Alaska Medicaid Pharmacy and Therapeutics Meeting

MINUTES OF MEETING
November 17, 2023

Committee Members Present:
Casey Gokey, Acting Chairman
Sarah Doren-Atchison, Pharm D
Charles Ryan, MD
Charles Semling PharmD, DHSS
Valarie Bixler, Pharm D
Claudia Phillips, MD
Trisha White, R.Ph.
Robert Carlson, MD
Matt Parrott,

Committee Members Absent:
John Riley, PA

Others Present:
Ryan Ruggles, Pharm D
Umang Patel
Shirley Quach, Novartis
Kristen Heard, Neurelis
Rajena Ameen, UCB Pharma
Nirmal Ghuman, Janssen
Erin Nowak, AbbVie
Madeline Shurtleff, Otsuka
Rachelle Yang, Teva
William Olsfuka, Axsome Therapeutics
Lynda Finch, Biogen
David Gross, Pfizer
Samuel Riega, Braeburn
Jessica Jay, Pharm D
Desiree Crevecoeur-MacPhail, Hikma Community Health
Cheryl Bony, Sobi Inc.

1. Call to Order – Chair

Dr. Casey Gokey called the meeting to order.

2. Roll Call

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

3. Public Comments - Local Public/Health Practitioners

None.

4. Class Review, Discussion & Vote

4-A. Cystic Fibrosis: CFTR Potentiator (blue), Antibiotics, Inhaled (green), Pancreatic Enzymes (green), Multiple Sclerosis Agents (red), Stimulants & Related Agents (blue), Sedative Hypnotics (blue)

Ryan Ruggles opened the floor for public comment regarding Cystic Fibrosis. There was none.

Ryan Ruggles gave the Magellan presentation of the disease state description for Cystic Fibrosis.

CFTR Potentiator (Blue Class)

In April 2023, the FDA expanded the indication of Trikafta to include children with CF ages 2 through 5 years who have at least one F508del mutation in the CFTR gene or other mutation in the CFTR gene that is responsive; previously only approved for use in patients older than 6 years of age with this mutation. FDA also approved an oral granule formulation to accommodate dosing in this younger age group.

Ryan then discussed dosage and availability of Trikafta.

In May 2023, the FDA approved an expanded indication for Kalydeco for the treatment of cystic fibrosis in patients who have greater than or equal to one mutation in the CFTR gene that is responsive to ivacaftor potentiation to be expanded to patients greater than 1 month of age. Ivacaftor was previously approved for this indication in patients greater than 4 months of age. Also in May 2023, the new 5.8 mg and 13.4 mg oral granules in unit-dose packages were added to the PI.

The indication, dosage and availability was discussed.

Utilization is 100 percent in line with PDL.

Previous motion Dr. Ryan moved the drug in the class were therapeutic alternatives. Seconded by Dr. Liljegren. The motion passed unanimously.

DR. PHILLIPS MOVED THE SAME MOTION AS LAST YEAR. SECONDED BY MRS. WHITE. THE MOTION PASSED UNANIMOUSLY.

Antibiotics, Inhaled (Green Class)

Given that this is a green class Ryan moved directly into utilization.

Utilization shows that 85.7 percent is in line with PDL.

Previously Mrs. White moved the drugs in the class were therapeutic alternatives. This was seconded by Dr. Ryan and passed unanimously.

DR. PHILLIPS PROPOSED LAST YEARS MOTION. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

Pancreatic Enzymes (Green Class)

Given that this is a green class Ryan moved directly into utilization.

Utilization shows that 97.3 percent is in line with PDL.

Previous motion has Dr. Phillips moving a class effect seconded by Dr. Doran-Atchison. The motion passed unanimously.

DR. PHILLIPS MOVED THE SAME MOTION, SECONDED BY VALARIE BIXLER. THE MOTION PASSED UNANIMOUSLY.

Multiple Sclerosis Agents (Red class)

Public comments for Multiple Sclerosis Agents (Red class)

SHIRLEY QUACH, Value Evidence Lead in the Pacific Northwest for Novartis gave updated information on Kesimpta. Novartis respectfully requested that Kesimpta be added to the preferred list of the Alaska PDL. Kesimpta is the first fully human anti-CD20 monoclonal antibody that is self-administered and is approved for adults with relapsing multiple sclerosis or RMS. Five year long term efficacy and safety data was presented and shared at the American Academy of Neurology in April 2023. More than 80 percent of patients in the study remain free of six month CDW, confirmed disability worsening, over the same five period. Additionally, brain volume change remained low, less than 1.5 percent loss, with Kesimpta treatment over five years and overall patients initially randomized to Kesimpta had lower levels of brain volume loss at year five than those initially randomized to teriflunomide. Long term efficacy data supports findings from the 96-week core ASCLEPIO studies indicating that Kesimpta shows sustained efficacy in patients with RMS. 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.

Ryan Ruggles gave the presentation for the disease state description for multiple sclerosis.

In December 2022, the FDA expanded the indication of Tascenso IDT for treatment of relapsing forms of MS, including clinically isolated syndrome, relapsing remitting disease and active secondary progression disease to include all patients greater than 10 years of age. The indication, limitation, dosage and availability were given.

In December 2022, the FDA approved Briumvi, a CD20-directeed cytolytic monoclonal antibody indicated for treatment of relapsing forms of MS in adults to include clinically isolated syndrome, relapsing remitting disease and active secondary progressive disease. Indication is for the treatment of relapsing forms of multiple sclerosis to include clinically isolated syndrome, relapsing remitting disease and active secondary progressive disease in adults. Limitations include fetal risk stating that it may cause fetal harm. Females are to be advised of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for at least six months after stopping Briumvi. Infusion reactions may also occur. Management recommendations for infusion reactions depend on the type and severity of the reaction. Permanently discontinue Briumvi if a life threatening or disabling infusion reaction occurs. Dosage states that it is to be administered by intravenous infusion with the first infusion being 150 mg, the second infusion being 450 mg two weeks after the first dose and any subsequent infusions being 450 mg 24 weeks after the first infusion and every 24 weeks thereafter. It is available in an injection, 150 mg/6mL (25 mg/mL) in a single dose vial.

In August 2023, the FDA approved Tyruko, the first biosimilar to natalizumab making it the first biosimilar for treatment of relapsing forms of MS. The indication for MS is to be used as monotherapy for the treatment of relapsing forms of multiple sclerosis to include clinically isolated syndrome, relapsing remitting disease and active secondary progressive disease, in adults. Natalizumab products increase the risk of PML. When initiating and continuing treatment with Tyruko physicians should consider whether the expected benefit of Tyruko is sufficient to offset this risk. In Crohn's disease it is indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease with evidence of inflammation who have had an inadequate response to or are unable to tolerate conventional CD therapies and inhibitors of TNF-a. Limitations include that it may cause fetal harm and that products increase the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. Dosage is available in 300 mg infused intravenously over one hour, every four weeks. Do not give as an intravenous push or bolus. Tyruko solution must be administered within four hours of preparation. It is available as an injection 300 mg/15mL (20mg/mL) solution in a single dose vial for dilution prior to infusion.

Utilization shows that 65.9 percent is in line with PDL. Previous motion Dr. Ryan moved that the drugs in the class were therapeutic alternatives. This was seconded by Dr. Doran-Atchison and passed unanimously.

Dr. Phillips wondered why the numbers aren't higher than 65 percent on the PDL. Charles Semling stated it is a tough class to manage based on the medications that are involved. A lot of

them are physician administered drugs so the reason some of them are not seen on the PDL currently is because when they do a data pull it is from the pharmacy system and not the medical side. Therefore, it probably looks a little different than what it normally is because the physician administered drugs are covered outpatient drugs.

DR. PHILLIPS MOVED THE DRUGS WERE THERAPEUTIC ALTERNATIVES, SECONDED BY DR. DORAN ATCHISON. THE MOTION WAS PASSED UNAMIMOUSLY.

Stimulants and Related Agents (Blue Class)

Ryan Ruggles gave the presentation for the disease state description for attention deficit hyperactivity disorder (ADHD).

The Medical Letter in 2020, suggests that school age children, adolescents and adults begin with an oral stimulant noting that none of the agents have shown to be more effective than another, however, some patients may respond better to amphetamines than to methylphenidate and vice versa. They advised that use of long acting formulations which generally contain both immediate and extended release components has become standard clinical practice and the addition of a short acting stimulant may improve symptom control early in the morning or to prolong the duration of action in the afternoon. While the alpha agonists clonidine and guanfacine and the selective norepinephrine reuptake inhibitor atomoxetine can reduce ADHD symptoms these agents are considered less effective than stimulants. Use of pitolisant and solriamfetol were not addressed drugs for ADHD.

In October 2022, Evekeo ODT labeling was revised to change the indication for the treatment of ADHD in pediatric patients 3 – 17 years of age to now include only patients 6 – 17 years of age. The 2.5 mg strength was previously indicated as a starting dose in patients 3 – 5 years of age. Labeling has been updated to remove all information related to the 2.5 mg strength. The 5 mg, 10 mg, 15 mg and 20 mg ODTs remain available and are indicated for use in patients 6 – 17 years of age. The indication has been updated to remove that age group and the availability has been updated to reflect that change.

There are drug shortages with amphetamine mixed salts (Adderall). In October 2022, the FDA has released shortage information for immediate release amphetamine mixed salts as Teva is currently experiencing ongoing intermittent manufacturing delays. In May 2023, the FDA has updated its shortage information for amphetamine aspartate, amphetamine sulfate, dextroamphetamine saccharate and dextroamphetamine sulfate. Several manufacturers have product unavailable with supply contracting or on allocation. Teva has brand Adderall tablets available and limited supply of generic product. In July 2023, Takeda is anticipating a shortage of Vyvanse 60 mg and 70 mg capsules with ETA in late September 2023. Shortage due to temporary delay at contract manufacturing sites. All other capsule strengths are available. There is also a drug shortage with methamphetamine (Desoxyn). In March 2023, both manufacturers of generic methamphetamine (Hikma and Mayne) are reporting that product is currently unavailable. Estimated resolution by Mayne in September 2023. Brand Desoxyn remains unavailable.

In May 2023, the FDA has released a Drug Safety Communication detailing updates to the boxed warning and other sections of product labeling for amphetamine and methamphetamine stimulants regarding the risk for misuse, abuse, addiction and overdose with these medications.

In August 2023, the DFA and DEA provided an update on the ongoing actions being taken to resolve stimulant shortages. Some of the steps being taken include encouraging manufacturers to meet allotted quota amounts, supporting the development of nonstimulant alternatives and encouraging development of guidelines and diagnostic standards.

July 14, 2023, the FDA approved the first generic for Adzenys XR-ODT (amphetamine ER ODT) by Actavis.

September 1, 2023, the FDA approved first time generic for Vyvanse capsules and chewable tablets by several manufacturers indicated for ADHD in patients greater than or equal to 6 years of age and for moderate to severe binge-eating disorders (BED) in adults.

Utilization was roughly 92.8 percent in line with the PDL. Previous motion, Dr. Phillips moved that the drugs in the class were therapeutic alternatives. Seconded by Dr. Ryan. The motion passed unanimously.

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

Sedative Hypnotics (Blue Class)

Ryan Ruggles gave the presentation for sedative hypnotics. He gave the disease state description for insomnia.

In May 2023, the FDA approved a new generic, zolpidem tartrate capsule (C-IV), a gamma-aminobutyric acid (GABA) A receptor positive modulator for the short term treatment of transient insomnia characterized by difficulties with sleep initiation in adults less than 65 years of age. Supplied as an oral capsule in the strength of 7.5 mg; if a 5 mg or 10 mg dosage is needed, another zolpidem tartrate immediate release (IR) product should be used. The lowest effective dosage of zolpidem should be utilized and use should be avoided in geriatric patients. The capsules are for short term use only and are taken once per night before bedtime with greater than or equal to 7 or 8 hours remaining before planned awakening. In females the recommended starting dosage is 5 mg once nightly, as a result use another zolpidem IR product for dosage initiation in these patients. Males can initiate zolpidem at a dose of 5 mg IR, 7.5 mg IR or 10 mg IR once nightly. For males and females if a 5 mg dose is not effective the dose can be increased to 7.5 mg or 10 mg once nightly with a max recommended dosage of 10 mg IR once nightly. Boxed warning for complex sleep behaviors.

Utilization is 82.1 percent in line with PDL. Previous years motion Dr. Liljegren moved the drugs in the class were therapeutic alternatives. This was seconded by Dr. Ryan. The motion passed unanimously.

DR. PHILLIPS PROPOSED LAST YEARS MOTION. SECONDED BY ROBERT CARLSON. THE MOTION PASSED UNANIMOUSLY.

4-B Central Nervous System: Anticonvulsants (blue), Antipsychotics – Atypical (blue), Antidepressants (red), Alzheimer's Agents (red)

Anticonvulsants (Blue class)

Public comments for Anticonvulsants (Blue class)

KRISTEN HEARD, Director of Medical Information in the Department of Clinical Development and Clinical Affairs at Neurelis. She respectfully requested that Valtoco remains in the preferred position without restrictions. She reviewed a few key highlights on Valtoco. It is an intranasal diazepam spray for emergency rescue treatment of seizure clusters. It is the first and only intranasal rescue treatment for adults and children down to the age of 6. Neurelis is currently conducting a clinical trial in patients aged 2 – 5 where they are investigating the safety and pharmacokinetics of Valtoco for label expansion to include these younger children. Upon approval, Valtoco was designated clinically superior to Diastat diazepam rectal gel by the FDA. Valtoco is the only intranasal rescue medication that allows for customized dosing based on age and weight with 5, 10, 15 and 20 mg doses available an optimal dose may be administered to pediatric and adult patients alike. Each box contains two doses of Valtoco. If a second dose is needed it may be administered at least four hours after the initial dose. The PK studies demonstrate a consistent and reliable dosing with 97 percent absolute bioavailability of diazepam relative to IV and PK parameters that were 2 – 4 fold less variable when compared to Diastat. When treating seizure clusters with rescue medication the primary goals are to stop the initial seizure and prevent recurrence of seizure activity over time. Valtoco, which has a half-life of 49.2 hours, would allow coverage within the expected 24 hour timeframe of a seizure cluster. In exploratory analysis from a long term safety study patients with epilepsy and their caregivers reported rapid Valtoco administration and seizure cessation with a median time to administration of two minutes and a median time to seizure cessation of four minutes. A separate exploratory analysis demonstrated that in almost 4,000 seizure cluster events treated with Valtoco 87 percent of events were treated with a single dose over a 24 hour period. Valtoco has a boxed warning as do all benzodiazepines regarding concomitant use with opioids, abuse, misuse and addiction and dependence and withdrawal reaction. The most common local adverse events were nasal discomfort, dysgeusia and epistaxis. In a long term safety study, the rate of somnolence was 1.8 percent. For additional prescribing and important safety information the committee was referred to the full prescribing information for Valtoco. She asked the committee to allow patients to continue to have unrestricted access to Valtoco.

REJENA AMEEN, Senior Medical Outcome Liaison for UCB Pharma. She spoke today about seizure clusters, specifically the unmet need for treatment, socioeconomic burden and UCB's product midazolam nasal spray. She discussed the definition of seizure clusters. Nayzilam is the

first FDA approved nasal formulation for the treatment of acute seizures in the outpatient setting for patients 12 years and older. It is the only midazolam based option available for treatment in seizure clusters. Nayzilam is a benzodiazepine indicated for the treatment of intermittent stereotypic episode of frequent seizure activity that is different from the patient's usual seizure pattern in epilepsy patients 12 years and older. Nayzilam has a T-max of 17 minutes after a single dose and a half-life of 2 – 6 hours. Nayzilam demonstrates efficacy in stopping seizure cluster in a phase 3 double blinded placebo controlled study of 292 patients. In 81 percent of Nayzilam treated patients' seizures terminated within 10 minutes and 50 percent had no seizure recurrence up to 6 hours. Patients were defined as being able to return to what they were doing prior. The median return to full baseline functionality was 90 minutes with Nayzilam. Like all benzodiazepines Nayzilam has a box warning for the continued use opioids with abuse, misuse, addiction and dependence. The committee was referred to the PI for the full box warning and other important warnings, precautions and additional safety information. The most common adverse reactions were somnolence, headache, nasal discomfort, throat irritation and rhinorrhea. Nayzilam is supplied in a single dose in a box containing two 5 mg dose nasal spray units and does not require weight based dosing. While the majority of the patients in the trial did not require a second dose, a second dose can be administered as early as 10 minutes after the first. She asked the committee to consider adding Nayzilam to the PDL.

Ryan Ruggles gave the presentation for anticonvulsants. He gave the disease state description for epilepsy. He also gave the disease state description for Lennox-Gastaut syndrome, Infantile spasm and Dravet syndrome.

In regard to topiramate, in March 2023, the FDA approved the first generic for the 200 mg ER oral capsule of Supernus' Trokendi XR from Zydus.

In April 2023, the DEA published a final rule declaring the removal of fenfluramine and associated salts, isomers, and salts of isomers from the schedules of the controlled substances act effective December 23, 2022. Fenfluramine was previously a scheduled IV controlled substance since 1973. UCB Pharma has filed with the FDA for a labeling supplement to remove the schedule IV designation from the label.

With Vimpat, lacosamide, in May 2023, PI updated to include loading dose and/or higher initial dosage during week 1 as an alternative option for initiation of lacosamide in patients greater than or equal to 1 month to less than or equal to 17 years of age with partial onset seizure (monotherapy of adjunctive treatment) and for patients greater than or equal to 4 years of age to less than 17 years of age with primary generalized tonic-clinic seizure (adjunctive treatment). This new dosing can be applied for all formulations of the drug and can be utilized when reaching the maintenance dosage in a shorter timeframe is indicated. Labeling includes a table with recommended loading dosages according to the patient's age and weight.

In May 2023, the FDA approved a new formulation of lacosamide ER capsules (Motpoly XR) for treatment of partial onset seizures (POS) in adults and in pediatric patients weighing greater than or equal to 50 kg. The indication is for treatment of partial onset seizures in adults and pediatric patients weighing at least 50 kg. Warnings include fetal toxicity stating that use during pregnancy can cause cleft lip and or palate and being small for gestational age, suicidal behavior

and ideation stating that antiepileptic drugs increase the risk of suicidal behavior or ideation and cardiac rhythm and conduction abnormalities stating that an ECG should be obtained before beginning and after titration to steady state maintenance in patients with underlying proarrhythmic conditions or on concomitant medications that affect cardiac conduction. Those patients should be closely monitored. Dosage in adults ages 17 and older is listed as an initial dosage for monotherapy as 200 mg once daily. The initial dosage for adjunctive therapy is 100 mg once daily. The maximum recommended dose for monotherapy and adjunctive therapy is 400 mg once daily. Dosage for pediatric patients weighing at least 50 kg is an initial dosage for partial onset seizures of 100 mg once daily. It is available in 100 mg, 150 mg and 200 mg extended release capsules.

With utilization 92.8 percent were in line with PDL. Previous years motion Dr. Phillips moved the drugs in the class were therapeutic alternatives. This was seconded by Dr. Liljegren and passed unanimously.

DR. PHILLIPS PROPOSED LAST YEARS MOTION. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Antipsychotics - Atypical (Blue Class)

Public comments for Antipsychotics - Atypical (Blue class)

NIRMAL GHUMAN, Pharmacist and Principal Scientific Account Lead with Janssen Scientific Affairs. She took the time to discuss Invega Hafyera once every six month injection indicated for the treatment of schizophrenia in adults after they have been adequately treated with either Invega Sustenna for at least four months or Invega Trinza following at least one three month injection cycle. She directed the committee to the full prescribing information for complete information. Long acting injectables are recommended for schizophrenia patients who are not adherent, partially adherent or frequently relapsing in response to therapy or when the patients care environment is such that an LAI is a more reliable route of administration. The American Psychiatric Association practice guidelines for the treatment of patients with schizophrenia also recommend that LAIs should be used in patients with a preference for LAIs. Data suggests approximately 40 percent of patients have difficulty adhering to a daily oral treatment regimen. LAIs promote treatment adherence and transparency by insuring that patients with schizophrenia receive a known quantity of medication at appropriate dosing intervals. LAIs have been shown to be superior to oral antipsychotics in reducing relapses, hospitalizations and increasing adherence. In patients with schizophrenia use of LAIs is associated with approximately 30 percent lower risk of mortality compared with oral antipsychotics. The long term safety and efficacy of Invega Hafyera was evaluated in an international open label extension study where patients who remain relapse free in the double blind study were given the option to receive Invega Hafyera for up to 24 months. 96.1 percent of patients were relapse free at 24 months. No new safety signals were identified and no deaths were reported. A systematic review and metanalysis of real world comparative studies that reported hospitalizations, ER admissions, healthcare costs or medication adherence in adults with schizophrenia treated with LAIs versus oral antipsychotics was conducted. Of the 25 studies included, 14 studied included Medicaid data. Compared with patients treated with oral antipsychotics, patients initiated on LAIs have 38

percent lower odds of hospitalization, 25 percent fewer all cause hospitalizations and 14 percent fewer all cause ER admissions. Patients initiated on LAI treatment were 89 percent more likely to be adherent to their medication. Higher pharmacy costs associated with LAI initiation were offset by lower medical costs which resulted in no significant net cost difference. She thanked the committee for their time.

ERIN NOWAK, Medical Affairs at AbbVie, spoke today about Vraylar or cariprazine. She thanked the committee for having cariprazine on the PDL for Alaska patients. She used her time to share a new indication and updated information. Cariprazine is now approved for the adjunctive treatment to antidepressants for major depressive disorder in adults or AMDD. Cariprazine has the broader set of indications among the branded atypical antipsychotics. Other indications include schizophrenia, acute treatment of manic or mixed episode bipolar I disorder and the treatment of depressive episodes associated with bipolar I disorder. For AMDD the starting dose is 1.5 mg orally once daily with a dose range of 1.5 – 3 mg daily. This can be taken without regard to food. Efficacy of cariprazine as adjunctive therapy to antidepressants for the treatment of MDD was evaluated in two trials in adult patients. The primary endpoint in each trial was changed from baseline in the Montgomery-Asberg Depression Rating Scale or MADRS total score. In trial 1 cariprazine 1.5 mg plus antidepressant therapy or ADT was superior to placebo plus ADT. In trial 2 the cariprazine group that was on the dose range of 2 – 4.5 mg of cariprazine plus ADT was superior to placebo plus ADT in the MADRS total score. She also shared that in an IBM market scan database retrospective cohort study there was comparison of MDD related healthcare resource utilization and cost in patients that utilized cariprazine versus other atypical antipsychotics for the treatment of MDD. The study showed that MDD related in patient stays and MDD related ED visits were significantly lower for cariprazine which corresponds to reduced costs. As a reminder cariprazine has two characteristics that distinguish it from other therapies in the class. The first is that cariprazine has the longest effective half-life of the orally available atypical antipsychotics estimated to be approximately 1 week given its 2 major active metabolites. Secondly, cariprazine has a neutral metabolic profile with lower risk of weight gain and sedation which is important because weight gain is a common reason for discontinuation with other second generation atypical antipsychotics. For cariprazine safety information including the box warnings the committee was directed to review the full prescribing information. Given the broad set of indications, and the available information that supports cost effectiveness and unique characteristics, cariprazine remains a valuable treatment option for Medicaid patients of Alaska. She thanked the committee for the PDL status and access.

MADELINE SHURTLEFF, Pharmacist and Managed Market Liaison with Otsuka. She spoke today providing information on Abilify Asimtufii and Rexulti. Abilify Asimtufii is the first and only once every two month long acting aripiprazole injection indicated for treatment for both schizophrenia and bipolar I disorder in adults. The [unintelligible] study. Patients were randomized to either receive four injections of asimtufii 960 mg every 8 weeks or eight injections of abilify maintena 400 mg every 4 weeks. Both asimtufii and maintena showed similar aripiprazole plasma concentrations. The safety profile between the two drugs was similar with most commonly adhered adverse reactions being increased weight, injection site pain, akathisia and anxiety. Therefore, building on the proven efficacy of abilify maintena, abilify asimtufii offers comparable efficacy, safety and tolerability with two full months of sustained efficacy in patients with schizophrenia or bipolar I disorder. She then pointed out the box

warning for asimtufii of increased mortality in elderly patients [unintelligible]. She respectfully asked that asimtufii be added on the formulary for Alaska Medicaid members. Secondly, she provided [unintelligible]. Rexulti is now the first and only FDA approved medication indicated for the treatment of agitation associated with dementia due to Alzheimer's disease. The efficacy of Rexulti in the treatment of agitation associated with dementia in Alzheimer's disease was demonstrated in two 12 week randomized double blind placebo controlled fixed dose studies. She then discussed the studies numbered STUDY 6 and STUDY 7 and how they were run. She called attention to the box warnings. The first warning is increased suicidal thoughts and behaviors in patients 24 years of age and younger and the other warning is increased mortality in elderly patients with dementia related psychosis therefore Rexulti is not approved for the treatment of patients with dementia related psychosis without agitation associated with dementia due to Alzheimer's disease. Otsuka respectfully requested that Rexulti be available to patients with agitation associated with dementia due to Alzheimer's disease with no [unintelligible] drug list.

ROCHELLE YANG, Medical Affairs with Teva, provided some information about Uzedy which is a risperidone LAI that was approved in April 2023. Risperidone is one of the most commonly prescribed and well characterized antipsychotics used in schizophrenia. Uzedy is indicated for the treatment of adults with schizophrenia. It comes in monthly and bi-monthly dosing intervals. Patients can go directly onto the bi-monthly interval without needing to do the monthly first which might be beneficial for discharge situations where more time is needed to coordinate and establish outpatient care. Uzedy is available is 50 – 250 mg strengths which is comparable to oral risperidone daily dose equivalent of 2, 3, 4 and 5 mg. This offers a wide range of dosing options for patients. The 5 mg of oral risperidone equivalent is unique to the LAI market. In studies Uzedy has delivered therapeutic drive levels of risperidone within 24 hours after the first injection. That means it does not require any loading doses or oral supplementation or bridging for starting therapy. The patient is in the maintenance phase upon their first injection of Uzedy. It is administered subcutaneously in either the abdomen or the back of the upper arm using a short 5/8" needle, 21 gauge. It has a very low injection volume of 0.7 ml at its highest strength and for ease of use for HCPs it is supplied as a pre-filled syringe and does not require any reconstitution. Uzedy was studied in a phase 3 randomized control trial for 880 patients studied and was shown to significantly reduce the risk of relapse versus placebo. It was well tolerated with a safety profile similar to other formulations of risperidone, as expected. The committee was referred to the PI for more information. She respectfully requested that Uzedy be added as an option for the PDL for the vulnerable patients in Alaska living with schizophrenia.

Ryan Ruggles gave the presentation for antipsychotics – atypical and gave the disease state description for schizophrenia.

In November 2022, the FDA temporarily exercised enforcement discretion with respect to certain clozapine REMS program requirements to ensure continuity of care for patients taking clozapine. The FDA does not intent to object pharmacists dispense clozapine without a REMS dispense authorization (RDA).

In February 2023, Janssen will discontinue manufacture of Invega 1.5 mg tablets. Generic versions of this strength are available. Invega 3 mg, 6 mg and 9 mg tablets remain available.

In regard to Vraylar, in December 2022, the FDA approved a new indication for the adjunctive therapy to antidepressants for treatment of major depressive disorder (MDD) in adults. The indication was given along with the black box warnings which remained the same. The new dosage indication was given as well as the availability.

In January 2023, the FDA approved risperidone, a new formulation for the atypical antipsychotic as an ER injectable suspension for IM use. The product is indicated for treatment of schizophrenia in adults and as monotherapy or adjunctive therapy to lithium or valproate for maintenance treatment of Bipolar I Disorder in adults. The indications, black box warnings, dosage and availability were given.

In April 2023, Risperidone extended release injectable suspension has been approved for treatment of schizophrenia in adults. Uzedy will be available as 50mg/0.14 mL, 75mg/0.21 mL, 100 mg/0.28 mL, 125 mg/0.35 mL, 150mg/0.42 mL, 200 mg/0.56 mL and 250 mg/0.7 mL single dose prefilled syringes. The indication is for the treatment of schizophrenia in adults. Black box warnings are the same as other risperidone products. The dosage of Uzedy was given as well as the availability.

In April 2023, aripiprazole extended release injectable suspension has been approved for treatment of schizophrenia in adults and as maintenance monotherapy for treatment of bipolar I disorder in adults. Product will be available as 720 mg/2.4 mL and 960 mg/3.2 mL single dose prefilled syringes for IM use by a healthcare practitioner. The indication is given for the treatment of schizophrenia in adults and as maintenance monotherapy treatment of bipolar I disorder in adults. Black box warnings, dosage and availability were given.

In May 2023, the FDA has approved a new indication for brexpiprazole for the treatment of agitation associated with dementia due to Alzheimer's disease (AD). The new indications carries a limitation of use stating it is not indicated as an as needed treatment for agitation associated with dementia due to AD. Indication and limitations were listed as well as the black box warnings, dosage and availability.

Utilization shows 92.4 percent was in line with PDL. Previous years motion Dr. Phillips moved the drugs in the class were therapeutic alternatives, seconded by Dr. Ryan. The motion passed with one committee member not responding.

Dr. Phillips spoke up to make a statement saying that a couple of years ago she advocated for expanding the LAIs and she really appreciates that they have expanded that because there is a subset of people that truly would benefit from it. She is welcome to it being expanded further.

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

Antidepressants (Red Class)

Public comments for Antidepressants (Red class)

WILLIAM OLSUFKA, Senior Medical Scientist Liaison at Axsome Therapeutics, gave testimony for Auvelity dextromethorphan and bupropion extended release tablets for the treatment of major depressive disorder in adults. The STAR-D study clearly demonstrated that after ineffective treatment with an SSRI switching to an alternative SSRI or SNRI or bupropion all result in a likelihood of remission of only about 20 percent. The lack of pharmacologic diversity among oral treatment is a known unmet need. Auvelity is the first and only oral NMDA receptor antagonist approved for the treatment of MDD and represents the first oral treatment whose mechanism is not primarily monoaminergic. Dextromethorphan is an antagonist of the NMDA receptor and a SIGMA1 agonist through its clinical utility in treating CMS conditions was historically unrealized due to its rapid metabolism. The role of bupropion in Auvelity is primarily to increase and prolong plasma levels of dextromethorphan by inhibiting its CYP2D6 mediated metabolism. In the pivotal placebo controlled double blind randomized GEMINI study Auvelity demonstrated a statistically significant improvement in MADRS total score at week 6 achieving its primary outcome. Significant improvement in the MADRS was also demonstrated at week one. No other oral antidepressant has FDA approved labeling stating improvement in depressive symptoms starting at week one. Auvelity also demonstrated a statistically significant greater remission rate at week 2. As with all antidepressants, Auvelity has a box warning for increased risk of suicidal thoughts and behaviors in pediatric and young adult patients. The most common adverse reactions were dizziness, headache, diarrhea, somnolence, dry mouth, sexual dysfunction and hyperhidrosis. Auvelity is patented, proprietary extended release formulation. The doses and release profile of the individual components were determined based on extensive PK studies and result in dextromethorphan concentrations that target the relative neurotransmitter systems. There is no other formulation or combination of dextromethorphan that is approved for the treatment of MDD. Auvelity is now among the recommended first line treatments in the recently updated Florida best practice psychotherapeutic guidelines for adults with MDD. Auvelity is a novel oral rapidly active antidepressant that addresses important clinical needs in MDD and should be considered for addition to the preferred drug list.

Dr. Phillips had a question regarding Auvelity. She tried finding the study but only found that there was only 80 people in the first study. She's wondering if that had enough power to pull the way at two weeks.

Mr. Olsufka stated there were two studies and the one she was looking at was their first study. He directed her to the Phase 3 GEMINI study which had a much larger sample size of roughly 160 patients per treatment arm.

Dr. Phillips wondered if there was a way that she could actually see the study results.

Mr. Olsufka stated he will have the studies sent to her. He will send it to Charles Semling who will forward it to her.

Dr. Phillips then had a second question. She is concerned about the abuse potential with dextromethorphan.

Mr. Olsufka stated their compound is not a scheduled substance. They did not systematically evaluate for abuse potential in the trial but it is not a controlled substance. There is a warning in their PI however, that if there is a patient with a history of abuse then it should be considered.

There were no other questions for Mr. Olsufka.

NIRMAL GHUMAN, Pharmacist and Principal Scientific Account Lead with Janssen Scientific Affairs. She spoke about Spravato, esketamine nasal spray. Spravato is an NMDA receptor antagonist indicated in conjunction with an oral antidepressant for the treatment of treatment resistive depression or TRD in adults and depressive symptoms in adults with major depressive disorder, MDD, with acute suicidal ideation or behavioral referred as MDSI. Spravato has a boxed warning for sedation, dissociation, respiratory depression, abuse and misuse and suicidal thoughts and behaviors. Spravato is a schedule III controlled substance. Due to the risks of serious adverse outcomes Spravato is available only through a restrictive program called Spravato REMS. Further information is available at SpravatoREMS.com. She referred the committee to the full prescribing information for complete information. TRD and MDSI are two clinically distinct populations although overlap may occur. Although there is no consensus on the definition of TRD, TRD is commonly defined as a failure to achieve response or remission after two or more treatment attempts of adequate dose and duration. Approximately 1/3 of patients with MDD go on to develop TRD. The sequenced treatment alternative to relieve depression or STAR-D trial found that the proportion of patients achieving remission dropped to 31 percent with the second treatment trial and 14 percent with the third treatment trial. SUSTAIN3, a phase III open label single arm extension study evaluated the long term safety and efficacy of flexibly dosed Spravato with an oral antidepressant in patients with TRD. The mean treatment duration was 42.9 months and patients were followed for up to 6 1/2 years. A total of 1,148 adults with TRD entered. Treatment with Spravato demonstrated improvements in the MADRS total score starting at week one and continuing to improve during the induction phase. The percentage of responders with greater than or equal to 50 percent reduction of MADRS total score increased over time from 15 percent at day 8 to 50.6 percent at day 28. 35.6 percent of participants were in remission at the induction phase endpoint and 50 percent at the maintenance phase endpoint. No new safety signals were identified. In ESCAPE-TRD a randomized open label [unintelligible] blinded international phase III B clinical trial comparing the efficacy and safety of Spravato with Quetiapine XR in patients with TRD significantly more patients treated with Spravato achieved remission at week 8 compared to the Quetiapine XR arm. Spravato has demonstrated efficacy in the treatment of TRD and MDSI in clinical studies when compared to standard of care. It is for these reasons she asked that the committee consider adding Spravato to the Alaska Medicaid preferred drug list.

LYNDA FINCH, Medical Account Director for Biogen, spoke today about Zurzuvae or zuranolone. Zurzuvae was approved by the FDA on August 4, 2023, for the treatment of adults with postpartum depression. Zurzuvae is a neuroactive steroid that acts as a positive allosteric modulator of GABA-A receptors. It is the first oral medication approved to treat postpartum depression. It is taken once daily for 14 days at a dose of 50 mg a day. It is a schedule IV controlled substance and contains a boxed warning for impaired ability to drive or engage in other potentially hazardous activities due to CNS depressant effects that can last up to 12 hours

after administration so it is administered at night. The committee was referred to the PI for full warnings and precautions as well as dosage adjustments that are needed for patients with severe hepatic impairment, moderate to severe renal impairment and for use with strong CYP3A4 inhibitors. Efficacy and safety was evaluated in two phase III randomized double blind placebo controlled multicenter studies in women ages 18 – 45 with severe postpartum depression as assessed by the Hamilton Depression Rating Scale or HAMD 17. Onset of symptoms was in the third trimester or up to 4 weeks postpartum with ongoing severe depression up to 12 months postpartum in one study and up to 6 months postpartum in the other study. In both studies patients in the Zurzuvae treatment groups experienced statistically significant improvements in their symptoms compared to placebo as measured by the change from baseline on the HAMD 17 scale. The treatment effect was seen as early as day 3 after two doses and was maintained 4 weeks after the last dose. She added that the HAMD 17 is a well validated research tool accepted by the FDA as the gold standard for antidepressant trials but other validated tools such as the PHQ-9 or the Edinburgh Perinatal Depression Scale are the tools that are used commonly in the clinical care setting. Perinatal mental health conditions leading to suicide is the leading cause of overall preventable maternal mortality and perinatal depression is underdiagnosed and inadequately treated ultimately leading to greater healthcare resource utilization and long term effects on mothers, their children and their partners. She respectfully requested that the committee add Zurzuvae to the PDL as an option for this area of high unmet need.

Ryan Ruggles gave the presentation for antidepressants. He gave the disease state description for MDD and TRD. In 2023 the American College of Physicians published an evidence review of nonpharmacologic and pharmacologic treatments for adult patients with MDD in which the reviewed data showed similar benefit between most nonpharmacologic treatments and antidepressants when used initially in treatment. The review did note that antidepressants have higher risk for discontinuation due to adverse effects. Further, ACP published a 2023 guideline on nonpharmacologic and pharmacologic treatments of adults in the acute phase of MDD. The guideline states that patients with acute mild MDD should initiate CBT as initial treatment while patients with acute moderate or severe MDD undergo monotherapy with either CBT or a second generation antidepressant. Combination therapy with CBT and a second generation antidepressant can be considered as initial therapy for certain patients with moderate to severe MDD depending on factors such as adverse effects, symptoms, comorbidities and patient preference. For patients who fail to respond to an adequate dosage of a second generation antidepressant ACP suggests switching to or augmenting with CBT or switching to a different second generation antidepressant or augmenting with a second pharmacological treatment.

In January 2023, the FDA has approved the first generic to Allergan's Fetzima, levomilnacipran, from Aurobindo.

In May 2023, the indication for escitalopram for generalized anxiety disorder (GAD) has been expanded to include patients 7 – 17 years of age. Previously the indication covered adults only. The indication is for the treatment of MDD in adults and pediatric patients ages 12 and older as well as the treatment of GAD in adults and pediatric patients ages 7 and older. Black box warnings include increased risk of suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants as well as the risk for fetal harm. Dosage and availability were given.

In August 2023, the FDA has approved zuranolone, a neuroactive steroid GABA-A receptor positive modulator as the first oral treatment indicated to treat postpartum depression in adults. There is a black box warning of impaired ability to drive or engage in other potentially hazardous activities as well as fetal harm. Dosage and availability were given.

In September 2023, the FDA has approved gepirone (Exxua), an antidepressant indicated for the treatment of major depressive disorder in adults. Black box warnings include the increased risk of suicidal thoughts and behavior in pediatric and young adult patients taking antidepressants. There is also a pregnancy warning that use in the third trimester may increase the risk for persistent pulmonary hypertension and symptoms of poor adaptation such as respiratory distress, temperature instability, feeding difficulty, hypotonia and irritability in the neonate. It is stated to correct electrolyte abnormalities and perform ECG prior to initiating treatment. Do not initiate treatment if the QTc is greater than 450 msec. Perform ECGs during dosage titration and periodically during treatment. Dosage and availability were given.

Utilization was broken up into two different motions. The antidepressant SSRIs were at 95.4 percent in line with PDL and the antidepressant other was at 92.8 percent in line with PDL. Prior motion SSRI was moved as a class effect by Dr. Phillips and second by Dr. Doran-Atchison and passed unanimously. Prior year motion for antidepressant others was moved by Dr. Phillips that the drugs in the class were therapeutic alternatives and seconded by Dr. Bregay-Bruno and passed unanimously.

Dr. Phillips had a question regarding Zurzuvae as it is not on the list but is available if deemed medically necessary. She just wanted to confirm that. Dr. Semling confirmed that.

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

FOR THE OTHER ANTIDEPRESSANTS DR. PHILLIPS MOVED THAT THE DRUGS IN THE CLASS ARE THERAPEUTIC ALTERNATIVES. SECOND BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Alzheimer's Agents (Red Class)

Ryan Ruggles gave the presentation on Alzheimer's agents. He gave the disease state description on dementia and Alzheimer's disease.

In January 2023, the FDA granted accelerated approval to lecanemab-irmb (Leqembi) an amyloid beta directed antibody indicated for the treatment of Alzheimer's disease. Labeling states treatment should be started in patients with mild cognitive impairment of mild dementia stage of disease, the population in which treatment was initiated in clinical trials as there is not safety or effectiveness data on starting treatment at earlier or later stages of the disease than were studied. Limitations include pregnancy warning stating that based on animal data it may cause fetal harm. There is a black box warning stating that monoclonal antibodies directed against aggregated forms of beta amyloid including Leqembi can cause amyloid related imaging

abnormalities characterized as ARIA with edema and ARIA with hemosiderin deposition. ARIA is usually asymptomatic although rarely serious and life threatening events can occur. Serious intracerebral hemorrhage greater than 1 cm have occurred in patients treated with this class of medications. Dosage and availability were given.

CMS communication announced that Medicare Part B will cover drugs that slow the progression of Alzheimer's disease if the drug is granted traditional FDA approval rather than accelerated approval, the patient is diagnosed with mild cognitive impairment or early dementia due to Alzheimer's disease or the patient is followed by a qualified physician participating in a registry and has appropriate follow up care.

Utilization shows that 98 percent are in line with PDL. The previous motion Dr. Ryan moved for therapeutic alternatives, seconded by Dr. Liljegren. Passed unanimously.

DR. RYAN MOVED FOR THERAPEUTIC ALTERNATIVES, SECONDED BY TRISH WHITE. THE MOTION PASSED UNANIMOUSLY.

4-C Analgesics: NSAIDS (blue), Analgesics, Opioid Short-Acting (blue), Analgesics, Opioid Long-Acting (green), Neuropathic Pain (green), Antimigraine Agents (red), Skeletal Muscle Relaxants (green), Restless Leg Syndrome (green), Smoking Cessation Agents (green), Opioid Dependence (blue), Opioid Reversal Agents (blue)

NSAIDS (Blue Class)

Ryan Ruggles gave the presentation on NSADs. He gave the disease state description for NSAIDs.

In 2023, the ADA endorsed new guidelines by the American Dental Association Science and Research Institute, the University of Pittsburgh School of Dental Medicine and the Center for Integrative Global Oral Health at the University of Pennsylvania School of Dental Medicine for the management of acute dental pain in children less than 12 years of age. They recommend use of NSAIDs plus or minus acetaminophen for acute dental pain after one or more simple tooth extractions and for the temporary management of toothache in children. If NSAIDs were contraindicated, acetaminophen alone is recommended. Use of codeine and tramadol in children for managing acute pain is contraindicated.

In 2022, the CDC released updated clinical practice guidelines for prescribing opioids for pain. It includes 12 recommendations for managing acute, subacute and chronic pain in adults. The recommendations do not apply to pain related to sickle cell disease or cancer or to patients receiving palliative or end of life care. The guideline addresses the following 4 areas; decision to initiate opioids for pain, opioid selection and dose determination, duration of initial opioid prescription and conducting follow up and assessing risk and addressing potential harms of opioid use.

In October 2023, the FDA approved oxaprozin 300 mg capsule for relief of the signs and symptoms of osteoporosis and juvenile rheumatoid arthritis. Thre is a black box warning for risk of CV and GI events. Dosage and availability were given.

In October 2023, acetaminophen/ibuprofen combination (Combogesic IV) indicated in adults where an intravenous route of administration is considered clinically necessary for the relief of mild to moderate pain or the management of moderate to severe pain as an adjunct to opioid analgesics. Indicated for a short term use of 5 days or less. Black box warning includes the risk of hepatotoxicity, CV and GI events. Not recommended for patients with renal impairment or hepatic impairment. Dosage by weight and availability were given.

In March 2023, the FDA approved the combination of acetaminophen and ibuprofen (Combogesic) as 325/97.5 mg tablets for the management of mild to moderate acute pain. Black box warning of risk of hepatotoxicity, CV and GI events. NSAID containing products are associated with reversible infertility. Consider withdrawal of tablets in women who have difficulties conceiving. It is not recommended for patients with renal or hepatic impairment. Dosage and availability were given.

In August 2023, the FDA reported that Horizon has made a business decision to discontinue the manufacture of Duexis (ibuprofen/famotidine).

Utilization was approximately 99.3 percent in line with PDL. Previously Dr. Doran-Atchison moved a class effect to include a topical preparation, seconded by Dr. Liljegren. The motion passed unanimously.

DR. DORAN-ATCHISON MOVED A CLASS EFFECT TO INCLUDEE A TOPICAL PREPARATION, SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

Analgesics, Opioid Short-Acting (Blue Class)

Ryan Ruggles gave the presentation for analgesics, opioid short-acting with the disease state description. He informed the committee that there are guidelines over a year old in the Appendix.

In April 2023, the FDA announced multiple updates to the PI of opioid pain meds to provide added guidance of using these meds. A new warning will be added about the potential for opioid induced hyperalgesia among other updates. The required label updates will be for both immediate release and extended release/long acting opioid. The safety label updates are to add clarity on intended patient populations for these agents, appropriate dosage and administration and update details on the risks associated with using these meds.

In May 2023, Teva has issued a voluntary recall to the consumer level of 13 lots of fentanyl citrate buccal tablets CII (various strengths), manufactured and labeled for Mayne, due to a labeling error where safety updates were omitted from PI and Medication Guide. Teva has not received any complaints to date from the labeling error.

In July 2023, tapentadol (Nucynta) indicated for the management of acute pain severe enough to require opioid analgesic in which body alternative treatments are inadequate has been expanded to include patients aged greater or equal to 6 years of age with body weight greater or equal to 40 kg. Warnings, dosage and availability remain the same.

Utilization was 45.8 percent in line with PDL though Ryan wanted to note that the way that is calculated is based on the name of the generic and unfortunately the hydrocodone/APAP has two different strengths, 10/300 is not preferred but the 325 is preferred. If we added those back in that would be approximately 40 percent back up onto the preferred line making it closer to 85 percent. Previous years motion Dr. Ryan moved the drugs in the class were therapeutic alternatives, seconded by Dr. Phillips. The motion passed unanimously.

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

Analgesics, Opioid Long-Acting (Green Class)

Given this was a green class they went right into utilization. Utilization was approximately 63.3 percent in line with PDL. Prior motion Dr. Phillips moved the drugs in the class were therapeutic alternatives, seconded by Dr. Ryan. The motion passed but was not unanimous as there were two NAYs.

Dr. Phillips asked if the generics also skewed this utilization. Ryan replied stating that oxycontin skewed it by 15 percent and the oxycodone skewed it by 8 percent.

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

Neuropathic Pain (Green Class)

This was a green class so they moved directly into utilization. Utilization was approximately 98.9 percent in line with PDL. Previously Dr. Ryan moved that the drugs in the class were therapeutic alternatives, seconded by Dr. Phillips and the motion passed unanimously.

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

Antimigraine Agents (Red Class)

Public comments for Antimigraine Agents (Red class)

ERIN NOWAK, Medical Outcomes Science Liaison with Medical Affairs at AbbVie spoke about atogepant or Qulipta. Atogepant is an oral CGRP receptor antagonist now covering both episodic and chronic migraine. It is currently the only oral CGRP therapy covering the full spectrum of migraine prevention. The recommended dose is 10, 30 or 60 mg once daily for episodic migraine and 60 mg once daily for chronic migraine. Dose modifications may be recommended for drug interactions and special populations as listed in the prescribing information at rxabbvie.com. Following oral administration atogepant is absorbed with a peak plasma concentration at approximately 1- 2 hours and has a half life of approximately 11 hours. This affords the suitability for daily dosing as well as fast clearance of the drug in approximately 3 days should a patient need to withdrawal therapy for any reason. In clinical trials monthly migraine days were reduced, social and work related activity functions were significantly improved, acute medication use was reduced and 50 percent responder rates were improved. 55 – 60 percent of patients in episodic migraine and 41 percent of patients in chronic migraine were able to reduce their monthly migraine days by half or better over the 12 week trial periods. Outcomes data have demonstrated that atogepant has the lowest number needed to treat when compared to all approved CGRPG-pants and monoclonal antibodies use for the purposes of migraine prevention when looking at 50 percent responder rates. Additionally, when using this information to calculate cost for responder atogepant chose a lower cost for an additional 50 percent responder among the oral CGRPG-pants potentially results in cost savings for the state of Alaska among the oral CGRP treatments for migraine prevention. As for safety there is one contraindication and warning of hypersensitivity and the most frequently reported adverse events in the phase III trials were constipation, nausea and fatigue. Discontinuation rates due to adverse events were low. She directed the committee to the prescribing information at rxabbvie.com for more information. Given the safety and efficacy information covered and that atogepant is the only oral therapy in the CGRP class covering both episodic and chronic migraine she closed by respectfully asking that atogepant or Qulipta be added to the PDL for migraine sufferers in Alaska.

DAVID GROSS, Pfizer Medical Affairs, joined today to provide information on Nurtec ODT. Nurtec ODT is indicated for both the acute treatment of migraine both with and without aura in adults and for the preventative treatment of episodic migraine in adults. For acute treatment of migraine, the recommended dose is 75 mg taken orally as needed with the maximum dose in a 24 hour period being 75 mg. For preventative treatment of episodic migraine, the recommended dosage is 75 mg taken orally every other day. The efficacy of Nurtec ODT for the acute treatment of migraine in adults was demonstrated in a randomized double blind placebo controlled trial. Patients in the study were randomized to either receive 75 mg of Nurtec or placebo. The primary outcome variables measured pain freedom and most bothersome freedom at 2 hours after dosing compared to placebo. The percentage of patients achieving headache pain freedom and most bothersome symptom freedom 2 hours after a single dose was statistically significantly greater in patients that received Nurtec ODT compared to those who received placebo. Nurtec ODT was well tolerated with the most common adverse reaction being nausea and hypersensitivity occurred in less than 1 percent of the patients treated. The efficacy of Nurtec ODT for the preventative treatment of episodic migraine in adults was demonstrated in one randomized double blind placebo controlled trial where patients received every other day dosing of Nurtec 75 mg or placebo for 12 weeks. The primary efficacy endpoint was the change from baseline in the mean number of monthly migraine days during weeks 9 – 12. Nurtec 75 mg

dosed every other day demonstrated statistically significant improvements for this efficacy endpoint compared to placebo. Most common adverse reactions in this study were nausea and abdominal pain or dyspepsia. He respectfully asked the committee to maintain Nurtec ODT on the preferred drug list.

ROCHELLE YANG, Medical Affairs at Teva, spoke about Ajovy which is an injectable CGRP inhibitor. She gave a quick reminder that Ajovy or fremanizumab-vfrm is a monoclonal antibody that binds to the CGRP and blocks its binding to the receptor. It is a self-administered subcutaneous CGRP inhibitor and the only one of which that is approved for both monthly and quarterly dosing for the prevention of migraine. In addition to the 3 phase III trials that were done they have published evidence studies since the approval of Ajovy. Ajovy has been [unintelligible] reduction in monthly migraine days by an average of 9 days down from a mean baseline of 12.7 days 6 months posttherapy initiation. They have also seen high adherence in persistence to Ajovy with over 3/4 of patient's adherent to therapy based on [unintelligible] analysis post 6 months. Ajovy has also been associated with decreased claims for acute medications including those with opioids, triptans and have also been found to be effective in migraine prevention for patients with comorbid depression and anxiety which are common comorbidities of migraine. She noted that there are important limitations with retrospective observational studies and they do not prove causality however the real-world evidence to date is consistent with what they have seen in the phase III randomized controlled trials and add to the [unintelligible] evidence to support the safety and efficacy seen with Ajovy across a broad population of patients with migraine. She asked the committee to allow Alaksa Medicaid patients continued access to Ajovy.

Dr. Semling had a question or any of the manufacturers stating that they were wondering if there was any new research showing benefits of a large molecule and a small molecule taken together and also two small molecules taken together as far as safety and efficacy of that combination. He asked that any of the manufacturers send any literature on that to him.

ERIN NOWAK, spoke up stating that they can confirm that at AbbVie they have some information on using therapies together. It is more safety information and she will send it over to him in an email.

Dr. Semling stated he will disseminate that to the committee.

Ryan Ruggles gave the disease state description presentation on Antimigraine Agents. This covered migraine headache and cluster headache.

In March 2023, AstraZeneca will be discontinuing brand name Zomig ZMT (zolmitriptan ODT).

In August 2023, the FDA is reporting discontinuation of Imitrex 5 mg and 20 mg nasal spray by GlaxoSmithKline. The last date that product will be available for ordering is January 31, 2024. Generic remains.

In March 2023, the FDA approved a new calcitonin gene-related peptide (CGRP) receptor antagonist zavegepant (Zavzpret) for the acute treatment of migraine with or without aura in

adults. It is not indicated for the preventative treatment of migraine. Warnings include that it should not be used in patients with severe hepatic impairment or in patients with CLcr less than 30 mL/min. Dosage and availability were given.

In April 2023, the FDA approved rizatriptan oral film (RizaFilm) 10 mg for the acute treatment of migraine with or without aura in adults and pediatric patients 12 – 17 years of age weighing greater than or equal to 40 kg. Use is limited to treatment after a clear diagnosis of migraine has been established; the product is not indicated for prevention of migraine or treatment of cluster headache. Warnings include myocardial ischemia, myocardial infarction and Prinzmetal's angina. Providers should perform cardiac evaluation in patients with multiple cardiovascular risk. Discontinue if arrythmia occurs. Dosage and availability were given.

In April 2023, the FDA approved atogepant (Qulipta) for the preventative treatment of chronic migraine in adults previously approved only to prevent episodic migraine. Warnings include pregnancy stating that based on animal studies may cause fetal harm and providers should avoid use in patients with severe hepatic impairment. Dosage and availability were given.

For antimigraine agents – triptans the utilization was approximately 96.6 percent in line with PDL. Previous motion Dr. Ryan moved that the drugs be considered a class effect to include at least one non-oral preparation, one drug for acute treatment and a drug for prophylactic treatment, seconded by Dr. Phillips. The motion passed unanimously.

FOR ANTIMIGRAINE AGENTS – TRIPTANS DR. DORAN ATCHISON MOVED THAT THE DRUGS BE CONSIDERED A CLASS EFFECT TO INCLUDE AT LEAST ONE NON-ORAL PREPARATION, ONE DRUG FOR ACUTE TREATMENT AND A DRUG FOR PROPHYLACTIC TREATMENT, SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

For antimigraine agents – other the utilization was 92.5 percent was in line with PDL. Previous motion Dr. Phillips moved the drugs be considered a therapeutic alternative for acute and prophylactic treatment, seconded by Dr. Liljegren. The motion passed unanimously.

FOR ANTIMIGRAINE AGENTS – OTHER DR. PHILLIPS MOVED THE DRUGS BE CONSIDERED A THERAPEUTIC ALTERNATIVE FOR ACUTE AND PROPHYLACTIC TREATMENT, SECONDED BY VALARIE BIXLER. THE MOTION PASSED UNANIMOUSLY.

Skeletal Muscle Relaxants (Green Class)

Given that this is a green class they moved directly into utilization. Utilization was approximately 97.5 percent in line with PDL. Previous motion Dr. Liljegren moved the drugs in the class were therapeutic alternatives, excluding carisoprodol from the PDL, seconded by Mrs. White. The motion passed unanimously.

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

Restless Leg Syndrome (Green Class)

Given that this was another green class they went directly to utilization which was 0 percent in line with PDL. Ryan Ruggles stated that the summary was for a lot of other medications. His notes stated that there is actually only 252 that were specifically indicated for RLS and ….

Dr. Semling stepped in and stated that it got lumped into the anti-Parkinson's which is a non-reviewed class which is why 100 percent would be non-PDL because it is not reviewed. He states there is quite a bit of utilization on those and they are covered.

DR. RYAN MOVED A CLASS EFFECT, SECONDED BY VALARIE BIXLER. THE MOTION PASSED UNANIMOUSLY.

Smoking Cessation Agents (Green Class)

Another green class so they moved directly to utilization was approximately 98.4 percent was in line with PDL. Prior motion Dr. Liljegren moved the drugs in the class were therapeutic alternatives, seconded by Dr. Doran-Atchison and passed unanimously.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, SECONDED BY [FEMALE SPEAKER]. THE MOTION PASSED UNANIMOUSLY.

Opioid Dependance (Blue Class)

Public comments for Opioid Dependence (Blue class)

SAMUEL RIEGA, Medical Science Liaison with Braeburn Pharmaceutical Medical Affairs, spoke today about opioid use disorder and Brixadi. In 2017 the US Department of Health and Human Services declared the opioid crisis a public health emergency with over 40,000 deaths at that time. Since that the HHS have reaffirmed this crisis continues in effect with opioid deaths now surpassing 82,000 deaths as of 2022 as reported by the CDC. Despite these statistics and the recent advances in the treatment of opioid use disorder a recent Journal of the Medical American Association study found that only 22 percent of [unintelligible] patients received medications for the opioid use disorder (MOUD) in 2021. MOUD utilization was even lower in African American adults, women, the unemployed and those living in non-metropolitan areas. He spoke briefly about Brixadi which is a long acting injectable form of buprenorphine which is now available to provide patients with an additional treatment option to initiate and sustain long term recovery of opioid use disorder. Brixadi is available in four weekly and three monthly formulations designed to deliver an individualized lowest effective dose while also optimizing tolerability and minimizing side effects. Brixadi is an option for individuals who struggle to stabilize their opioid use disorder treatment and is indicated for patients that are both new to

treatment as well as those currently using sublingual buprenorphine. Brixadi utilizes a unique fluid crystal technology that delivers buprenorphine. This technology allows for a low volume half cc or less to be injected into the subcutaneous space and quickly forms a gel that is nearly unpalpable and allows for the steady release of buprenorphine over one week or one month. When compared to sublingual buprenorphine Brixadi has demonstrated significant reductions in opioid use. Furthermore, in a 24 week phase III clinical trial that included over 400 patients, 25 percent of which were exposed to fentanyl and up to 30 percent that were also exposed to other polysubstances such as amphetamines, barbiturates, benzodiazepines, cocaine, cannabinoids and PCP found no overdoses occurred in the Brixadi group compared to 5 overdoses in the sublingual group and a 4 fold reduction in hospitalizations. Common adverse drug events reported by these patients receiving Brixadi in clinical trials to date have included injection site reaction and typical buprenorphine associated side effects such as headache, constipation and nausea. [Unintelligible] have been described as mild to moderate and transient in nature. He wanted to advocate for the addition of Brixadi to the PDL as well as the removal for prior authorizations for all long acting injectable buprenorphine for OUD patients.

JESSICA JAY, PharmD and she is with Indivior Medical Outcomes and Value Liaison Team. She spoke today about SUBLOCADE, buprenorphine extended release injection, for subcutaneous use. SUBLOCADE is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a buprenorphine containing product followed by dose adjustment for a minimum of 7 days. SUBLOCADE should be used as part of a complete treatment plan which includes counseling and psychosocial support. In September 2023 they updated the label for storage considerations. The time out of refrigerator storage requirements have been updated because of an upcoming change in the packaging from containing oxygen absorber to containing an oxygen absorbing [unintelligible]. It should continue to be stored and refrigerated at 2 – 8 degrees Celsius. Once outside of the refrigerator the new package containing an oxygen absorbing [unintelligible] will allow for a longer storage time at room temperature at 12 weeks prior to administration. The old packaging containing an oxygen absorber will adhere to the previous storage requirements of 7 days at room temperature. Indivior anticipates that the new and updated packaging will be released into the drug supply in mid-2024 as Indivior works through a dissemination plan that minimizes a period of dual inventory with the customers drug inventory. This will minimize confusion for providers, pharmacies and distributors during the period of transition. They requested that the committee maintain the coverage of SUBLOCADE to help patients suffering from opioid use disorder.

Umang Patel gave the disease state description presentation on Opioid Dependence.

In May 2023, the FDA approved Brixadi, an ER buprenorphine injection for the treatment of moderate to severe opioid dependence patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine. It should be used as part of a complete treatment plan that includes counseling and support. There is a black box warning of risk of serious harm or death with IV administration. Dosage and availability was given.

In September 2023, the FDA approved the first generic for Vivitrol Er injectable suspension by Teva.

In May 2023, the FDA and SAMHSA have issued a letter providing clarification on buprenorphine prescribing recommendations, specifically detailing that a separate waiver is no longer required for dispensing certain medications such as buprenorphine. The letter also reiterates that prescribing buprenorphine should not be contingent upon the patient's participation in counseling or other services such as case management or peer support. Although counseling and other services should be offered, the decision to utilize these services should be made in collaboration with the patient.

Utilization was approximately 91.9 percent in line with PDL. Previous motion Dr. Liljegren moved the drugs in the class were therapeutic alternatives to include at least one long acting injectable product, seconded by Dr. Phillips. The motion passed unanimously.

DR. CARLSON MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. [FEMALE]. THE MOTION PASSED UNANIMOUSLY.

Opioid Reversal Agents (Blue Class)

Public comments for Opioid Reversal Agents (Blue class)

DESIREE CREVECOEUR-MACPHAIL, Medical and Scientific Advisor for Hikma Community Health. She spoke today about Kloxxado 8 mg and wanted to ask that it maintain its status as a preferred drug rather than be changed to one that requires a preauthorization. Kloxxado is an opioid antagonist indicated for the emergency treatment of known or expected opioid overdose as manifested by respiratory and or central nervous system depression in adult and pediatric patients. Opioid overdose deaths have increased from 2019 – 2022 in Alaska. Across the country deaths attributed to other synthetic opioids like illicitly manufactured fentanyl exceed those caused by other opioids. In addition, in 2021 almost 3/4 of cocaine involved deaths and half of stimulant related deaths also involved synthetic opioids. Overdoses involving illicitly manufactured fentanyl often require multipole doses of naloxone. Data examining naloxone administration shows increases in the number of opioid overdose events where two or more doses of the 4 mg naloxone nasal spray was used from 34 percent in one 2016 study to as high as 78 percent in a 2021 study. EMS data shows an increase of 96 percent over 8 years in the number of opioid overdose events where two or more doses of naloxone were used. In addition, a study conducted by the US Department of Health and Human Services found that over 75 percent of opioid overdose victims reported one or more post overdose complication related to opioid induced hypoxic brain injury. Complications can include ataxia, catatonia, impaired memory, mental disorientation, etc. The report noted that the risk for these complications is higher for repeated and longer episodes of hypoxia. Current doses of naloxone may not displace illicitly manufactured fentanyl rapidly enough. Furthermore, a sample of over 1100 individuals entering treatment for an opioid use disorder reported a greater preference for a high dose naloxone nasal spray at 36 percent compared to the standard dose at 13 percent. The warnings and precautions for Kloxxado are the same as any other naloxone product. There is a risk of recurrent respiratory and central nervous system depression, there is a risk of limited efficacy with partial agonist or mixed agonist antagonists and for those who are opioid dependent there is

a risk of precipitated opioid withdrawal. Kloxxado addressed the unmet need for higher dose naloxone. Respiratory depression creates a risk for death for naloxone is considered a safe medication we consider Kloxxado to have a favorable risk benefit profile for patients at risk of an opioid overdose and request that Kloxxado maintain its status as a preferred drug rather than being changed to one requiring a preauthorization.

JESSICA JAY, PharmD with Indivior's Medical Outcome Liaison Team. She spoke about OPVEE nasal spray. As an overview OPVEE nasal spray is for emergency treatment of known or suspected overdose induced by natural or synthetic opioids in patients 12 years or older as manifested by respiratory or central nervous system depression. OPVEE is for immediate administration as emergency therapy in settings where opioids may be present and is not a substitute for emergency medical care. OPVEE is for intranasal use only. Each unit dose nasal spray delivers 2.7 mg of nalmefene and 0.1 mL. Each carton contains two unit dose nasal spray devices. Always seek emergency medical assistance after the administration of the first dose of OPVEE. Additional doses of OPVEE may be required until emergency medical assistance becomes available. Readminister OPVEE using a nasal spray in the nose every 2 – 5 minutes if the patient does not respond or responds and then relapses into respiratory depression. OPVEE is contraindicated in patients known to be hypersensitive to nalmefene or to any of the other ingredients. OPVEE warnings and precautions include risk of recurrent respiratory and central nervous depression, limited efficacy with partial [unintelligible], precipitation of a severe opioid withdrawal, risk of cardiovascular effect and risk of opioid overdose from attempts to overcome the blockade. The most common adverse reactions are nasal discomfort, headache, nausea, dizziness, hot flash, vomiting, anxiety, fatigue, nasal congestion, throat irritation, pain of the nose, decreased appetite, changes in sense of taste, skin redness and increased sweating. In regard to the clinical development of OPVEE it was studied in 61 healthy volunteers. Each volunteer received the hypercapnic gas mixture containing 7 percent CO2 which was utilized at safely [unintelligible] 25 minutes. Just prior to the initiation of remifentanil infusion at negative 15 minutes the baseline minute ventilation was recorded. At time 0 which is 15 minutes after infusion the lowest minute ventilation point was observed at which point OPVEE was administered. The volunteers were then monitored for changes in minute ventilation over 120 minutes. For the results following OPVEE administration the time to onset of effect was observed between 2.5 – 5 minutes. At 5 minutes the estimated mean increase in minute ventilation was 5.745 liters per minute. Full recovery of respiratory function was noted between 5 and 15 minutes after OPVEE administration. They requested that the committee consider the coverage of OPVEE as an additional emergency treatment option to help patients of known or suspected overdose.

Umang Patel did not give a disease state description presentation since there were no new background or guideline updates, he went right into drug specific updates.

In May 2023, the FDA approved an Rx naloxone 4 mg nasal spray formulation, Rextovy, for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and or central nervous system depression for adults and pediatric patients. The opioid antagonist is intended for immediate administration as emergency treatment in settings where opioids may be present and is not a substitute for emergency medical care. There is a warning of the risk of recurrent respiratory and CNS depression due to the duration of action of naloxone relative to the

opioid the patient needs to be kept under continued surveillance and administer repeat doses of naloxone using a new nasal spray device with each dose as necessary while awaiting emergency medical assistance. Dosage and availability were reviewed.

In August 2023, the FDA approved RiVive OTC naloxone 3 mg/0.1mL nasal spray for the emergency treatment of known or suspected opioid overdose. The drug label specifies it may be used to "revive" someone during an overdose from many prescription pain medications or street drugs such as heroin and the medicine can save a life. Label instructs how to first check for a suspected overdose and give 1 dose in 1 nostril and call 911 immediately after administration. A second dose may be given 2 – 3 minutes after the first dose if the person has not awakened. Additional doses may be given if the person becomes very sleepy again and all the doses in the pack may need to be used. Package contains two 3 mg single dose devices. Launch is planned for early 2024.

In August 2023, there is an Rx to OTC switch for Narcan, naloxone hydrochloride. The FDA has approved a full prescription to nonprescription switch for Narcan (naloxone hydrochloride) nasal spray. The drug facts panel uses are to "revive" someone during an overdose from many prescription pain medications or street drugs such as heroin; this medication can save a life. Directions are to check for an overdose, give the first dose in the nose, call 911 immediately after giving the dose, wait 2 – 3 minutes after the first dose and if the person wakes up stay until the ambulance arrives and give another dose if the person becomes very sleepy again; if the person does not wake up continue to give doses every 2 – 3 minutes until the person wakes up. All the doses in the pack may need to be given. Supplied as 4 mg of naloxone hydrochloride in each spray (each device only sprays one time). Launch of the OTC version is expected by late summer 2023. OTC Narcan nasal spray became available online and in drugstores starting the week of September 4, 2023. Various stores will have it available for sale behind the pharmacy counter or at the register.

Utilization was approximately 100 percent in line with PDL. Previous motion Dr. Liljegren moved the drugs in the class were therapeutic alternatives, seconded by Dr. Ryan and the motion passed unanimously.

Charles Semling wanted to mention that from the previous class reviewed all the naloxone was lumped into that category but they should fall in with this one. That would shift some of the utilization that way. He just wanted to make that known.

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

Charles Semling had one more comment on the Naloxone OTC. Since it does meet the definition of a covered outpatient drug, we will be covering that and with pharmacists' scope of practice they are actually able to prescribe that so if it is needed and they don't have prescription Narcan on their shelf they can actually bill for the OTC version as well.

4-D Antiviral Monoclonal Antibodies: RSV Agents (red)

RSV Agents (Red Class)

Public comments for RSV Agents (Red class)

CHERYL BONDY, Account Director for Sobi Inc, spoke today about Synagis also known as palivizumab. Synagis is a humanized monoclonal antibody produced by recombinant DNA technology that exhibits both neutralizing and fusion inhibitory activity against respiratory syncytial virus or RSV. Synagis was approved by the FDA in 1998 for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease. Safety and efficacy of Synagis were established in children with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season, infants with a history of premature birth of less than or equal to 35 weeks gestational age and who are 6 months of age or younger at the beginning of RSV season and children with hemodynamically significant congenital heart disease and who are 24 months of age or younger at the beginning of RSV season. As you may be aware the American Academy of Pediatrics Committee on Infectious Disease published an updated guidance on palivizumab prophylaxis in high risk infants and young children in July 2014. The guidance asserted that preterm infants without chronic lung disease and born at 29 – 35 GA would not have a substantial clinical benefit from RSV prophylaxis and thus removed recommendations for palivizumab prophylaxis for this gestational age group. On June 26, 2023, the American Academy of Pediatrics Committee on Infectious Disease published their latest technical report on palivizumab prophylaxis in infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. This updated technical report reasserts their statement that palivizumab be recommended for preterm infants at less than 29 weeks gestational age who are less than 12 months of age at the start of RSV season, preterm infants who developed CLD of prematurity defined as GA age of less than 32 weeks and required greater than 21 percent oxygen for at least the first 28 days after birth and who continue to require medical support during the six month period before the start of the second RSV season and children of hemodynamically significant CHD during their first RSV season. The August 1, 2023 edition of AAP news highlighted a letter written by the current AAP President Sandy Chung [phonetic] urging health officials to develop a comprehensive strategy as new RSV prevention modalities roll out including to support continued use of palivizumab for the prevention of RSV disease in high risk infants for the coming season. Based on today's testimonies and previous testimonies Sobi requests that Synagis is continued to be administered to infants at greatest risk for severe RSV disease and preserve physician choice.

Umang Patel gave the disease state description for RSV agents.

In August 2023, the AAP and CDC released recommendations for the use of nirsevimab-alip (Beyfortus). The recommendations for Beyfortus apply to infants and children recommended to receive palivizumab by AAP and to broader patient population than recommended for palivizumab. However, due to a likely limited initial supply of nirsevimab-alip, continued use of palivizumab is recommended during the 2023 – 2024 RSV season for eligible children at high risk of severe RSV illness who cannot access Beyfortus. In addition, the AAP advises if nirsevimab is administered the first season palivizumab should not be administered later that

season. If palivizumab was administered initially for the season and less than five doses were administered the infant should receive one dose of nirsevimab. No further palivizumab should be administered. If palivizumab was administered in season one and the child is eligible for RSV prophylaxis in season two the child should receive nirsevimab in season two if available.

In July 2023, the FDA approved Beyfortus, nirsevimab-alip, for the prevention of RSV lower respiratory tract disease in neonates and infants born during or entering their first RSV season and in children up to 24 months who remain vulnerable to severe RSV disease through their second RSV season. Dosage and availability were given.

Utilization was roughly 100 percent in line with PDL. Previous motion Dr. Ryan moved a class effect, seconded by Dr. Liljegren. The motion passed unanimously.

Charles Semling spoke up stating the reason it shows little utilization is because this was from the previous quarter. The Synagis season generally runs from about the end of November through May so there would be very little utilization. One other thing is they probably from the pharmacy system will not see utilization of Beyfortus at this point. They did categorize that into the vaccines for children program so it falls under that program so it is a covered medication through the federal government.

Ryan Ruggles stated he ran a report from the last 12 months and saw approximately 280 claims.

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

5. End of Public Meeting

6. Review Minutes from September 2023 meeting

There were no changes to the meeting minutes from September 2023.

DR. PHILLIPS MOVED TO APPROVE THE MEETING MINUTES FROM THE SEPTEMBER 2023 MEETING. SECONDED BY RYAN. THE MOTION WAS PASSED BY ALL MEMBERS.

7. Comments From Committee Members

Dr. Phillips stated she is curious to see how the RSV vaccine might reduce the need in some of the monoclonal antibodies.

Charles Semling stated that under a Federal mandate now they do cover all vaccines with no cost sharing for all ages. That is one good thing that has come about as far as October 1st.

Matt Parrott stated that anything with a ACIP approval is now covered by Medicaid programs with no cost sharing.

8. Adjourn

DR. PHILLIPS MOVED TO ADJOURN THE MEETING. THE NEXT MEETING WAS SCHEDULE FOR JANUARY 19, 2024. WITHOUT OBJECTION, THE MEETING WAS ADJOURNED.