Alaska Medicaid Pharmacy and Therapeutics Meeting

MINUTES OF MEETING

September 19, 2025

Committee Members Present:

Charles Ryan, MD

John Riley, PA, Acting Chairman

Robert Carlson, MD

Anna Brecheisen, PharmD

Sarah Doran-Atchison, PharmD

Casey Gokey, MD

Valarie Bixler, PharmD

Claudia Phillips, MD

Others Present:

Nina Huynh, PharmD, BCPS

Ryan Ruggles, PharmD

Erin Nowak, AbbVie

Kirk Latibeaudiere, Teva

Kat Khachatourian, PharmD

Natalie Rose, Gilead

Steven Willis, AAPA

Matthew Parrott PharmD, DOH HCS

Charles Semling PharmD, DOH HCS

Committee Members Absent:

1. Call to Order – Chair

Mr. Riley called the meeting to order at 8:10 a.m.

2. Roll Call

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

3. Public Comments - Local Public/Health Practitioners

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)

Nina gave a brief overview of biosimilars.

Antiemetic – Antivertigo Agents (Blue Class)

June 2025, Transderm Scop (scopolamine transdermal system) had a new warning added for serious heat related risks. It can raise the body temperature and poses a risk for hyperthermia, hospitalization, or death. Most cases occur in patients equal to or less than the age of 18 or equal to or older than the age of 60. Serious harm often occurred with 72 hours of application in patients equal to or less than 18 years of age. FDA mandates a label update to highlight these risks.

Utilization was 99.2 percent in line with 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. BRECHEISEN. THE MOTION PASSED UNANIMOUSLY.

Cytokine & Cell Adhesion Molecules (CAM) Antagonist – GI Indicated (Red Class)

ERIN NOWAK, medical outcomes and science liaison with AbbVie. Thank you for a few minutes to provide information on Skyrizi and Rinvoq. And I acknowledge that the committee has already reviewed these therapies, but my purpose in providing comment today is to highlight a few updates for each treatments for your awareness as well as to support the request to add Skyrizi to the Alaska PDL. First, I'll start with Rinvoq. I

acknowledge that this is on the PDL. But just to provide you a quick update, Rinvoq is now approved for nine indications, the most recent being GCA or giant cell arteritis. And then as a reminder, Rinvoq is approved for moderately to severely active ulcerative colitis and Crohn's disease in adults after inadequate response or intolerance to a TNF blocker. This therapy carries a class-wide box warning for mortality, malignancy, mace, and thrombosis, and a box warning for serious infections. And I'd also like to provide an update on safety. There are now more than ten years of clinical trial experience with Rinvoq from the products nine current indications. 27 clinical trials have accumulated over 37,000 patient years of exposure to support safety and an integrated safety analysis inclusive of IBD was published in August of this year, indicating a long-term safety profile that's consistent with previous findings. Next, for Skyrizi, this is an IL-23 antagonist now approved for four indications, two of which are moderately to severely active Crohn's disease and moderately to severely active ulcerative colitis in adults. In clinical trials, Skyrizi achieved superiority to placebo in clinical remission, endoscopic improvement, and endoscopic remission. Please note that Skyrizi may increase the risk of infection and there is a warning for hepatotoxicity in the treatment of IVD. For the GI indications and beyond, Rinvoq and Skyrizi have demonstrated fast onset of action, durability of response, ability to achieve rigorous treatment targets such as endoscopic remission. And these therapies have also been evaluated in difficult to treat patient populations across their indications so that the data collected is applicable to the patients that are being managed today. Furthermore, AbbVie is committed to conducting head-to-head clinical trials to support treatment and coverage decisions. To date, there are more than ten head-to-head trials across these two therapies and Skyrizi does have a head-to-head trial versus ustekinumab in Crohn's disease, where Skyrizi showed superiority. With this information, I respectfully request that Rinvoq remain available for patients and providers on the PDL and for the committee to consider adding Skyrizi to the preferred drug list. Thank you for your time and consideration and I'm happy to answer any questions you might have.

KIRK LATIBEAUDIERE, a pharmacist in the medical affairs division of Teva Pharmaceuticals. I appreciate the opportunity to speak to you today and provide information regarding Selarsdi, Teva's biosimilar to Stelara. Selarsdi is an FDA approved, interchangeable biosimilar to Stelara available in multiple formulations, 90 milligram and 45 milligram prefilled syringe launched February 2025, 130 milligram per 26 ml vial for Crohn's disease and ulcerative colitis that was launched in April of 2025. A 45 milligram vial for subcutaneous administration is expected later this year. As interchangeable biosimilar, Selarsdi may be substituted at the pharmacy level without prescription or prescriber intervention in accordance with FDA guidance and subject to Alaska State pharmacy laws.

Selarsdi is an interleukin-12 and interleukin-23 antagonist approved for all indications covered by the reference product, which include plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. Clinical data supporting Selarsdi's approval include a phase one multi-centered randomized double-blind study in 298 healthy adults demonstrating pharmacokinetic similarity to Stelara following a single 45 milligram subcutaneous dose. A phase three study in 581 adults with moderate to severe plaque psoriasis confirmed bio similarity showing no clinically meaningful difference in pharmacokinetics, efficacy, safety or immunogenicity with a reference product. Selarsdi is contraindicated in individuals with clinically significant hypersensitivity to ustekinumab or any excipients in the formulation. For full safety information, I refer you to the prescriber information. On behalf of Teva, we respectfully request that Selarsdi be considered for preferred status within Alaska Medicaid to ensure patient access to this important treatment option. Thank you for your time and opportunity to provide public comment. I'm here to answer any questions that you may have, but I do yield the rest of my time. He stated that Selarsdi is interchangeable with Stelara.

Nina gave the presentation for Cytokine & CAM Antagonists. She started by giving the description of Inflammatory Bowel Disease (IBD). She then gave the 2024 American Gastroenterological Association Guidelines as well as the 2021 American Gastroenterological Association (AGA) 2021 Guidelines.

September 2024, the FDA approved Tremfya for the treatment of adults with moderately to severely active ulcerative colitis (UC) and in March 2025 it was approved for the treatment of adults with moderately to severely active Crohn’s disease, adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy, and treatment of adults with active psoriatic arthritis. Dosing, availability, indications, and efficacy and safety were given.

Nina gave the biosimilars for Stelara along with when they were approved and what they were approved for along with the biosimilars for Humira and what they are approved for.

In January 2025, the FDA approved Omvoh for the treatment of adults with moderately to severely active Crohn’s disease as well as for the treatment of adults with moderately to severely active ulcerative colitis.

Utilization was 70.4 percent in line with PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives to include at least one oral formulation. Seconded by Dr. Doran-Atchison. Motion passed unanimously.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE ORAL FORMULATION. SECONDED BY DR. GOKEY. THE MOTION PASSED UNANIMOUSLY.

Irritable Bowel Syndrome & GI Motility (Green Class)

In January 2025, the FDA approved the first generic, prucalopride, for Takeda's Motegrity from Novitium.

Utilization was 83.7 percent in line with 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.

Proton Pump Inhibitors (Green Class)

Utilization was 96.9 percent in line with PDL.

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

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

Ulcerative Colitis (Green Class)

Utilization was 77 percent in line with PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives to include at least one delayed-release agent, one prodrug short acting agent, and one rectal preparation. The motion passed unanimously.

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

4-B. Endocrine/Metabolic: Hypoglycemics, Glucagon – like Peptide-1 (GLP-1) and Combinations (Blue); Hypoglycemics, Dipeptidyl Peptidase-4 Inhibitors (DPP-4) and Combinations (Blue); Hypoglycemics, Metformin (Green); Hypoglycemics, SGLT2 Inhibitors (Blue); Rapid Acting Insulins (Red); Regular Insulins (Green); Intermediate Insulins (Green);

Rapid/Intermediate Acting Combination Insulins (Green); Regular/Intermediate Acting Combination Insulins (Green); Long Acting Insulins (Green); Glucagon Agents (Green); Androgenic Agents, Topical (Blue); Antihyperuricemics (Green); Urea Cycle Disorders, Oral (Green); Bone Resorption Inhibitors (Red); Growth Hormone (Green); Phosphate Binders (Green); Potassium Binders (Red)

Hypoglycemics, Glucagon – like Peptide-1 (GLP-1) and Combinations (Blue Class)

KAT KHACHATOURIAN, a PharmD and scientific director with Novo Nordisk Medical Affairs. I appreciate the opportunity to provide you with an update on a new FDA indication for Ozempic and patients with type 2 diabetes and CKD. I do acknowledge this is currently on the PDL for Alaska. CKD occurs in approximately 40 percent of patients with type 2 diabetes. And despite standard of care treatments, it represents the leading cause of end stage kidney disease in the US and unfortunately, markedly increases the risk of MACE and death. In fact, the CDC highlighted CKD as the third fastest growing cause of death in the US and globally. As you are likely aware, Ozempic is a GLP-1 receptor agonist initially indicated to improve glycemic control in adults with type 2 diabetes and subsequently to reduce MACE in adults with type 2 diabetes and established ASCVD. On January 28th of this year, Ozempic gained an additional indication to reduce the risk of sustained eGFR decline, end stage renal disease, and CV death in adults with type 2 diabetes and CKD, representing the first FDA approved GLP-1 treatment option for people living with type 2 diabetes and CKD. This new indication was based on findings from the flow trial, a global kidney outcomes trial wherein greater than 3,500 patients with type 2 diabetes and CKD were randomized to receive Ozempic or placebo added to standard of care including RAS inhibitors and SGLT2s. The primary endpoint was a composite of five individual endpoints including sustained decline in GFR of 50 percent or more, sustained GFR less than 15 or need for chronic renal replacement therapy, renal death or CV death. After a median follow-up of 3.4 years, there was a decision by the independent data monitoring committee to stop the trial early due to efficacy. The result of a primary outcome event was 24 percent lower in the semaglutide group than in the placebo group. Specifically of note, CV death was reduced by 29 percent and all cause death was reduced by 20 percent. And the trial semaglutide had a safe and well tolerated profile in line with previous semaglutide trials. Serious adverse events were reported in low -- a lower percentage of participants in the semaglutide group than in the placebo group, mainly driven by a lower rate of CV events and infections. And finally, the 2025 standards of care in diabetes have included a class A recommendation for a GLP-1 with demonstrated benefit to reduce cardiovascular risk and

kidney disease progression in people with type 2 diabetes and CKD. Thank you and I'm pleased to answer any questions.

Nina then gave the presentation and disease state description for diabetes mellitus. Next, she gave the American Diabetes Association (ADA) Standards of Care for 2025.

In November 2024, AstraZeneca discontinued the manufacture of Bydureon Bcise ER x mg/0.85 mL injectable suspension.

In November 2024, AstraZeneca discontinued the manufacture of Byetta 300 mcg/1.2 mL and 600 mcg/2.4 mL injection.

In November 2024, the FDA approved the first generic for AstraZeneca's Byetta injection, exenatide, from Amneal.

In December 2024, the FDA approved the generic, liraglutide, for Novo Nordisk's Victoza from Hikma. It is available in an 18 mg/3 mL prefilled, single-patient use pen that delivers 0.6 mg, 1.2 mg, and 1.6 mg doses.

In December 2024, the FDA approved R2 formulation, semaglutide (Rybelsus) as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The R1 and R2 formulations are not substitutable on a mg per mg basis and should not be used at the same time. The limitations, warnings, dosage, forms, and strengths were given.

In January 2025, the FDA approved a new indication for Ozempic, the sub-q formulation of semaglutide, to reduce the risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes and chronic kidney disease. Dosage, safety, warnings, dosage, forms, strengths, and efficacy was given.

In April 2025, the FDA released a warning advising consumers against the use of counterfeit Ozempic products. Several hundred units of counterfeit Ozempic, 1 mg, were found in the US drug supply chain and were seized by the FDA.

Utilization was 89.1 percent in line with PDL.

Previous motion 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.

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

Hypoglycemics, Dipeptidyl Peptidase-4 Inhibitors (DPP-4) and Combinations (Blue Class)

In January 2025, the FDA approved an oral solution formulation of sitagliptin as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations, warnings, dosage, and availability were given.

In Marh 2025, AstraZeneca discontinued Qtern 5 mg/5mg and 10 mg/5 mg tablets.

Utilization was 93.8 percent in line with PDL.

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

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

Hypoglycemics, Metformin (Green Class)

Utilization was 99.6 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. RYAN MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Hypoglycemics, SGLT2 Inhibitors (Blue Class)

In December 2024, the FDA approved Invokana as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients ages 10 years of age and older with type 2 diabetes mellitus. Dosage forms and strengths were given. The pediatric safety and efficacy was given.

In December 2024, the FDA approved a new indication for Xigduo XR. It can now be used as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients age 10 years of age and older with type 2 diabetes mellitus. Dosage forms, strengths, warnings, efficacy, and safety was given.

In March 2025, the FDA approved a new indication for Synjardy to be used as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients age 10 years of age and older with type 2 diabetes mellitus. Dosage forms, strengths, warnings, efficacy, and safety was given. It can also be used to reduce the risk of sustained eGFR decline, end-stage kidney disease, CV death, and hospitalization for HF in patients with CKD at risk of progression in adults with type 2 diabetes mellitus. Dosage forms, strengths, warnings, efficacy, and safety were given.

Utilization was 86.7 percent in line with PDL.

Previous motion Dr. Ryan 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. Gokey. The motion passed unanimously.

DR. RYAN 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. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Rapid Acting Insulins (Red Class)

There was no one present who wished to give testimony.

February of 2025, the FDA approved Merilog as the first biosimilar rapid-acting insulin product to reference NovoLog. Merilog is indicated to improve glycemic control in adults and pediatric patients with diabetes, consistent with the reference product. Like NovoLog, the recommended dose is individualized and adjusted based on the patient's metabolic need, blood glucose monitoring, and glycemic targets. Dosage forms, strengths, warnings, efficacy, and safety were given.

May of 2025, the FDA approved a new presentation of the Humalog Tempo Pen as a prefilled three ml pen containing 200 units per ml of insulin lispro.

Utilization was 85 percent in line with PDL.

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

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

Regular Insulins (Green Class)

Utilization was 0 percent in line with PDL.

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

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

Intermediate Insulins (Green Class)

Utilization was 100 percent in line with PDL.

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

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

Rapid/Intermediate Acting Combination Insulins (Green Class)

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

Regular/Intermediate Acting Combination Insulins (Green Class)

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

Long Acting Insulins (Green Class)

Utilization was 81.5 percent in line with 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.

Dr. Philips asked that if next time they could put them all into one basket with a motion that it is therapeutic alternatives to include at least one from each class.

Dr. Semling stated that they were just discussing it and feel it is a great idea.

Glucagon Agents (Green Class)

Utilization was 98.2 percent in line with PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives to include one nasal formulation. Seconded by Dr. Gokey. The motion passed unanimously.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE NASAL FORMULATION. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

Androgenic Agents, Topical (Blue Class)

In March 2025**,** the FDA issued a class-wide labeling change for testosterone products based on findings from the TRAVERSE clinical trial and post-marketing ambulatory blood pressure monitoring studies. the FDA now recommends including the study results and the PI for all testosterone products and removing the box warning about the cardiovascular risk. For products with complete ambulatory blood pressure studies, labeling should include product specific data showing blood pressure increases. And then for those without such data, a general warning about increased blood pressure should be added.

Utilization was 50 percent in line with PDL. This is due to discontinuations of several older products including Androderm AndroGel pump which impacted product availability.

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

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

Antihyperuricemics (Green Class)

ANTIHYPERURICEMICS Uloric 40 mg and 80 mg tablets were discontinued. Generic febuxostat remains available.

Utilization was 94.3 percent in line with PDL.

Previous motion Dr. Doran-Atchison 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. RYAN. THE MOTION PASSED UNANIMOUSLY.

Urea Cycle Disorders, Oral (Green Class)

Utilization was 0 percent in line with 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.

Bone Resorption Inhibitors (Red Class)

Nina gave the disease state description for osteoporosis.

She gave the biosimilars for Prolia along with what each are indicated for and how they are dosed and administered. Next, she gave the biosimilars for Xgeva and what they are approved for and how they are dosed and administered.

Utilization was 84.3 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. RYAN. THE MOTION PASSED UNANIMOUSLY.

Growth Hormone (Green Class)

Humatrope 2.88 ml injection was discontinued. Distribution is expected to continue through 2026 subject to market demands.

Utilization was 87.2 percent in line with PDL.

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

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

Phosphate Binders (Green Class)

Utilization was 71.1 percent in line with PDL. This is due to the low claim count.

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

DR. PHILIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY ANNA BRECKHEISEN. THE MOTION PASSED UNANIMOUSLY.

Potassium Binders (Red Class)

This is the first time that this has been reviewed by the committee.

Nina gave the disease state description for hyperkalemia.

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

4-C. Single Class Review: HIV/AIDs (Blue); Movement Disorders (Green); Continuous Glucose Monitors (Blue)

HIV/AIDs (Blue Class)

NATALIE ROSE**,** medical value evidence liaison with Gilead on the patient access team. Stuart O'Brochta normally joins your meetings and unfortunately, as of this morning, came down ill and asked me to fill in somewhat quickly. So, here I am. Thank you for having me. I wanted to introduce a new option for HIV prevention today that was approved in June. Lenacapavir for prevention, brand name Yeztugo. As a reminder and to help with differentiation, brand name Sunlenca, also lenacapavir, was previously approved for HIV treatment and heavily treatment experienced individuals. Yeztugo is for HIV prevention and is an HIV capsid inhibitor indicated for HIV prevention to reduce the risk of sexual acquiring HIV in adults and adolescents weighing at least 35 kilograms who are at risk for HIV-1 acquisition. Yeztugo is the first and only twice yearly HIV prevention option and is now recommended by the International Antiviral Society, IAS, for prevention for all individuals with a rating of A1. And as of just yesterday, the CDC issued new guidelines strongly recommending Yeztugo as an additional HIV prevention option. The initiation dosing for Yeztugo includes two 300 milligram oral tablets as well as the injections, which is two 1.5 ml subcutaneous injections given on day one, then two 300 milligram oral tablets on day two, and then individuals can proceed to the injections every six months. It's important to note to screen all individuals for HIV-1 prior to initiating Yeztugo and with each following injection as this is not a complete treatment regimen for individuals with current HIV.

Yeztugo received priority approval by the FDA based on the purpose trial results. Purpose one was completed in over 5,000 sexually active cisgender women aged 16 to 25 in South Africa and Uganda, showing 100 percent efficacy rates in preventing HIV compared to the background HIV incident rate. Purpose two was completed in over 3,000 sexually active cisgender men, transgender women and men, and gender non-binary individuals in multiple countries, including the US, showing 96 percent efficacy compared to the background HIV incidents. The most common AEs are injection site reactions, headache, nausea, dizziness, vomiting, and diarrhea. Currently, the annual and cumulative healthcare costs are six to seven times higher for people living with HIV compared to those without HIV. And adding in and preventing a new HIV infections can actually save $1.1 million in lifetime healthcare costs. Please consider making Yeztugo accessible to all those in Alaska to prevent HIV. I am here if you have any questions and again, I appreciate your grace in allowing me to step in for Stuart today. Thank you so much.

Nina gave the disease state description for HIV.

In February of 2025, the FDA approved an expanded indication for Odefsey. A fixed dose combination of emtricitabine, rilpivirine, and tenofovir alafenamide previously approved for pediatric patients weighing 35 kilograms or more. The indication now includes those weighing between 25 and less than 35 kilograms. It is approved for use in two scenarios an initial therapy in treatment-naive patients with HIV-1 RNA less than or equal to a hundred thousand copies per ml and as a switch option for virologically suppressed patients with HIV-1 RNA less than 50 copies per ml for at least six months with no history of treatment failure and no known substitution associated with resistance to the individual components. Dosage, formulations, safety, efficacy, warnings, and indications were given.

In March of 2025, the FDA approved an expanded indication for Prezcobix. A fixed dose combination of darunavir and cobicistat. It is now approved for pediatric patients weighing at least 25 kg for the treatment of HIV-1 infection.

In May of 2025, the FDA approved the first generic version of Complera, a fixed dose combination of emtricitabine, rilpivirine, and tenofovir disoproxil fumarate.

Discontinuations in the past year, Fuzeon lyophilized powder and Reyataz. While the branded formulation of Reyataz has been discontinued, the generic version atazanavir sulfate remains available.

In 2025, the FDA approved Yeztugo lenacapavir to reduce the risk of sexually acquired HIV-1 in adults and adolescents weighing at least 35 kilograms who are at risk for HIV-1 acquisition. Dosage, formulations, safety, efficacy, and warnings were given.

June of 2025, the FDA expanded the indication for Descovy. A combination of emtricitabine with tenofovir alafenamide fumarate or TAF to include pediatric patient with HIV-1 who weigh between 14 and less than 35 kilograms. It's approved for use in combination with other antiretroviral agents including darunavir and cobicistat, but not with protease inhibitors that require a CYP3A inhibitor. Dosage, formulations, safety, efficacy, and warnings were given.

June of 2025, the FDA expanded the indication for cobicistat marketed as Tybost to include pediatric patients weighing at least 14 kilograms. Is approved to increase systemic exposure of either atazanavir or darunavir, both given once daily in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and children. Dosage, formulation, safety, efficacy, and warnings were given.

Utilization was 99.6 percent in line with PDL.

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

Dr. Phillips stated that Yeztugo having a six month active span could be significant in at risk populations that may not take their medications daily. She feels it is not enough to pull the medication out and make it a priority but feels it is something that the committee should think about.

DR. PHILLIPS moved the drugs in the class were therapeutic alternatives to include at least one PrEP formulation and at least one pediatric product. SECONDED BY DR. RYAN.

Casey Gokey stated that she feels that Yeztugo would be good for a subset of patients that they have now. She is wondering if it could be approved with a prior authorization if people have failed other options.

Dr. Semling said that at this time it does not require a prior authorization. PDL placement will come after this meeting.

THE MOTION PASSED UNANIMOUSLY.

Movement Disorders (Green Class)

Utilization was 96.9 percent in line with PDL.

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

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

Continuous Glucose Monitors (Blue Class)

February of 2025, The FDA issued a safety alert for diabetes devices, including continuous glucose monitors that uses smartphones to deliver safety alerts. Some alerts were not being received or heard, which may lead to serious health risk such as severe hypoglycemia, severe hyperglycemia, diabetic ketoacidosis, and even death. Most smartphone settings, new device connections, and unsupported software updates were identified as the potential issues. The FDA recommended that patients and caregivers regularly check alert settings, avoid automatic OS updates without verifying compatibility, and following manufacturer instructions closely to ensure alerts are properly configured and received.

Utilization was 100 percent in line with PDL.

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

STEVEN WILLIS, a physician assistant with 14 years of clinical adult endocrine experience. I'm currently a medical science liaison for AAPA diabetes care supporting research and education in the Pacific Northwest. As previously referenced, the American Diabetes Association, 2,000 standards of care was cited earlier regarding diabetes medications. The American Diabetes Association standards of care 2025 does recommend continuous glucose monitors for diabetes management for youth and adults with diabetes on any type of insulin therapy and should be considered for adults with type 2 diabetes treated with glucose lowering medications other than insulin to achieve and maintain individualized glycemic goals. The choice of CGM device should be made based on individual circumstances, preferences, and needs is determined by the patient and the clinician. I wanted to update this committee that the FreeStyle Libre 2 and 3 sensors will not be available after the end of September this year. Moving forward, the portfolio with FreeStyle Libre is going to be the Libre 2 Plus and 3 Plus sensors. Both feature a 15-day wear with a 15-day memory storage, allowing for no data gaps and continuous glucose monitoring, metric reporting, and may help provider treatment decision making. Robust glycemic reports are available on FreeStyle Libre apps and readers and readings are updated every

minute. The FreeStyle Libre systems are approved for common medical imaging procedures including X-ray, CT scans, and MRI, as long as the MRI is three Tesla or greater. Prior to 2024, the FDA did have a contraindication for sensors being worn during those radiologic procedures. Based on the unique technology of the FreeStyle Libre sensors and testing, those are the only CGM devices, at this time, that can be worn during those radiologic procedures. The smaller form factor can be important for the pediatric population and discreet wear for adults. An over patch is not required for wear of FreeStyle Libre sensors and the sensors do not contain common skin allergens known as IBOA, M-P-B-A, which is a potential allergen found in medical device adhesives linked to allergic contact dermatitis. Additionally, HEDIS has noted that the GMI, a continuous glucose monitoring metric, can be used for quality reporting. I yield the rest of my time for any questions that members of the committee may have.

DR. PHILLIPS MOVED THE BLOOD GLUCOSE MONITORS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BRECHEISEN. THE MOTION PASSED UNANIMOUSLY.

5. End of Public Meeting

6. Approval of Previous Meeting Minutes

MOTION BY * TO APPROVE THE MEETING MINUTES. SECOND BY *. MOTION PASSED UNANIMOUSLY.

7. Comments From Committee Members

8. Adjourn

MOTION TO ADJOURN BY *.

THE NEXT MEETING WAS SCHEDULE FOR NOVEMBER 21ST, 2025.