance use disorder, including 14.8 million people with an alcohol use disorder, 8.1 million people with an illicit drug use disorder, and 2 million had an opioid use disorder.

The U.S. Preventive Services Task Force issued a final recommendation statement on screening for unhealthy drug use. They recommended screening implemented when services for accurate diagnosis, effective treatment, and appropriate care can be offered or referred. For adolescents, the current evidence is insufficient to determine the benefits and harms of screening for unhealthy drug use.

Guidelines from the American Society of Addiction Medicine, 2015 (updated in 2020) were reviewed.

On December 11, 2019, the FDA issued a warning letter to Alkermes for misbranding Vivitrol by omitting warnings, including vulnerability to opioid overdose, a potentially fatal risk, about the most serious risks associated with the drug from promotional materials. FDA is requesting the company immediately cease advertising practices that misbrand Vivitrol and that the company include a comprehensive plan of action to disseminate truthful, non-misleading and complete corrective messages about the issues discussed.

On May 15, 2020, minor revisions, including changes to single-dose instead of single-use and changes to correlate with REMS. Alkermes announced additional provider locations to support access during COVID-19.

On July 24, 2020, the FDA has released a drug safety communication and a MedWatch for opioid pain relievers and opioid use disorder agents recommending healthcare practitioners discuss/consider Naloxone use with all patients at the time of prescribing. Furthermore, the FDA is requiring manufacturers for all opioid pain relievers and opioid use disorder treatments add recommendations on Naloxone to the product labeling for healthcare practitioners to consider/discuss prescribing Naloxone. When these meds are prescribed or renewed, the FDA is recommending the potential need for Naloxone prescriptions be evaluated. Corresponding updates will also be made to the Med Guides. In addition, for patients that are not receiving a prescription for an opioid analgesic or opioid use disorder treatment, consideration should be given to prescribing Naloxone for them if they are at a higher risk of opioid overdose. The FDA also recommends healthcare practitioners consider prescribing Naloxone when a patient has household members who may be at risk for accidental ingestion or opioid overdose.

On August 28, 2020, the FDA listed Bunavail's marketing status as discontinued.

The utilization report was reviewed, and 95.4% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include at one long-acting injectable product passed unanimously.

MR. RILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE AT LEAST ONE LONG-ACTING INJECTABLE PRODUCT. SECONDED BY DR. LILJEGREN. THE MOTION PASSED UNANIMOUSLY.

Substance Dependence: Opioid Reversal Agents (Green Class)

Dr. Umang Patel gave the Magellan presentation on Substance Dependence: Opioid Reversal Agents. The utilization report was reviewed, and 100% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives, to include Narcan, passed unanimously.

DR. LILJEGREN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE NARCAN. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

4-E. Antiviral Monoclonal Antibodies: Respiratory Syncytial Virus (Green)

Antiviral Monoclonal Antibodies: Respiratory Syncytial Virus (Green Class)

Dr. Umang Patel gave the Magellan presentation on Monoclonal Antibodies: Respiratory Syncytial Virus. The utilization report was reviewed, and there were no claims. At the last review, a motion to add Synagis to the formulary as a class effect pass unanimously.

DR. LILJEGREN MOVED A CLASS EFFECT.

Dr. Semling pointed out that when the data for the utilization was pulled, it was not during the Synagis season which is from November 20 to May 15. There are now quite a few claims. Dr. Umang Patel agreed with Dr. Semling and noted there were about 300 claims for Synagis in a one-year window.

Dr. Erin Narus pointed out that social distancing efforts related to COVID also had an impact on the rates of RSV. We hope that additional efforts being utilized for COVID will also help with protecting our youth from RSV through this season as well.

SECONDED BY MR. RILEY. THE MOTION PASSED UNANIMOUSLY.

The public portion of the meeting concluded, and the committee went into closed session.

5. Break as Needed - 15 Minutes

6. Review Minutes from September 2020

The meeting minutes of September 2020 were reviewed. No changes were made. The meeting minutes were approved with no objections.

7. Comments from Committee Members or Chair

Dr. Heistand said this would be her last meeting because she was moving to Syracuse, New York. The committee members wished her well.

8. Adjourn

The meeting adjourned at 11:59 a.m.