Alaska Medicaid Pharmacy and Therapeutics Meeting

MINUTES OF MEETING
November 15, 2024

Committee Members Present:
Charles Semling PharmD, DHSS
John Riley, PA, Acting Chairman
Sarah Doran-Atchison, PharmD
Robert Carlson, MD
Casey Gokey
Claudia Phillips, MD
Trisha White, R.Ph.
Valarie Bixler, PharmD
Charles Ryan, MD

Committee Members Absent:

Others Present:
Ryan Ruggles, Pharm D
Nina Huynh, PharmD, BCPS
Matthew Parrot
Christopher Taylor, Neurelis
John Flatt, Marinus
Michelle Manzo, UCB
Mandeep Sohal, Teva
Nirmal Ghuman, Johnson and Johnson
Aaron Fayose, Bristol Meyers Squibb
William Rowe, Intra-Cellular Therapies
Paul Thompson, Alkermes
Shirley Quatch, Novartis
Michelle Stratton, Biogen
Lisa Carman, Genentech
Ronnie DePue, Axsome
Jennifer Melbourne, Braeburn

1. Call to Order – Chair

Mr. Riley called the meeting to order at * a.m.

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. Central Nervous System: Alzheimer's Agents (Red); Anticonvulsants (Blue); Antidepressants (Green); Antipsychotics – Atypical (Blue); Multiple Sclerosis Agents (Blue); Sedative Hypnotics (Green); Stimulants and Related Agents (Blue)

Alzheimer's Agents (Red Class)

There was no one present within to give testimony.

Nina provided the disease state description for dementia and Alzheimer's disease.

In February 2024, Biogen announced a realignment of resources in the Alzheimer's disease portfolio resulting in discontinuation of the development and commercialization of aducanumab-avwa (Aduhelm). Biogen has stated the decision to withdrawal resources was not the result of any safety or efficacy concerns but allows for a reprioritization to focus on lecanemab-irmb (Leqembi) as well as potential pipeline products. Rights to aducanumab-avwa will revert to Neurimmune, and the phase 4 post-marketing confirmatory ENVISION study will be terminated. Aduhelm received accelerated approval in 2021.

In August 2024, AbbVie announced discontinuation of brand name Namenda XR capsules. Generics remain available.

In June 2024, the FDAs Peripheral and Central Nervous System Drugs Advisory Committee unanimously voted in favor of donanemab of the treatment of early Alzheimer's disease.

In July 2024, the FDA approved an amyloid beta-directed antibody, Kisunia (donanemab-azbt) for treatment of Alzheimer's disease. Treatment should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trial. Warnings, dosage, and availability were given.

In August 2024, the FDA approved a cholinesterase inhibitor, Zunveyl (benzgalantamine), indicated for the treatment of mild to moderate dementia of the Alzheimer's type in adults. Warnings, dosage, and availability were given.

Utilization was 97.9 percent in line with PDL.

Previous motion Dr. Ryan moved for therapeutic alternatives. Seconded by Trish White. The motion passed unanimously.

DR. SEMLING MOVED FOR THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Anticonvulsants (Blue Class)

CHRISTOPHER TAYLOR, Senior Medical Science Liaison with Neurelis, requested that Valtoco remain a preferred position without restrictions and he provided a brief update. It is a diazepam spray for the treatment of seizure clusters. It is the first and only intranasal rescue treatment for adults and children down to the age of six. Neurelis recently completed a clinical study evaluating the safety and pharmacokinetics of Valtoco in patients aged two to five. They are currently seeking authorization for children down to the age of two.

JOHN FLATT, Medical Director of Scientific Affairs for Marinus pharmaceuticals. He spoke today on Ztalmy. It was approved by the FDA in March 2022 as the first and only indicated treatment for seizures associated with CDKL5 deficiency disorder or CDD in patients two years of age and older. It is the first neuroactive steroid anticonvulsant classified as a schedule 5 controlled substance by the DEA. He gave a brief description of what CDD and CDKL5 is. He also discussed the MARIGOLD study. He stated this medication fills an unmet clinical need in the treatment of seizures associated with CDD and CDKL5 disorder. He directed the committee to the website for full prescribing information. He asked that the committee consider increasing the initial approval period for Ztalmy from three months to at least four months in duration, a timeframe more related to that of suggested epilepsy clinical trial guidance documents for the evaluation of sustained efficacy.

MICHELLE MANZO, Epilepsy Outcomes Liaison at UCB. She yielded her time back to the committee and stated she is available if there are any questions.

Nina then gave the presentation for Anticonvulsants. She first gave the disease state description for epilepsy and seizure disorders as well as infantile spasm.

In 2017 the ILAE revised seizure classifications which are based on three key features: seizure origin of the brain, level of awareness during the seizure, and other seizure features.

In 2022, the ILAE developed classifications of epilepsy syndromes. Nina shared this with the committee.

In 2024, the American Academy of Neurology issued a guideline for use of antiseizure medications in patients with epilepsy of childbearing potential. Healthcare professionals should recommend antiseizure medications and doses that optimize seizure control and fetal outcomes at the earliest possible opportunity prior to conception. To reduce risk for major congenital malformations, lamotrigine, levetiracetam, or oxcarbazepine should be considered when appropriate and valproic acid should be avoided when possible. The guideline also recommends

supplementation with greater than or equal to 0.4 mg folic acid daily before and during pregnancy for all patients with epilepsy of childbearing potential treated with antiseizure medications.

In December 2023, the FDA issued a drug safety communication on potential for life threatening drug reaction with Eosinophilia and Systemic Symptoms reactions with levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan). Symptoms usually start within two to eight weeks after initiation but could occur earlier or later. Patients who experience any unusual symptoms, including rash, at any time while using these drugs should immediately seek emergency care. Although fever with rash and swollen lymph nodes or swelling in the face are common some individuals do not develop a rash.

In December 2023, the FDA reported the Mylan is discontinuing manufacture of brand name Felbatol (felbamate)oral suspension (600 mg/5 mL).

In December 2023, Cipla Limited announced that its wholly-owned subsidiary, InvaGen Pharmaceuticals is voluntarily recalling one lot of vigabatrin for oral solution, USP 500 mg, to the consumer level due to seal integrity issues that could allow powder to leak from the pouch and cause inaccurate dosage. Product is used for the treatment of refractory complex partial seizures as adjunctive therapy in patients two years of age or older who have responded adequately to several alternative treatments. No adverse events have been reported to date.

In July 2024, Endo has voluntarily recalled one lot of clonazepam orally disintegrating tablets in the strength of 0.25 due to mislabeling. Incorrect strength appears on the cartons of some packs showing the strength as 0.125 mg and not 0.25 mg. The blister strips inside the product packaging does reflect the correct 0.25 mg strength.

In June 2024, the FDA approved Libervant (diazepam) for acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern in patients with epilepsy ages two to five years old. Warnings, recommended dosage, and availability were given.

In June 2024, the FDA approved Motpoly XR (lacosamide) for adjunctive therapy for treatment of primary generalized tonic-clonic seizure in adults and pediatric patients weighing at least 50 kg. Indications, warnings, dosage, and availability were given.

In July 2024, the FDA approved Vigafyde (vigabatrin oral solution) as monotherapy for treatment of infantile spasms in pediatric patients one month to two years of age for whom the potential benefits outweigh the potential risk of vision loss. A concentrated formulation compared to other vigabatrin products (currently available vigabatrin for oral solution products have a final concentration of 50 mg/mL). Warnings, dosage, and availability were given.

Utilization was 94 percent in line with PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives. Seconded by Dr. Liljegren. Motion passed unanimously.

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

Antidepressants (Green Class)

In October 2024, Eli Lilly will be discontinuing brand name Prozac capsules. Generics will remain available.

The antidepressant class was broken down into two subclasses by the committee, SSRIs and Other.

Utilization for the SSRIs was 95.3 percent in line with PDL.

Previous motion Dr. Phillips moved a class effect, seconded by Dr. Doran-Atchison and passed unanimously.

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

Utilization for Antidepressants, Other was 91.8 percent in line with PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives. Seconded by Dr. Doran-Atchison. The motion passed unanimously.

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

Antipsychotics – Atypical (Blue Class)

MANDEEP SOHAL, Pharmacist with Teva, gave testimony on Uzedy. It is a long acting subcutaneous risperidone injection that does not require oral supplementation or additional loading doses. It is the only risperidone LAI with a 5 mg oral risperidone daily dose equivalence. He thanked the committee for having this medication on the preferred drug list.

NIRMAL GHUMAN, Pharmacist and Principal Scientific Account Lead with Johnson and Johnson Innovative Medicine. She gave testimony today on Invega HAFYERA. This a 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. Long acting injectables or LAIs are recommended for patients with schizophrenia who are non-adherent, partially adherent, frequently relapsing in response to therapy, or when the patient's care environment is such that an LAI is a more reliable route of administration such as unstable housing, homelessness, or lacking social support for treatment. Several guidelines also recommend that LAIs should be

used in patients with a preference for LAIs. Approximately 40 percent of patients have difficulty adhering to a daily oral treatment regimen. LAIs promote treatment adherence and transparency by ensuring that patients with schizophrenia receive a known quantity of medication at a propriate dosing interval. 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 relapse rate was 4.1 percent in a three year analysis that followed patients receiving Invega HAFYERA in a double blind trial through an open label extension study. 80.2 percent of participants experienced one or more treatment emergent adverse events. Relapse rates were comparable to the trials from SUSTENNA and TRINZA. Invega HAFYERA demonstrated non-inferiority to Invega TRINZA in a one year double blind trial. Long term efficacy of Invega HAFYERA was maintained for up to an additional two years in the following open label extension study. Patients with up to three years of Invega HAFYERA treatment had efficacy and safety outcomes consistent with the overall open label extension cohort.

AARON FAYOSE, Director of Health Economics and Outcomes Research Field Scientist of Neuroscience Division at Bristol Meyers Squibb. He came to ask the committee's consideration for the addition of Cobenfy to the preferred drug list. Cobenfy is a combination medication that was approved by the FDA in September 2024 for the treatment of adult patients with schizophrenia. It is a first in class orally administered combination medication and is thought to function through a different mechanism of action modulating multiple neurotransmitters without directly blocking D2 receptors. The efficacy and safety of Cobenfy were evaluated in adult patients with schizophrenia experiencing acute psychosis over five weeks in a randomized double blind placebo controlled EMERGENT2 and EMERGENT3 trials. The primary endpoint was the change form baseline to week five in the PANS positive and negative syndrome score, PANS total score, and in each trial Cobenfy demonstrated a statistically significant and clinically meaningful improvement in PANS total score compared with placebo starting as early as week two and maintained through week five. Cobenfy was generally well tolerated with the most comment adverse events seen in five percent of patients and at least twice that in placebo of nausea, dyspepsia, constipation, vomiting, hypertension, abdominal pain, diarrhea, tachycardia, dizziness, and GERD. They were mild to moderate in severity. He thanked the committee for their consideration.

DR. PHILLIPS had a question and asked how many people started the EMERGENT5 trial and how many actually completed the 52-week trial. Aaron Fayose stated that the EMERGENT5 currently had 568 patients and the final data set has not been published yet. There are some posters that look at the interim analysis but they do know that when the full data set is available it will be posted to the public. Dr. Phillips was interested in the long term data of the medication.

WILLIAM ROWE, Senior Medical Science Liaison with Intra-Cellular Therapies, gave testimony on Caplyta. This is indicated for the treatment of adults with schizophrenia as well as depressive episodes associated with bipolar 1 or bipolar 2 disorder. It is both a monotherapy and an adjunctive therapy with lithium. He shared some data from a study that should be published soon as it is currently under review. This study was in patients with the DSM5 mixed features criteria in both bipolar 1 and 2 disorder. This was a study using Caplyta 42 mg using DSM5 criteria for major depressive episodes with mixed features in which bipolar depressed patients

were also concurrently experiencing subsyndromal symptoms of mania or hypomania. Based on the criteria (unintelligible) features occur in approximately one-third of bipolar patients experience major depressive episodes. Patients with bipolar depression experiencing mixed features have a greater severity of illness, higher rates of comorbidities, suicide, and recurrence. Consequently, these patients are more difficult to treat than those without mixed features. This was a six-week randomized placebo controlled monotherapy study of Caplyta 42 mg in a subgroup of 199 bipolar depressed patients that were statistically significant on the primary endpoint of symptom reduction on the MADR score with a p-value of less than 0.0001. The most commonly reported adverse events were somnolence, dizziness, and nausea though changes in body weight, weight circumference, and metabolic parameters were similar to placebo and not clinically relevant. There were no notable changes in EPS, clinical scales, and no cases of treatment emergent mania or hypomania. There are boxed warnings for increased risk of mortality in elderly patients with dementia related psychosis and increased risk of suicidal thoughts and behaviors in pediatric and young adults. Additional warnings are in the full prescribing information. He asked that Caplyta be added to the PDL as preferred.

DR. PHILLIPS asked if there are any head to head trials that have occurred. Nirmal stated they do have Phase3 and Phase 4 studies that are head to head that will be coming out within the years. They are usually investigator initiated but they do not have any studies that they have sponsored that are head to head. They do have some long term safety data where patients have been switched so they can see a little bit of how they do switching from one to another and those are published especially in the schizophrenia population. He stated that would be the closest data to what she is looking for.

PAUL THOMPSON, Psychiatric Pharmacist and MSL with Alkermes, gave testimony on Lybalvi. It is a combination medication indicated for the treatment of schizophrenia and bipolar 1 disorder in adults. For bipolar 1 disorder it includes acute treatment of manic or mixed episodes as monotherapy or adjunct therapy as well as maintenance monotherapy treatment. It has a boxed warning for increased mortality in elderly patients with dementia related psychosis. He referred the committee to the prescribing information for complete information including the pivotal trials, contraindications, additional warnings, and precautions which was previously been presented to the committee. There are two new clinical studies. The first was a real-world data study and the second is a long-term four year safety tolerability and durability effect extension study. The real-world data study was a retrospective observational study looking at insurance claims from 2021 to 2022 and was aimed at comparing health care resource utilization six months before and after initiating Lybalvi in 855 adult patients with schizophrenia and 691 adult patients with bipolar 1 disorder. Lybalvi was associated with significant reduction for all cause and patient admissions and ED visits in patients with schizophrenia or bipolar 1 disorder. For the schizophrenia population inpatient admissions were reduced by 28.2 percent and ED visits by 11.5 percent. In patients with bipolar 1 disorder inpatient admissions were reduced by 30.9 percent and ED visits by 12.4 percent. Given the limitations of the study being that this is solely based on claims data, no conclusions of safety or efficacy can be derived. The next study highlighted is a phase 3, four year open label extension study looking at the long term safety, tolerability, and durability of treatment in 524 patients. In the study Lybalvi demonstrated safety profile consistent with previous studies. 242 patients completed two years of treatment showing an average weight gain of 0.8 kg and a reduction in waist circumference. 136 patients completed

the four year study and had an average weight gain of 2.7 kg and an average increase of 1.4 cm in waist circumference. Clinical and global impression severity scores continue to decrease over the four years. Long term metabolic stability was noted with small median changes in baseline lipids and glycemic laboratory parameters. Given the new long term safety data as well as the real world data they requested that Lybalvi be made accessible as a non-preferred agent without the current additional current clinical criteria. Alaska Medicaid's clinical criteria for Lybalvi is over three years old and does not take into consideration this new long term safety data that shows long term metabolic cholesterol and glycemic stability over four years of treatment. Please consider reviewing and reconsidering Lybalvi criteria for patients to have equitable access at parody to other atypical psychotic agents for Alaska Medicaid members.

Nina then gave her presentation. She started with giving the disease state description for schizophrenia. She then gave the disease state description for bipolar disorder. She gave the 2023 Department of Veterans Affairs and Department of Defense guideline updates for managing bipolar disorder.

In April 2024, the FDA approved Risvan, a prolonged release injectable risperidone that provides immediate and sustained plasma drug levels and does not require loading doses or supplementation with oral risperidone. Indications, warnings, dosage, and availability were given.

In April 2024, the FDA approved Fanapt as a new indication for acute treatment of manic or mixed episodes associated with bipolar 1 disorder in adults. Indications, warnings, dosage, and availability were given.

In August 2024, FDA approved Erzofri for the treatment of schizophrenia in adults and schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants. Warnings, dosage, and availability were given.

In September 2024, the FDA approved Cobenfy, a combination of xanomeline, a muscarinic agonist, and trospium chloride, a muscarinic antagonist, for the treatment of schizophrenia in adults. Warnings, dosage, and availability were given.

Utilization was 96.6 percent in line with PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives. Seconded by Dr. Doran-Atchison. The motion passed unanimously.

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

Multiple Sclerosis Agents (Blue Class)

SHIRLEY QUATCH, Value Evidence Lead for Novartis, gave testimony for new information for Kesimpta. She asked that Kesimpta be added as preferred on the PDL. Kesimpta is the first fully human anti-CD20 monoclonal antibody that is self-administered and approved for adult

patients with relapsing multiple sclerosis. Studies have shown that disease modifying therapies have been most effective when aggressive treatments have been applied very early in the clinical course of MS delaying disease progression and thus reducing societal economic burden of MS. Despite multiple DMTs being available for the treatment of MS there remains no standard treatment guideline and providers tend to make tradeoffs between efficacy and safety when choosing which agents to use. Kesimpta offers providers a highly efficacious MS agent with a favorable safety profile via a monthly self-administered injection. There is six year efficacy data from the ALITHIOS study which was given to the committee. 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 tolerable safety profile. Novartis respectfully requested that Kesimpta be added as preferred on the PDL.

MCKENZIE STRATTON, Pharmacist and Senior Medical Manager with Biogen, gave testimony for Vumerity. Vumerity was approved in October 2019 for treatment of relapsing forms of multiple sclerosis to include clinically isolated syndrome, relapsing remitting MS, and active secondary progressive MS in adults. Vumerity has a distinct chemical structure Tecfidera diroximel fumarate but is converted to the same active metabolite monomethylfumarate. Because of this bioequivalence we can expect to see the same efficacy and safety as Tecfidera which has been prescribed in approximately 607,400 patients representing over 1.3 million patient years. The ten year data from the long term ENDORSE trial was given. Vumerity has been studied for improved patient reported GI tolerability versus Tecfidera. EVOLVE MS1 phase 3 study information was given. EVOLVE MS2 phase 3 study information was also given. The National Institute for Health and Care Excellence published guidance in June 2022 recommending diroximel fumarate as a first line disease modifying drug option for treatment of active relapsing remitting MS. The committee was directed to the PI for the most common adverse reactions, warnings, and precautions. MS is a heterogeneous disease and it is important to have access to the appropriate medication early in order to prevent relapse and disability prevention. The oral disease modifying therapies are different medications with different mechanisms of action, tolerability profiles, monitoring requirements, drug interactions and contraindications, all of which factor into appropriate drug selection. Options are needed for patients stepping down from high efficacy therapy. Potential reasons to switch from a high efficacy therapy include elevated risk of infections, reduced vaccination response, increased risk for adverse events in older patients, and family planning. Many patients who switch after treatment with another high efficacy DNT remain relapse free. Treatment does not impair vaccine response and the long term safety and efficacy has been demonstrated. She asked that the committee consider adding Vumerity to the PDL as a first line option.

LISA CARMAN, Pharmacist with Genentech, gave a couple updates for Ocrevus with an FDA approval as well as an update on data. In mid-September they received FDA approval for the sub-q formulation of Ocrevus which has been an infusion on the market for every six months. This new approval is for Ocrevus Zunovo since it is a different product and new NDC and dose. It is given as a sub-q push versus the infusion every six months. It is 920 mg given in the abdomen as either a push or syringe pump. It has to be given by a healthcare professional. The purpose of brining this to market is to give additional options for patients and healthcare practitioners, especially in areas like Alaska with some potential challenges that this would hopefully help with patients that cannot get to an infusion center. It does reduce care time. It is

a ten minute push with some observation afterwards versus the longer effusions. There have been incidence of injection related reactions around pain, swelling, or itching. Ten year data updates were given. Patients were followed for eight years and they have data for over 50 percent of those patients. She mentioned a few of the outcomes. A few of the long term disability outcomes is after ten years the relapse rate is one relapse almost every 60 years and after ten years on continuous Ocrevus eight out of ten patients were progression free. Thereby starting Ocrevus two years earlier saves almost ten years of disease progression. 80 percent after ten years still did not require a wheelchair. The differences in an early start versus a later start on Ocrevus has an effect on disability that does not get made up.

Nina went into her presentation and started with giving the disease state description for multiple sclerosis. She also gave the clinical course of MS.

In May 2024, the FDA alerted patients, caregivers, and healthcare professionals of labeling updates for glatiramer acetate injection products that includes a new warning that using an autoinjector that is not compatible with a specific glatiramer acetate injection product may increase risk for medication errors, such as missed dose or administration of a partial dose. The availability of optional compatible autoinjectors for each glatiramer acetate injection drug product may change with time. The FDA will no longer update this information on their website. Patients can continue to confirm the compatibility of their autoinjector by speaking with the HCP, visiting the drug manufacturer's patient information website, contacting the drug manufacturer for more information, or referring to the autoinjector labeling.

In September 2024, the FDA approved Ocrevus Zunovo a combination of ocrelizumab and hyaluronidase-ocsq indicated for the treatment of relapsing forms of multiple sclerosis to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease in adults and primary progressive MS in adults. Warnings, dosage, and availability were given.

Utilization was 64.6 percent in line with PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives. Seconded by Dr. Doran-Atchison. The motion passed unanimously.

Dr. Phillips wondered if when they asked for therapeutic alternatives they picked the wrong ones. Wondering why the numbers are so low. Is it a statistical issue or do they need to include different medications on the preferred list? Charles Semling replied stating that generally with the preferred and non-preferred there is a very small sample size of claims so it does skew the data very easily one way or the other. Generally, the preferred medications are ones that are a step through to the non-preferred so the non-preferred are ones that have already stepped through the preferred drug. These drugs are thousands of dollars to hundreds of thousands of dollars so there is a reason why it is preferred and non-preferred.

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

Sedative Hypnotics (Green Class)

Utilization was 83.3 percent in line with PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives. Seconded by Dr. Carlson. 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

Stimulants and Related Agents (Blue Class)

RONNIE DEPUE, Pharmacist and Senior Director of Field Medical Affairs at Axsome Therapeutics, gave testimony on Sunosi which is indicated for the treatment of excessive daytime sleepiness associated with obstructive sleep apnea or narcolepsy. Sunosi is a schedule IV medication defined by the DEA as having a low potential for abuse and dependence and is a wake promoting agent, not a stimulant. A recently published independent network metanalysis of 14 clinical trials concluded that Sunosi reduced daytime sleepiness for patients with obstructive sleep apnea with Sunosi having superior effectiveness. Two metanalysis for narcolepsy found that Sunosi was the most effective treatment in managing effective daytime sleepiness when compared to other medications. The American Academy of sleep medicine clinical practice guidelines provide a strong recommendation for the use of Sunosi for excessive daytime sleepiness associated with narcolepsy. The most common adverse events reported with Sunosi in twelve-week clinical studies in narcolepsy and obstructive sleep apnea were headache, nausea, decreased appetite, anxiety, and insomnia. He referred the committee to the prescribing information for a complete list of warnings, precautions, and adverse events. Sunosi exhibits robust improvements in wakefulness in narcolepsy and obstructive sleep apnea and has a well established safety profile. He asked that the committee consider adding Sunosi as a preferred agent on the preferred drug list.

Nina went into the presentation giving the disease state description for attention deficit hyperactivity disorder as well as the updated guidelines from 2019 from the American Academy of Pediatrics. She then gave the disease state description for hypersomnolence along with the 2021 guidelines from the American Academy of Sleep Medicine.

In January 2024, Azurity voluntarily recalled one lot (F230169A) of the stimulant medication Zenzedi CII (dextroamphetamine sulfate tablets USP) 30 mg to the consumer level. The recall was initiated after one report of a bottle of Zenzedi 30 mg tablets containing carbinoxamine maleate tablets, an antihistamine.

In May 2024, the FDA approved clonidine Er oral suspension, Onyda XR, for the treatment of ADHD as monotherapy or as adjunctive therapy to CNS stimulant medications in pediatric patients six years of age or older. Warnings, dosage, and availability were given.

In June 2024, the FDA granted a new indication of Wakix for the treatment of excessive daytime sleepiness in pediatric patients six years of age or older with narcolepsy. Indications, warnings, dosage, and availability were given.

Utilization was 85.8 percent in line with PDL.

Previous motion Dr. Phillips moved that the drugs in the class were therapeutic alternatives. Seconded by Dr. Carlson. The motion passed unanimously.

Dr. Phillips wondered if they need to separate the medications for ADHD from those that are targeting wakefulness. Nina stated the market basket is predefined already but it is something she can bring back and see if they are able to do that. Matthew Parrot stated that is something they could look into and see if there are two separate market baskets. He stated that when the therapeutic alternatives are selected for management, they do consider the separate alternatives as well so depending on indication they would not necessarily consider all the products in this basket in the same therapeutic category.

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

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

Opioid Dependance (Blue Class)

JENNIFER MELBOURNE, Medical Science Liaison with Braeburn, gave testimony Brixadi for the treatment of opioid use disorder. In 2017 the United Stated declared an opioid crisis and public health emergency and in that year, there were a reported 40,000 deaths due to opioid overdose. Today the opioid crisis remains at a national public health emergency and last year the CDC reported approximately 80,000 deaths due to opioid overdoses. There is clearly a huge need for more accessible treatment options to help those with opioid use disorder begin and sustain recovery. Brixadi is a long acting injectable formation of buprenorphine that was approved in the US in May 2023. It is indicated for patients who are currently being treated with sublingual buprenorphine formulations as well as patients who are new to buprenorphine treatment. It is available as both a weekly and monthly injection administered only by a healthcare provider. It works by a fluid crystal technology. This lipid based drug delivery technology allows for a small volume of liquid to be injected into the subcutaneous space forming a gel that results in a steady release of buprenorphine into the body. The flexibility in dosing options, four for the weekly formulation and three for the monthly formulation, allow the provider to optimize treatment for their patients. This is injected to meet the patient where they are and provide them with a treatment option to help initiate and sustain long term recovery. A phase 3 trial that lasted 24 weeks and included over 400 patients, over 25 percent of whom were positive for fentanyl, found that when compared to sublingual buprenorphine participants who were treated with Brixadi demonstrated reductions in opioid use. No overdoses occurred in the Brixadi group compared with five overdoses in the sublingual buprenorphine group. Adverse

drug events reported included injection site reactions, headache, nausea, and constipation all of which were described as mild to moderate in nature. She would like to advocate for the addition of Brixadi to preferred status on formulary as soon as possible.

DR. PHILLIPS asked if she knew where she could find the information on plasma levels for this medication compared to other similar medications. Jennifer stated that could be found in the prescribing information there is a table that gives the plasma levels for each dose on the bottom of page 37, table 7.

Nina moved into the presentation starting with the disease state description of opioid dependence and opioid abuse and misuse information. She also gave the 2022 CDC guidelines on opioid dependence.

In December 2023, the FDA approved AutoGenomics AvertD test. This is the first test that uses DNA in assessing whether certain individuals may have an elevated risk of developing an opioid use disorder. It is intended to be used prior to first exposure to oral opioid pain medications in patients being considered for a four to 30 day prescription for the treatment of acute pain such as in patients scheduled to undergo a planned surgical procedure. Approved as a prescription use only generic laboratory test to be used only in adults who consent to the test and have no prior use of oral opioid analgesics.

In August 2024, the FDA approved lofexidine, the first generic to USWMs Lucemyra 0.18 mg tablets from Indoco. It was anticipated to be launched immediately.

Utilization was 94.8 percent in line with PDL.

Previous motion Dr. Carlson moved that the drugs in the class were therapeutic alternatives. Seconded by a female committee member. The motion passed unanimously.

Trish White asked when there are so many people using the non-PDL buprenorphine without the naloxone, there is usually no problem getting that covered or getting a prior authorization but she is wondering if it makes any sense if there are so many to just add that on to the motion. Matthew Parrot stated that it has been an issue of the availability of the product and trying to manage the rebate status of the drugs. This is why it was structured the way it was going forward. It is something that can be overridden at the pharmacy level. It does not require a PA. There have been some changes with regard to the rebate status to these products recently so it is likely that what is being seen there would have to change following this meeting. It was initially set up this way to maximize the efficiency of state dollars of the products. John Riley stated there was a letter from Dr. Brian Dawson from the Opioid Treatment Clinic in Anchorage requesting Brixadi be added to the PDL. Mr. Riley stated it looked like there were 29 prescriptions that were filled for it through the medically necessary pathway. He wondered if people like Dr. Dawson are aware of the medically necessary option. Matthew Parrot stated that is a really good point. Just because something is not a preferred status on the PDL does not mean that Alaska Medicaid does not cover it. That is something that they have worked hard to get the word out. The non-preferred status is not the same thing as not covered. He agreed that may be a common understanding in the provider community. John Riley asked if there was a

way to push out information like that periodically. Matthew Parrot stated that following these meetings one of the things he does is he puts out the public notices and releases information to all of the enrolled pharmacies and providers in the state. He could include information in there reiterating and referencing them to the section in the billing manual that talks about how to put that through.

CASEY GOKEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PHILLIPS.

Robert Carlson asked if there are any real-world studies showing that any plan is more effective than another plan. This is a very difficult societal issue and the problem in the state seems to be growing rather than shrinking in spite of good effort. Is there any real-world efficacy differences on the different products? Matthew Parrot stated that one of the things that needs to be kept in mind is they are not always comparing apples to apples in these questions. He stated that the first thing you have to ask when you are defining efficacy is what is your endpoint? Is your endpoint reducing the risk of fatal overdose? Is your endpoint reducing the risk of relapse? When we are looking at effectiveness, the first thing we have to do is define what the therapeutic goal is. Robert said he thinks the real-world is messy and maybe his question is unanswerable and they should vote on therapeutic alternatives and leave his question to somebody in the future. Dr. Phillips stated that is why she was wondering about the plasma levels because she wondered if there (unintelligible) and if that would be significant. Matthew Parrot stated that what he has seen on this, and a lot of it is still ongoing research, there have been alternative dosing strategies that they are currently researching and looking at. One of the questions in regard to Brixadi is if they change the frequency of the dosing is there a residual effect because one of the challenges with the long acting injectables is getting people to keep their appointments and showing up to get their shot. That is one of the challenges with the population. If the goal is preventing fatal overdose the question becomes not only the product itself but do we need to look at some point at how we adjust the cadence of that dosing. He agreed that Dr. Phillips' point about plasma concentrations is a relevant point but at this point the jury is still out.

THE MOTION PASSED UNANIMOUSLY.

Opioid Reversal Agents (Blue Class)

There was no one wishing to give testimony.

Nina went into her presentation.

In January 2024, following FDA request emergent extended shelf life of newly produced naloxone HCI (Narcan) 4 mg nasal spray to four years, it was previously three years. The extension is only applicable to products manufactured after the date of the announcement (1/17/24). Product previously manufactured is not impacted and maintains the same shelf life printed on the products packaging.

In June 2024, the FDA approved Rezenopy, an opioid antagonist for the indication of the emergency treatment of known or suspected opioid overdose and manifested by respiratory

and/or CNS depression in adults and pediatric patients. It is intended for immediate administration as emergency therapy in settings where opioids may be present. It is not a substitute for emergency medical care. Warnings, dosage, and availability were given.

In August 2024, the FDA approved Zurnai, the first nalmefene auto-injector for the emergency treatment of known or suspected opioid overdose in adults and pediatric patients twelve years of age and older. It is an opioid antagonist indicated for emergency treatment of known or suspected opioid overdose induced by natural or synthetic opioids as manifested by respiratory and/or CNS depression. It is intended for immediate administration as emergency therapy in settings where opioids may be present. It is not a substitute for emergency medical care. Warnings, dosage, and availability were given.

Utilization was 43.9 percent in line with PDL.

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

John Riley asked for a motion. There was hesitation due to the high non-PDL. Matthew Parrot stated that part of that in this case is it had to do with the naloxone going over the counter. There were some issues in terms of the available formulations. It is something that they are going to have to look at when they realign the preferred products on the class. Some of the issue simply was that as those products became available without a prescription and as the formulations changed the disease change and it is difficult to align with what is available in the marketplace right now because it has been shifting.

Dr. Phillips asked if the only difference between the Kloxxado and the Narcan is that Kloxxado is 8 mg and Narcan is 4 mg. Matthew Parrot stated that believes the primary difference is the strength.

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

Smoking Cessation Products (Green Class)

Utilization was 79.9 percent in line with PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives. Seconded by a female committee member. The motion passed unanimously.

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

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

Antimigraine Agents (Green Class)

Utilization for the triptans was 96.6 percent in line PDL.

Previous motion Dr. Doran-Atchison moved the drugs to 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.

DR. PHILLIPS MOVED THE DRUGS TO 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 CASEY GOKEY. THE MOTION PASSED UNANIMOUSLY.

Utilization for antimigraine agents, other was 86.2 percent in line with PDL.

Previous motion Dr. Phillips moved the drugs to be considered therapeutic alternatives for acute and prophylactic treatment. Seconded by Dr. Liljegren. The motion passed unanimously.

DR. PHILLIPS MOVED THE DRUGS TO BE CONSIDERED THERAPEUTIC ALTERNATIVES FOR ACUTE AND PROPHYLACTIC TREATMENT. SECONDED BY CASEY GOKEY. THE MOTION PASSED UNANIMOUSLY.

Analgesics, Opioid Long-acting (Green Class)

In December 2023, the FDA approved required updates to all (brand and generics) immediate release and extended release long acting opioid analgesics to include the addition of language stating; the risk of overdose increases as the dosage increases for all opioid pain medicines, immediate release opioids should not be used for an extended period of time unless a patients pain remains severe enough to require them and alternative treatment options continue to be inadequate, many acute pain conditions treated in the outpatient setting require no more than a few days of an opioid pain medicine, and it is recommended to reserve extended release/long acting opioid pain medicines for severe and persistent pain that requires an extended treatment period with a daily opioid pain medication for which alternative treatment options are inadequate. The required updates also includes a new warning about opioid induced hyperalgesia, a condition in which opioid use causes an increase in pain or an increased sensitivity to pain and regarding differentiating OIH symptoms from those of opioid tolerance and withdrawal.

Utilization was 66.6 percent in line PDL.

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

Dr. Phillips stated that oxycontin is still fairly popular but non-preferred. She was looking for information. Matthew Parrot stated that oxycontin requires a prior authorization. That is the case with all the single agent oxycodone products as well simply being because it requires a step through preferred long acting agent, for instance they have morphine extended release, fentanyl patches, BUTRANS patches, etc. It is actually a clinical PA that drives that. Single agent oxycodone tablets also (unintelligible) on that and again that is because it requires a step through a preferred combination agent such as Percocet or something like that. They are still made available where it is clinically appropriate but that is why they are not preferred.

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

Analgesics, Opioid Short-acting (Blue Class)

There was no one that wished to give testimony.

Nina moved into the presentation. She started with giving the 2024 American Academy of Pediatrics guideline update.

In September 2024, the FDA announced that Teva will discontinue marketing of Fentora buccal tablets and Actiq lozenges. No generics will be available.

Utilization was 91.8 percent in line PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives. Seconded by Dr. Doran-Atchison. The motion passed unanimously.

DR. PHILLIPS MOVED THAT THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY VALARIE BIXLER. THE MOTION PASSED UNANIMOUSLY.

Neuropathic Pain (Green Class)

Utilization was 99.1 percent in line PDL.

Previous motion Dr. Phillips moved therapeutic alternatives. Seconded by Dr. Doran-Atchison. The motion passed unanimously.

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

NSAIDs (Blue Class)

There was no one present that wished to give testimony.

Nina gave the presentation of the updated 2024 guidelines from the American Dental Association.

Utilization was 99.0 percent in line PDL.

Previous motion Dr. Doran-Atchison moved a class effect to include a topical preparation. Seconded by Dr. Carlson. The motion passed unanimously.

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

Restless Leg Syndrome (Green Class)

Utilization was 90.1 percent in line PDL.

Previous motion Dr. Ryan moved the drugs in this class were therapeutic alternatives. Seconded by Valarie Bixler. The motion passed unanimously.

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

Skeletal Muscle Relaxants (Green Class)

Utilization was 97.7 percent in line PDL.

Previous motion Trish White moved the drugs in the class were therapeutic alternatives excluding carisoprodol from the PDL. Seconded by Dr. Ryan. The motion passed unanimously.

DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY CASEY GOKEY.

John Riley wanted to confirm whether or not Dr. Ryan wanted to include or exclude the carisoprodol. Dr. Ryan stated he thought it had possibly been excluded last year. Matthew Parrot stated that it was moved to non-preferred but these specific drugs so long as they meet a definition of a covered outpatient drug, they have to cover it. They could put criteria around it to ensure appropriate utilization of it.

THE MOTION PASSED UNANIMOUSLY.

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

Antibiotics, Inhaled (Green Class)

Utilization was 54.5 percent in line PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives. Seconded by Dr. Carlson. The motion passed unanimously.

Matthew Parrot stated that if anyone is looking at that percentage and wondering why there are two things. It is a very small claim set. You are only looking at just over ten claims and they are incredibly expensive drugs. These few patients constitute a massive percentage of the spend. For that reason, there are step therapy on some of these agents due to the cost associated. That is where these come in.

DR. PHILLIPS MOVED THERAPEUTIC ALTERNATIVES. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.

CFTR Potentiator Agents (Green Class)

Utilization was 100 percent in line PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives. Seconded by Trish White. The motion passed unanimously.

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

Pancreatic Enzymes (Green Class)

In December 2023, the FDA approved a new strength of Zenpep (pancrealipase) delayed capsules containing 60,000 USP units of lipase, 189,600 USP units of protease, and 252,600 USP units of amylase.

Utilization was 99 percent in line PDL.

Previous motion Dr. Phillips moved a class effect. Seconded by Valarie Bixler. The motion passed unanimously.

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

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

Respiratory Syncytial Virus (Green Class)

Utilization was 100 percent in line PDL.

Previous motion Dr. Ryan moved a class effect. Seconded by Dr. Phillips. The motion passed unanimously.

DR. RYAN MOVED A CLASS EFFECT. SECONDED BY DR. PHILLIPS.

Charles Semling thanked them for making the motion and stated that with this class he would advise the committee to potentially retire this class. Synagis is no longer preferred in RSV. Beyfortus became available and that is available through the vaccines for children so the class ceases to exist at this time. He stated they may bring it back if there are other RSV medications that come to market but he recommends retiring it for next time.

DR. PHILLIPS MOVED THAT THE CLASS BE RETIRED. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.

5. End of Public Meeting

6. Comments From Committee Members

7. Adjourn

THE NEXT MEETING WAS SCHEDULE FOR *.