# Alaska Medicaid Pharmacy and Therapeutics Meeting

## MINUTES OF MEETING
## September 20, 2024

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

Committee Members Absent:
Robert Carlson, MD
Charles Ryan, MD

Others Present:
Ryan Ruggles, Pharm D
Nina Huynh, PharmD, BCPS
Matthew Parrot, DOH
Erin Novak, AbbVie
Nirmal (unintelligible), Johnson & Johnson
Kat Khachatourian (phonetic), Nova Nordisk
Male Speaker 2
Nicole Tran (phonetic)
Stewart Obrochta (phonetic), Gilead
Kaitlin Winn (phonetic), ViiV Healthcare
Ray Kong, Neurocrine Bioscience

### 1. Call to Order – Chair

Mr. Riley called the meeting to order at 8:07 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. Gastrointestinal:** Antiemetic-Antivertigo Agents (Blue); Cytokine & Cell-Adhesion Molecules (CAM) Antagonist – GI Indicated (Red); Irritable Bowel Syndrome & GI Motility (Green); Proton Pump Inhibitors (Green); Ulcerative Colitis (Green)

***Gastrointestinal: Antiemetic-Antivertigo Agent (Blue Class)***

There was no one present that wished to give testimony.

Nina then gave the disease state description along with the 2020 guidelines.

In August 2023, the FDA approved Focinvez (fosaprepitant) as a 150 mg/50 mL injection for adults and pediatric patients age 6 months and older in combination with other antiemetic agents for prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high dose cisplatin as well as for use in prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.

Nina also gave the limitations, precautions, dosing, and formulations.

Utilization was 98.8 percent in line with PDL.

Previous 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 TRISH WHITE. THE MOTION PASSED UNANIMOUSLY.**

***Gastrointestinal: Cytokine & Cell-Adhesion Molecules (CAM) Antagonist – GI Indicated (Red Class)***

**ERIN NOVAK**, with AbbVie, gave testimony on Skyrizi. She wanted to highlight a few updates. This is an IL23 antagonist that is approved for four indications, two of which are GI indications of moderately to severely active Crohn's disease in adults and the most recent being moderately to severely active ulcerative colitis in adults, approved June 2024. Skyrizi may increase the risk of infection and there is an increased warning for hepatotoxicity in the treatment of IBD. She then spoke on Rinvoq which is already on the PDL. It is now approved for eight indications and has a new formulation. Rinvoq is approved for moderately to severely active ulcerative colitis and Crohn's disease in adults. There is a boxed warning for serious infections. Full prescribing and safety information for both medications can be found on their website. She

asked that Skyrizi be added to the preferred drug list and that they continue to keep Rinvoq on the preferred drug list.

**NIRMAL** *, Johnson and Johnson, spoke on Tremfya. On September 11, 2024, the FDA approved Tremfya for the treatment of adult patients with moderately to severely active ulcerative colitis or UC. Additionally, it is approved for adults' patients for the treatment of moderate to severe plaque psoriasis as well as active psoriatic arthritis. Please refer to the full prescribing information for complete information. Guselkumab is currently under investigation of the treatment of adult patients with moderately to severely active Crohn's disease. Recommended dosage for colitis is 200 mg administered by IV infusion over 1 hour at week 0, 4, and 8. The recommended maintenance dosage is 100mg administered by sub-q injection at week 16 and every 8 weeks thereafter or 200 mg administered by sub-q injection at week 12 and every 4 weeks thereafter. Tremfya may provide rapid symptomatic relief with separation from placebo as early as 1 week. Over 1/3 of patients received endoscopic remission at 1 year. Efficacy and safety were assessed across three key studies. She requested that Tremfya be added to the preferred drug list.

Nina then gave the disease state description for cytokine and CAM antagonists. She also gave the disease state description for ulcerative colitis and Crohn's disease. Next, she gave the AGA guidelines for 2021 for Crohn's disease.

In September 2023, the FDA approved Entyvio, single dose prefilled syringe and single dose prefilled pen for subcutaneous self-injection of ulcerative colitis. Previously it was only available as IV injection for moderate to severe active UC and CD. She gave precautions, dosing, and formulations as well.

In October 2023, the FDA approved Velsipity, a S1P modulator for the treatment of moderately to severely active ulcerative colitis in adults. Precautions, dosing, and formulations were given.

In October 2023, Abrilada was designated by the FDA as an interchangeable biosimilar to the corresponding presentations of adalimumab (Humira). This interchangeable designation applies to all indications.

In October 2023, the FDA approved Zymfentra, for the maintenance treatment of adults with moderately to severely active ulcerative colitis or Crohn's disease following treatment with an IV administered infliximab product. This is the only infliximab product that is given via SC injection and can be administered by the patient or caregiver. Indications, precautions, dosing, and formulations were given.

In October 2023, the FDA approved Wezlana as an interchangeable biosimilar to ustekinumab (Stelara). Launch date is anticipated to be no later than January 1, 2026. Indications, precautions, dosing, and formulations were given.

In October 2023, the FDA approved Omvoh as an interleukin 23-antagonist for the treatment of moderately to severely active ulcerative colitis in adults. In May 2024, the FDA approved a 100

mg/mL single dose prefilled syringe presentation that patients may self-inject after training in subcutaneous technique. Precautions, dosing, and formulations were given.

In January 2024, the FDA approved Idacio SDV kit for institutional use only. In June 2024, additional presentations for the unbranded biologic product: prefilled syringe 40 mg/0.8 mL, prefilled pen 40 mg/0.8mL, starter package (4 count and 6 count), and single dose 40 mg/0.8 mL glass vial kit for institutional use only. Previously the single dose prefilled pen was supplied in a two count carton only. Indications, precautions, dosing, and formulations were given.

In March 2024, Skyrizi was approved as a 90 mg/mL single dose prefilled syringe to allow for subcutaneous self-administration of maintenance dosage for treatment of moderate to severely active Crohn's disease. In June 2024, the FDA approved new indications for the treatment of moderate to severely active ulcerative colitis in adults. The indications, precautions, dosing, and formulations were given.

In April 2024, the DFA granted Hyrimoz interchangeability status to Humira. Indications, precautions, dosing, and formulations were given.

In July 2024, the FDA approved Pyzchiva as an interchangeable biosimilar to ustekinumab (Stelara). Launch is anticipated to be February 2025. Indications, precautions, dosing, and formulations were given.

Utilization was 79.8 percent in line with PDL.

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

**DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC TO INCLUDE AT LEAST ONE ORAL FORMULATION. SECONDED BY DR. DORA-ATCHISON. THE MOTION PASSED UNANIMOUSLY.**

***Gastrointestinal: Irritable Bowel Syndrome & GI Motility (Green Class)***

Given this is a green class they moved directly to utilization. Utilization was 78.4 percent in line with PDL.

Previous motion Dr. Ryan moved the drugs were therapeutic alternatives, seconded by Dr. Phillips and passed unanimously.

**DR. PHILLIPS MOVED THE DRUGS ARE THERAPEUTIC ALTERNATIVES. SECONDED BY TRISH WHITE. THE MOTION PASSED UNANIMOUSLY.**

***Gastrointestinal: Proton Pump Inhibitors (Green Class)***

Given this is a green class they moved directly to utilization. Utilization was 96.3 percent in line with PDL.

Previous motion Dr. Ryan moved the drugs were therapeutic alternatives. This was seconded by Dr. Phillips and passed unanimously.

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

***Gastrointestinal: Ulcerative Colitis (Green Class)***

In October 2023, the FDA posted that AbbVie will discontinue Delzicol 400 mg delayed release capsules and its generic. A generic version is available by Teva.

Utilization was 73.5 percent in line with PDL.

Previous motion Dr. Ryan moved that the drugs in the class were therapeutic alternatives to include at least one delayed release agent, one prodrug short acting agent, and one rectal preparation. Seconded by Trish White. The motion passed unanimously.

Dr. Phillips questioned why utilization was so far off. It was stated that there are a lot of generics and that there have been some supply changes and product discontinuations which shifted the availability.

**DR. PHILLIPS MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE DELAYED RELEASE AGENT, ONE PRODRUG SHORT ACTING AGENT, AND ONE RECTAL PREPARATION. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.**

**4-B.** **Endocrine/Metabolic:** Hypoglycemics, Incretin Mimetics/Enhancers (Blue); Hypoglycemic, Metformin (Green)**;** Hypoglycemics, SGLT2 Inhibitors (Blue); Insulin (Green); Glucagon Agents (Green); Androgenic Agents, Topical (Green); Antihyperuricemics (Green); Urea Cycle Disorders, Oral (Red); Bone Reorption Inhibitors (Red); Growth Hormone (Green); Phosphate Binders (Red); Progestins for Cachexia (Green)

***Endocrine/Metabolic: Hypoglycemics, Incretin Mimetics/Enhancers (Blue Class)***

**KAT KATCHATORIAN** (phonetic), Nova Nordisk, deferred her time to the committee if they had any questions for her regarding (unintelligible) and Ozempic.

Nina then went into disease state description for diabetes mellitus as well as the 2023 American Heart Association guidelines, the 2023 American Association of Clinical Endocrinologist updates and recommendations, the 2024 American Diabetes Association updates, and the 2024 American College of Physicians guidelines.

In August 2023, the FDA approved Mounjaro as a single use glass vial presentation for all available strengths. Indications, precautions, dosing, and formulations were given.

In December 2023, the FDA released a communications regarding Ozempic instructing wholesalers, pharmacies, healthcare professionals, and patients to check their product supply for counterfeit Ozempic 1 mg injection following seizure of counterfeit products from the US drug supply chain.

In January 2024, regarding all GLP-1RA medications the FDA is evaluating three potential safety signals (alopecia, aspiration, suicidal ideation) with GLP-1s per the FDA's FDA Adverse Event Reporting System from July to September 2023.

In January 2024, regarding all GLP-1RA medications the FDA has issued a drug safety communication which provides updates on its ongoing evaluation of reports of suicidal thoughts and actions in patients taking GLP-1RAs.

In April 2024, regarding all GLP-1RA medications the EMAs Pharmacovigilance Risk Assessment Committee concluded that available evidence does NOT support a causal association between GLP-1Ras and suicidal thoughts and actions.

In June 2024, Teva launched an authorized generic of Victoza (liraglutide) in the US.

Utilization for GLP-1 was 93.7 percent in line with PDL.

Previous motion Dr. Ryan moved a class effect to include at least one weekly injection product and one oral product. Seconded by Casey Gokey. The motion passed unanimously.

**JOHN RILEY** asked if anyone knew if the information had been obtained regarding the side effects of alopecia and aspiration for these medications.

**MALE SPEAKER 1** stated that last he knew it was still under review at the FDA level. It was still being assessed.

**DR. PHILLIPS MOVED A CLASS EFFECT TO INCLUDE AT LEAST ONE WEEKLY INJECTION PRODUCT AND ONE ORAL PRODUCT. SECONDED BY DR. DORAN ATCHISON. THE MOTION PASSED UNANIMOUSLY.**

**DPP4 Inhibitors** was discussed next.

In October 2023, the FDA approved Zituvio, a DPP4 inhibitor as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations, precautions, dosing, and formulations were given.

In November 2023, the FDA approved Zituvimet, a combination product, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

In July 2024, the FDA approved Zituvimet XR as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The launch date is yet to be determined.

Precautions, limitations, dosing, and formulations for both were given.

Utilization for DPP4 Inhibitors was 92 percent in line with PDL.

Previous motion Dr. Phillips moved a class effect. Seconded by Casey Gokey. Motion passed unanimously.

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

***Endocrine/Metabolic: Hypoglycemics, Metformin ( Green Class)***

Given that this is a green class Nina went straight to utilization.

Utilization was 99.8 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 THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.**

***Endocrine/Metabolic: Hypoglycemic, SGLT2 Inhibitors (Blue Class)***

There was no one present who wished to give testimony.

In September 2023, the FDA approved Jardiance to reduce the risk of sustained decline in eGFR end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of procession. Indications, precautions, dosing, and formulations were given.

In June 2024, the FDA expanded the indication for Farxiga for use as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus to include pediatric patients greater than 10 years of age. This was previously only approved for adults in this indication. Indications, precautions, dosing, and formulations were given.

In June 2024, the indications for Xigduo XR was expanded to include use as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus to include pediatric patients greater than 10 years of age. This was previously only approved for adults in this indication. Indications, precautions, dosing, and formulations were given.

Utilization was 82.2 percent in line with PDL.

Previous motion Dr. Phillips moved a class effect to include at least one medication that decreases cardiovascular risks and at least one that shows renal protective effect. Seconded by Dr. Ryan. The motion passed unanimously.

**DR. RYAN MOVED A CLASS EFFECT TO INCLUDE AT LEAST ONE MEDICATOIN THAT DECREASES CARDIOVASCULAR RISK AND AT LEAST ONE THAT SHOWS RENAL PROTECTIVE EFFECT. SECONDED BY DR. GOKEY. THE MOTION PASSED UNANIMOUSLY.**

***Endocrine/Metabolic: Insulin (Green Class)***

Nina stated that this class is broken down into multiple classifications so she will review all motions separately.

*Rapid Acting Insulins*

In March 2024, Eli Lilly will discontinue Humalog injection 3 mL vials. Alternatives include 10 mL vial and KwikPen presentations of Humalog and Insulin Lispro injection.

Utilization was 89.6 percent in line with PDL.

Previous motion Dr. Ryan moved a class effect, seconded by Dr. Phillips, and passed unanimously.

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

*Regular Insulins*

Utilization was 0 percent in line with PDL.

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

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

*Intermediate Insulins*

Utilization was 100 percent in line with PDL.

Previous motion Dr. Phillips moved a class effect. Seconded by Dr. Doran-Atchison. The motion passed unanimously.

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

*Regular/Intermediate-Acting Combination Insulins*

Utilization was 77.8 percent in line with PDL.

Previous motion Dr. Doran-Atchison moved a class effect. Seconded by Dr. Phillips. The motion passed unanimously.

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

*Long-Acting Insulins*

In November 2023, the FDA announced that Novo Nordisk will discontinue manufacture of Levemir 100 unit/mL FlexPen and vials. Discontinuation of Levemir FlexPen occurred on April 1, 2024. Vials will be available until the end of 2024. Full brand discontinuation will occur on December 31, 2024.

In May 2024, Sanofi-Aventis has announced discontinuation of insulin glargine 100 IU/mL injection, an unbranded biologic for Lantus, due to a business decision. Lantus remains on the market.

Utilization is 70.6 percent in line with PDL.

Previous motion Dr. Ryan moved a class effect. Seconded by Dr. Doran-Atchison. The motion passed unanimously.

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

***Endocrine/Metabolic: Glucagon Agents (Green Class)***

This is a green class so Nina moved directly to utilization.

Utilization was 98 percent in line with PDL.

Prior motion Dr. Phillips moved the drugs in the class were therapeutic alternatives to include a nasal formulation, seconded by Dr. Ryan and passed unanimously.

**DR. PHILLIPS MOVED THE DRUGS IN THE CLASS ARE THERAPEUTIC ALTERNATIVES TO INCLUDE A NASAL FORMULATION. SECONDED BY DR. GOKEY. THE MOTION PASSED UNANIMOUSLY.**

***Endocrine/Metabolic: Androgenic Agents, Topical (Green Class)***

In December 2023, Endo discontinued Fortesta (testosterone gel metered 10 mL/0.5 g). Generics remain.

Utilization was 60 percent in line with PDL.

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

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

***Endocrine/Metabolic: Antihyperuricemics (Green Class)***

This is a green class so Nina moved directly to utilization.

Utilization was 93.8 percent in line with PDL.

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

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

***Endocrine/Metabolic: Urea Cycle Disorders, Oral (Red Class)***

**MALE SPEAKER 2,** (unintelligible) pharmaceuticals, spoke on (unintelligible 01:25:33).

**NICOLE (phonetic) TRAN**, spoke on urea cycle disorders, and stated that (unintelligible) is seeking Carbaglu tablets for oral suspension 200 mg to be paired with generic carglumic acid for three indications. The first indications is adjunctive treatment for acute hyperammonemia due to probiotic acidemia known at PA or methylmalonic acidemia MMA. The second indication is adjunctive treatment of acute hyperammonemia due to NAGS deficiency. The third is maintenance of treatment of chronic hyperammonemia due to NAGS deficiency. She is requesting Carbaglu to be in parody with generic carglumic acid since it is currently approved for use in three noted indications while the generic carglumic acid is only approved for individuals with NAGS deficiency. NAGS deficiency is less than 1 per 2 million patients, PA is 1 per 100,000 patients, and MMA is 1 per 50,000 patients. They are the only carglumic acid approved for the NAGS deficiency management and for hyperammonemia due to PA and MMA. She requested Carbiglu to be in parody with generic carglumic acid.

Nina then gave the disease state description for urea cycle disorders. She also gave the 2019 Trans-European Guidelines.

Since this is a new drug class there was no utilization and no prior motion.

**DR. PHILLIPS** needed clarification and stated that these were all oral products and noted that in recommendations there were intravenous products that were recommended. She is asking if these medications are for maintenance on an outpatient basis.

**NINA** stated that this is the oral urea cycle disorder which is why there is no IV therapies.

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

***Endocrine/Metabolic: Bone Resorption Inhibitors (Red Class)***

There was no one present wishing to give testimony on this class.

Nina proceeded with giving the disease state description for osteoporosis.

Next Nina gave the guidelines from the American College of Physicians, 2023. This was an update to the guidelines from 2017.

In January 2024, the DFA released a drug safety communication to warn that Prolia increases the risk of severe hypocalcemia in patients with advanced chronic kidney disease including dialysis dependent patients. Cases of serious harm including hospitalization, life-threatening events, and death have been reported. Severe hypocalcemia is more common in patients with CKD who also have mineral and bone disorders.

In March 2024, the FDA approved Wyost as a new interchangeable biosimilar to Xgeva (denosumab). The indications, precautions, dosing, and formulations were given.

In March 2024, the FDA approved Jubbonti as a new interchangeable biosimilar to Prolia. Jubbonti approval includes a REMS program. The launch date is to be determined. Indications, precautions, dosing, and formulations were given.

In June 2024, the FDA approved teriparatide injection, a parathyroid hormone analog indicated for:

1. Treatment of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.
2. Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.
3. Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.

Launch date to be determined. Precautions, dosing, and formulations were given.

Utilization was 90.3 percent in line with PDL.

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

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

***Endocrine/Metabolic: Growth Hormone (Green Class)***

In March 2024, Genentech announced they will discontinue distribution of Nutropin AQ injection 5mg/2 mL, 10/2 mL, and 20 mg/2 mL based on a business decision given the availability of generic and alternative treatments.

Utilization is 86.8 percent in line with PDL.

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

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

***Endocrine/Metabolic: Phosphate Binders (Red Class)***

There was no one present who wished to give testimony.

Nina went in to the disease state description for hyperphosphatemia.

Nina then gave the 2017 guidelines from The Kidney Disease: Improving Global Outcomes.

In October 2023, the FDA approved Xphozah, a sodium hydrogen exchanger 3 (NEH3) inhibitor indicated to reduce serum phosphorus in adults with chronic kidney disease on dialysis and as an add on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. Precautions, dosing, and formulations were given.

In July 2024, Velphoro, which is used for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis has been expanded to include pediatric patients 9 years of age and older. The indications, dosing, and formulations were given.

Utilization as 61.6 percent in line with PDL.

Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternative. Seconded by Dr. Doran-Atchison. Motion passed unanimously.

Dr. Phillips and Dr. Doran-Atchison both wondered why the numbers were so low. Male Speaker 1 stated that it is because the claim volume is very small and the two drugs that were non-preferred made up the vast majority of them. Dr. Phillips asked if that was going to be reassessed. Male Speaker 1 stated they will look at that.

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

***Endocrine/Metabolic: Progestins for Cachexia (Green Class)***

Utilization was 94.7 percent in line with PDL.

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

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

**CHARLES SEMLING**, stated that he would like to ask the committee if there is very low utilization and it is pretty much the same product if they would consider retiring that class from review. He asked that a note of that be made.

**DR. PHILLIPS MOVED TO RETIRE THE CLASS. SECONDED BY TRISH WHITE. THE MOTION PASSED UNANIMOUSLY.**

**4-C. Antiretrovirals: HIV/AIDs (Blue)**

***Antiretrovirals: HIV/AIDs (Blue Class)***

**STEWART OBROCHTA (phonetic)**, Gilead, presented the most recent PrEP data for lenacapavir. Lenacapavir is a first in class multistage HIV-1 capsid inhibitor with high potency and a long half life supporting twice a year injections. It is the only subcutaneous twice a year option available. He reviewed the two trials PURPOSE1 and PURPOSE2.

**KAITLIN WINN (phonetic),** ViiV healthcare, spoke on the importance of access to innovative drug therapies that are essential in ending the HIV epidemic. To achieve their national goals of reducing new HIV infections by 90 percent they must leverage the advances in HIV care to overcome stigma and adherence challenges. Cabenuva, the only complete long-acting regimen, offers every other month dosing for people struggling with daily pills. Clinical trials demonstrated its safety and durable efficacy over three years with 98 percent preferring Cabenuva over oral ART. It shows similar efficacy to Biktarvy and superior outcomes in people with a history of non-adherence to oral regimens. Guidelines support Cabenuva for a strategy for individuals unable to adhere to oral regimens. Apretude is a novel every 2 month PrEP option proven safe, well tolerated, and effecting including during pregnancy. Apretude achieved superior efficacy versus oral Truvada. It remained highly effective. Zero HIV cases were

reported in the real world study. She requested the committee's continued support in allowing open access to the innovative options for their members.

Nina then followed with the disease state description for HIV. She then gave the 2023 guidelines from the Department of Health and Human Services for HIV. A table was shown for the recommendation initial regimen for most people with HIV according to the March 2023 DHHS guidelines.

In March 2024, the indication for Biktarvy has been expanded to include treatment of HIV-1 infection in virologically suppressed adults and pediatrics weighing 14 kilograms or more on a stable HIV-1 regimen with known or suspected M184V/I resistance. Indications, precautions, dosing, and formulations were given.

In March 2024, Edurant 25 mg tablets received expanded indication to include HIV-1 treatment naïve pediatric patients which HIV-1 RNA is equal to or less than 100,000 copies/mL who are between 2 to 12 years of age and weigh between 25 to 35 kilograms. Edurant Ped tablet cannot be substituted with Edurant tablets on a mg per mg basis. Indications, precautions, dosage, and formulations were given.

In April 2024, The indication for use as a complete regimen for treatment of HIV-1 infection with Dovato has been expanded to include adolescents 12 years of age or older and weighing 25 kilograms or more. This is the first oral two drug combination single tablet regimen to be available for adolescents living with HIV. Indications, precautions, dosing, and formulations were given.

Utilization was 98.4 percent in line PDL.

Previous motion Dr. Phillips moved that access would remain open, the drugs in the class were therapeutic alternatives to include at least one of at least one PrEP formulation and at least one pediatric product. Seconded by Dr. Doran-Atchison. The motion passed unanimously.

**DR. PHILLIPS MOVED THAT ACCESS WOULD REMAIN OPEN, THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE PREP FORMULTION AND AT LEAST ONE PEDIATRIC PRODUCT. SECONDED BY VALARIE BIXLER. THE MOTION PASSED UNANIMOUSLY.**

**4-D. Single Class Review: Movement Disorders (Blue); Continuous Glucose Monitors (Red)**

***Single Class Review: Movement Disorders (Blue Class)***

**RAY KONG,** Neurocrine Bioscience, spoke on Ingrezza. He thanked the committee for continuing to allow Ingrezza on the states PDL and making it available as an approved option. He provided a new formulation update. Ingrezza is FDA approved for both the treatment of tardive dyskinesia as well as chorea associated Huntington's Disease in adults. Ingrezza is now also available with a new FDA approved once daily sprinkle formulation in 40, 60, and 80 mg

dosing strengths. Ingrezza sprinkle provides an alternative administration option for those who have trouble swallowing or for those who prefer to not swallow a whole capsule. TD is often a persistent and disruptive condition associated with prolonged exposure to dopamine receptor blocking agents including antipsychotics and antiemetic agents. Clinical guidelines and systematic literature reviews have recommended the newer (unintelligible) such as Ingrezza as first like treatment for TD. A long term study was conducted as part of the clinical development program for TD. Ingrezza and Ingrezza sprinkle are an effective once daily treatment for adults with TD and adults with chorea associated with Huntington's Disease. It offers prescribers and patients multiple formulation options with a straight forward titration schedule and three available dosage strengths. N dosage adjustments are required for elderly or those with renal impairment. Dosage reductions are recommended in patients with moderate and severe hepatic impairment. There is a box warning regarding patients with Huntington's Disease. He respectfully asked the committee to continue to have Ingrezza and to add the new sprinkle formulation to the state PDL. He also kindly asked the committee for future consideration for the removal of the PA criteria removing "trial of at least one other medication used to treat TD for at least 30 days" prior to the use of FDA approved VMAT2 inhibitor such as Ingrezza.

Nina then gave the disease state description for Huntington's Disease. She then gave the 2022 guidelines from The International Parkinson and Movement Disorder Society.

In May 2023, the FDA approved new dosage forms for Austedo XR. They approved a higher strength ER tablet: 30mg, 36 mg, 42 mg, and 48 mg. The max recommended daily dose is 48 mg.

In July 2024, the FDA approved a new intermediate strength ER tablet for Austedo XR in 18 mg. A new 4 week titration kit has also been approved which contains seven 12 mg ER tablets, seven 18 mg ER tablets, seven 24 mg ER tablets, and seven 30 mg ER tablets.

In August 2023, the FFDA approved Ingrezza for the treatment of chorea associated with Huntington's Disease.

In May 2024, the FDA approved Ingrezza's sprinkle capsule for patients who have dysphagia or difficulty swallowing. The capsule contains oral granules that can be sprinkled on to soft food. The capsule contents should not be mixed with milk or water and should not be administered via enteral tubes. Indications, precautions, dosing, and formulations were given.

Utilization was 95.8 percent in line with PDL.

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

Dr. Philips asked if they were all VMAT inhibitors and if so, that would be class effect and she would propose that motion.

Charles Semling stated (unintelligible).

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

***Single Class Review: Continuous Glucose Monitors (Red Class)***

There was no one present that wished to give testimony.

Nina stated that all the CGM products that will be presented today have been approved by the FDA but have not yet launched in the United States.

In March 2024, the FDA approved Dexcom Stelo Glucose Biosensor System as the first OTC CGM. This is anticipated to launch in the summer of 2024. It is indicated to continuously measure, record, analyze, and display the glucose values in people 18 years of age and older not on insulin. Individuals with DM treated with oral medications, or those without DM who want to better understand how diet and exercise may impact blood glucose levels. The system is not intended for patients with problematic hypoglycemia. It will include a wearable sensor that pairs with an applications; sensors can be worn for up to 15 days. The sensor site location should be the back of the upper arm. This delivers glucose readings 24/7 directly to a smartphone for up to 15 days. The Stelo Glucose Biosensor System may also help the user to better understand how lifestyle and behavior modification including diet and exercise impact glucose excursion. The user is not intended to take medical action based on the device output without consultation with a qualified healthcare professional.

In June 2024, the FDA approved the OTC Lingo CGM system. There is an anticipated launch of summer 2024. It is intended for adults 18 years of age and older not on insulin who are looking to improve their overall health and wellness. It is not intended for diagnosis of disease including diabetes. It will include a biosensor that is worn on the upper arm for 14 days. The sensor will continuously stream glucose data to a coaching application on a smartphone translating the body's language and giving insights on the persons reactions to food, exercise, and life's daily stressors. Lingo will track glucose and provide personalized insights and customized coaching to help people create healthy habits, retraining their metabolism, and improve their overall well-being. Apple Health integration available and allows consumers to automatically log their workouts and keep personal information up to date. The Lingo program does not guarantee that everyone will achieve the same results as individual responses may vary. Consult healthcare professional before making changes to diet or exercise regimen or if there is an eating disorder or a history of eating disorders.

In June 2024, the FDA approved the OTC Libre Rio CGM system with a launch date to be determined. It is intended for people ages 18 and older with type 2 diabetes who do not use insulin and typically manage their diabetes through lifestyle modifications. It includes a biosensor that is placed on the back of the upper arm for 15 days as well as a reader or a compatible smartphone application which displays glucose measurements. The glucose range is extremely low or high (40 mg/dL to 400 mg/dL). Failure to use Libre Rio as instructed in labeling may result in missing severe low or high glucose events. If readings do not match symptoms or expectations use a fingerstick value from a blood glucose meter for treatment decisions.

Nina shows a chart from the 1 year utilization report. She noted that this is not the quarterly PDL compliant summary that were shown in the previous classes and all available products are preferred.

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

**DR. PHILLIPS MOVED THAT THE BLOOD GLUCOSE METERS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.**

**5. End of Public Meeting**

**6. Comments From Committee Members**

**7. Adjourn**

**THE NEXT MEETING WAS SCHEDULE FOR NOVEMBER 15, 2024.**