Alaska Medicaid Pharmacy and Therapeutics Meeting

MINUTES OF MEETING
April 17, 2026

Committee Members Present:
John Riley, PA, Acting Chairman
Charles Ryan, MD
Robert Carlson, MD
Valarie Bixler, PharmD
Claudia Phillips, MD
Casey Hammond

Committee Members Absent:

Others Present:
Nina Huynh, PharmD, BCPS
Charles Semling PharmD, DHSS
Ryan Ruggles, PharmD
Matthew Parrot
Gerald Beaujrage, CalVista
Lisa Carmen, Genetech
Adam Furman, Sanofi
Rahsaan Agar, Pfizer
Jeff Baldwin, Amgen
Richard Oliver, Liquidia
Kimberly Simpson, United Therapeutics Corp.

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

4. Class Review, Discussion & Vote

4-A. Single Class Review: Hereditary Angioedema (Red); Hemophilia (Red)

Hereditary Angioedema (Red Class)

GERALD BEAUJRAGE, Medical Science Liaison representing CalVista Pharmaceuticals. HAE is a rare inherited and potentially life-threatening disease where patients experience sudden edema in various locations of their body. It impacts approximately 6,000 patients in the U.S. Based on the hereditary angioedema association's medical guidelines, patients should always carry an on-demand medication with them and treat all HAE attacks as early as possible, shortening overall total attack time. Based on a patient survey conducted by the same group, adult patients wait on average 3.8 hours and adolescents wait 7.7 hours to treat an attack. 79% of survey participants reported treatment-related anxiety, which correlated with treatment delay. 80% of patients reported that that time to full recovery took longer when the treatment was delayed. All other approved on-demand medications are injectables requiring refrigeration or reconstitution. Having an oral alternative serves an unmet need for HAE patients. It's the ability to treat your acute HAE attacks anywhere, anytime. So introducing Ecterly, it's the first orally administered treatment for HAE and the first new on-demand treatment in more than a decade. It's approved for ages 12 and older. Ecterly is a plasma calocrine inhibitor, that is, film-coated tablet. It's rapidly absorbed and following a single oral dose of 600 milligrams, greater than 90% mean inhibition of plasma calocrine activity was observed beginning at 30 minutes. There has been no reports from patients having trouble swallowing the pill, regardless of attack location. In the phase three confident trial, median time to administration was 41 minutes, all primary and secondary endpoints were met and efficacy results were consistent across all various subgroups. Adverse reactions that were more common than placebo, the only one listed was headache at 3.2%. In closing from a survey conducted by the Regulatory Angioedema Association, adult patients on average waited about 3.8 hours to treat their attack. Versus in our confident trial, it was 41 minutes and within our long-term extension trial, patients are now treating their attacks at 10 minutes. They're achieving beginning of symptom relief and under two hours and achieving substantial symptom relief at 2.5 hours. Now that ECTRLY is available and orally administered, patients can adhere to the expert's guidelines that include always carrying their on-demand medication

with them wherever they go, treat all their attacks as early as possible and be able to successfully manage their HAE symptoms.

Nina gave the disease state description for hereditary angioedema.

In June of 2025, the FDA-approved garadacimab GXII, marketed as ANDEMBRY, this is the first monoclonal antibody targeting activated factor 12. It is indicated for prophylaxis to prevent HAE attacks in patients aged 12 years and older. It is available as a 200-milligram solution in a single-dose prefilled autoinjector or syringe and is administered subcutaneously by the patient or caregiver. Indications, limitations, warnings, dosage, and availability were given.

In August of 2025, the FDA-approved donidalorsen marketed as DAWNZERA. It is a pre-calocrine-directed antisense oligonucleotide indicated as prophylaxis to prevent HAE attacks in patients aged 12 years and older. DAWNZERA is available as an 80-milligram solution in a single-dose autoinjector and is administered subcutaneously every four to eight weeks by the patient or caregiver. It is not recommended for patients with moderate to severe hepatic impairment. Indications, limitations, warnings, dosage, and availability were given.

The FDA also expanded the indication for ORLADEYO to include pediatric patients aged two years and older for prophylaxis to prevent HAE attacks. Previously, this therapy was only approved for adults and adolescents 12 years and older, so this expansion now offers a once-daily oral option for younger children. Along with the new indication, the FDA also approved a pellet formulation in multiple strains, 72, 96, 108, and 132 milligram packets, allowing for weight-based dosing.

There was no utilization throughout this class.

Previous motion. Casey Gokey moved the drugs in the class were therapeutic alternatives. Seconded by Anna Breckheisen. The motion passed unanimously.

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

Hemophilia (Red Class)

LISA CARMEN, Genetech, stated, “Just wanted to call a few things out to your attention. So obviously Hemlibra, I wanted to just call out our 10 years of safety and efficacy. We have over 800 patients that have been treated for hemophilia A, patients with inhibitors and without. We have nine phase three trials, mainly four pivotal trials with different diverse populations. One trial I wanted to just point out to you that I think has long been submitted is Haven 7, which is previously untreated infants, which I think is a little bit of a different differentiator. One of the most common adverse reactions with Hemlibra is injection site reactions, headache and arthralgia. And the one thing I wanted to point out

today is within this considered new information submitted. I did do a written submitted information and had about five different more information from last year. And within that was a number of abstracts focused on real-world evidence that's newer and around cost-effectiveness. I'll just mention a couple today because of time. One was around preventing intracranial hemorrhage in infants. It was a cost-effective analysis. And then the second thing I'll mention that we submitted was an abstract poster at AMCP Nexus, which was 472 patients that we looked at impact of real-world healthcare utilization in the U.S. Patients 12 months pre and post looked at really cost utilization hospitals, ER visits, and was able to demonstrate a decreased utilization and cost on Hemlibra that demonstrated more predictable costs on Hemlibra around hospitalizations, ER, factor VIII usage and doctor visits."

ADAM FURMAN, Sanofi, spoke on Fetucerin. He stated, "So unlike traditional factor replacement therapies or rebalancing agents, Fetucerin works through a unique mechanism, the small interfering RNA, which targets antithrombin and antithrombin is a protein that naturally inhibits blood clotting. And so this approach allows thrombin generation to increase with the goal of restoring thrombin generation sufficient to help rebalance homeostasis and potentially prevent bleeding. So Fetucerin is administered subcutaneously and is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and pediatric patients age 12 and over with hemophilia A or hemophilia B with or that factor eight or factor nine inhibitors based on the results of the Atlas Clinical Trial Program. During the Atlas Clinical Trial Program, Fetucerin reduced overall annual bleeding rates by 71% in patients without inhibitors and 73% in patients with inhibitors compared to on-demand treatments. And these outcomes were achieved with as few as six subcutaneous injections per year. And when patients did experience a bleeding event while on Fetucerin prophylaxis, there was less utilization of factor to treat bleeds compared to those treating on-demand therapy. And that's outlined in the prescribing information. QFITLY is monitored with an FDA-cleared antithrombin blood assay, which reliably measures antithrombin levels. And this companion diagnostic test ensures appropriate dosing and monitoring. And the ability to precisely measure antithrombin level allows for personalized treatment approaches and helps prevent potential complications such as thromboembolic events. Detailed safety information, including box warnings of thrombotic events, gallbladder disease, and hepatotoxicity can be found in the prescribing information. So just really quick in conclusion, QFITLY represents a new treatment approach for hemophilia management, offering bleeding protection, simplified administration, reduced treatment burden, and comprehensive safety monitoring. And so we respectfully request that the board consider QFITLY inclusion on the PDL as a treatment option for hemophilia A and B with or without inhibitors. And with that, I'll give back my time and open myself up for questions.

RAHSAAN AGAR, Pfizer, spoke on Hympavzy. He stated, "So Hympavzy is a tissue factor pathway inhibitor antagonist indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients, 12 years of age and older, with either hemophilia A, so congenital factor eight deficiency without factor eight inhibitors, or hemophilia B, congenital factor nine deficiency without factor nine

inhibitors. Hympavzy should be administered subcutaneously beginning with a loading dose of 300 milligrams, which is 250 milligram injections by subcutaneous injection followed by a load of 250 milligrams injections weekly thereafter. Administer Hympavzy by subcutaneous injection once weekly on the same day at any time of day in either the abdomen or thigh. Rotate the injection sites weekly. There is a dose adjustment of 300 milligrams subcutaneously can be done in patients weighing greater than or equal to 50 kilograms when control of bleeding events is judged to be an adequate by a healthcare provider. For common indications, there are none. So under warning and precautions for thromboembolic events, Hympavzy may increase the risk of thromboembolic complications, interrupt Hympavzy prophylaxis if diagnostics findings consistent with thromboembolism occurs. For hypersensitivity reactions, hypersensitivity reactions may occur, so discontinue Hympavzy if a severe hypersensitivity reaction does occur. For embryo fetal toxicity based on Hympavzy's mechanism, Hympavzy may cause fetal harm, so advise females of the potential risk to the fetus and to use effective contraception. The efficacy of Hympavzy was established in 116 adult and pediatric patients aged 12 years of age and older, weighing 35 kilograms or more with severe hemophilia A or B without factor VIII and factor IX inhibitors. For the primary endpoint, efficacy was determined by changes in ABR. So for prophylaxis when compared to on-demand factor-based therapy, for treated bleeds, patients on Hympavzy experienced an ABR of 3.18 treated bleeds per year compared to 38 in the on-demand group, and compared to routine prophylaxis factor treatment with Hympavzy, those participants experienced an ABR of 5.08 treated bleeds compared to 7.85 on prior factor prophylaxis. So to conclude, with over 20 years of experience with hemophilia, we are committed to improving patient outcomes and urge you to add Hympavzy to the PDL. So thank you for your time and attention, and if there's no questions, I'll give you back the time.

Nina gave the disease state description for hemophilia.

The 2020 World Federation of Hemophilia Guidelines remain the most recent comprehensive international treatment guidelines, and the 2022 MASAC recommendations represent the most current U.S. guidance specifically addressing hemophilia prophylaxis.

Since 2022, several new therapies have been FDA approved for hemophilia prophylaxis, including TFPI antagonists such as Hympavzy and Alhemo, siRNA-based therapies such as Qfitlia, and one-time gene therapies such as hemogenic and Roctavian.

In March of 2025, the FDA-approved fitocerin (phonetic) marketed as Qfitlia, the first-in-class antithrombin-directed small interfering RNA for routine prophylaxis to prevent or reduce bleeding episodes in adults and pediatric patients 12 years and older with hemophilia A or B with or without inhibitors. Indications, limitations, warnings, dosage, and availability were given.

The FDA has expanded the indication for JIVI, extending its use to children age 7 to under 12 years with hemophilia A. Previously, it was only approved for patients 12 years

and older. JIVI remains indicated for on-demand treatment and control of bleeding episodes, perioperative management, and routine prophylaxis to reduce bleed frequency. It is not indicated for children under 7 years old due to higher risk of hypersensitivity reaction and potential loss of efficacy. It is also not indicated in previously untreated patients or for treating Von Willebrand disease. For on-demand treatment and perioperative management, dosing in all patients is individualized based on body weight and the desired rise in factor VIII. Indications, limitations, warnings, dosage, and availability were given.

In December of 2025, the FDA expanded the indication for Alhemo to now include routine prophylaxis in adults and pediatric patients 12 years and older with hemophilia A or B without inhibitors. Previously, it was only indicated for patients with inhibitors. Indications, limitations, warnings, dosage, and availability were given.

Disease stated description for Von Wildebrand Factor was given.

In September 2025, the FDA expanded the indication for Von Vendi, allowing much broader use across the Von Willebrand disease population. It is now approved for routine prophylaxis in adults with all types of VWD and for on-demand treatment and perioperative management in children. Previously, prophylaxis was only approved for adults with type III VWD and only in adults for on-demand or perioperative use. Indications, limitations, warnings, dosage, and availability were given.

Utilization was 100 percent in line with PDL.

Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternatives to include one prophylactic medication. Seconded by Dr. Carlson. Motion passed unanimously.

CHARLES RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE PROPHYLACTIC MEDICATION. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

4-B. Cardiovascular: Angiotensin Modulators (Blue); Angiotensin Modulator Combinations (Blue); Antianginal and Anti-ischemic Agents (Green); Anticoagulants (Blue); Colony Stimulating Factors (Red); Erythropoiesis Stimulating Agents (Green); Lipotropics, Other (Red); Platelet Aggregation Inhibitors (Green); Pulmonary Arterial Hypertension (PAH) Agents (Blue)

Angiotensin Modulators (Blue Class)

There was no one present who wished to give testimony.

Nina gave the disease state description for hypertension.

The 2025 ACC AHA hypertension guideline replaces the 2017 version. Blood pressure definitions are unchanged. Stage two hypertension still warrants immediate pharmacologic therapy, and the treatment target remains less than 130 per 80 millimeter of mercury. The less than 130 per 80 goal is positioned as a universal target for nearly all non-pregnant adults, reflecting accumulative evidence that tightened control reduces strokes, heart failure, kidney disease, and cognitive decline. The biggest operational change is the replacement of the ASCVD pooled cohort equation with the prevent risk calculator, which estimate total cardiovascular risk, including heart failure and kidney outcomes, and lowers the high risk threshold to 7.5% or more. As a result, more patients with stage one hypertension, particularly those with diabetes, CKD, established CBD, or elevated prevent risks are now recommended to start medication earlier rather than prolong lifestyle only management. The guideline also promotes early combination therapy, especially fixed dose single pill combination for stage two hypertension.

In March of 2025, the FDA approved ARBLY, a 10 milligram per ml oral solution of Losartan. ARBLY is approved for three key indications. The treatment of hypertension in adults and in children older than six years old, reducing the risk of stroke in patients with hypertension and left ventricular hypertrophy, and the treatment of diabetic nephropathy in adults with type two diabetes, elevated serum creatinine, and proteinuria, who also have a history of hypertension. Indications, limitations, warnings, dosage, and availability were given.

The FDA also approved Vostally, a one milligram per ml oral solution of Ramipril. This is taken once or twice daily. Recommended doses varies by indication and titrated based on clinical response. Indications, limitations, warnings, dosage, and availability were given.

Utilization was 99.5 percent in line with PDL. Nina stated this was so low due to the low claim count.

Previous motion Casey Gokey moved that all three subgroups in the class were therapeutic alternatives, seconded by Dr. Carlson. The motion passed unanimously.

DR. PHILLIPS MOVED THAT ALL THREE SUBGROUPS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.

Angiotensin Modulator Combinations (Blue Class)

There was no one present who wished to give testimony.

The FDA has approved a triple therapy combination containing telmisartan amlodipine and adipamide under the brand name WIDAPLIK. It is indicated for the treatment of hypertension, including an initial treatment to lower blood pressure. WIDAPLIK will be supplied in multiple fixed-dose tablets listed on the slide. Indications, limitations, warnings, dosage, and availability were given.

Utilization was 89.9 percent in line with PDL.

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

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

Antianginal and Anti-ischemic Agents (Green Class)

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

Anticoagulants (Blue Class)

There was no one present who wished to give testimony.

Nina gave the disease state description for venous thromboembolism (VTE).

Apixaban and edoxaban were excluded from the 2024 Pediatric VTE guideline recommendation because phase three trial data for these agents and children remain pending at the time of publication. However, since the publication, apixaban is now FDA approved for pediatric VTE while edoxaban is not yet approved for this population. So as mentioned on the earlier slide, apixaban is now indicated for the treatment of VTE and reduction in the risk of recurrent VTE in pediatric patients from birth and older following at least five days of initial anticoagulant therapy. Indications, limitations, warnings, dosage, and availability were given.

Utilization was 98.7 percent in line with PDL.

Previous motion, Dr. Ryan moved that drugs in the class were therapeutic alternatives to include at least one oral agent, one injectable agent, and one direct oral anticoagulant that can be used for PENVC prophylaxis, and warfarin. Seconded by Anna Brecheisen. The motion passed unanimously.

DR. RYAN MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE ORAL AGENT, ONE INJECTABLE AGENT, ONE DIRECT ORAL ANTICOAGULANT THAT CAN BE USED FOR PENVC PROPHYLAXIS, AND WARFARIN. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Colony Stimulating Factors (Red Class)

There was no one present who wished to give testimony.

Nina gave the disease state description for neutropenia.

The 2025 NCCN guidelines provide updated recommendations on the use of granulocyte CSFs in patients receiving myelosuppressive chemotherapy for solid tumors and lymphoid cancers. The guideline reaffirmed that all current available granulocyte CSFs agents have comparable safety profiles and subcutaneous administration remains the preferred route. The NCCN also notes that there is still insufficient evidence to declare clinical superiority of G-CSFs over GM-CSFs, so agent selection should continue to focus on availability, cost, dosing convenience, and patient factors. One of the most important elements of the update is the risk-stratified approach to febrile neutropenia prophylaxis. For patients receiving chemotherapy with a high risk of febrile neutropenia, defined as 20% or greater, primary prophylaxis with a G-CSF is a Category 1 recommendation. In the intermediate risk range, 10% to 20%, prophylaxis should be considered based on individualized risk factors, such as age 65 years or older, significant comorbidities, organ dysfunction, or a history of prior febrile neutropenia. In low-risk regimens, with a febrile neutropenia risk less than 10%, routine prophylaxis is not recommended. The guideline also reinforced caution when using G-CSFs in the setting of concurrent chemo radiation, as prophylaxis use can amplify toxicity in this case. Finally, regarding therapeutic use for established febrile neutropenia, the NCCN states that there's no new evidence supporting routine G-CSF use, while therapeutic G-CSFs may shorten the duration of neutropenia and the length of hospitalization. There is no proven survival benefit, and they are not recommended as standard therapy. So this slide shows Neulasta and its biosimilars.

Armlupeg was approved in November of 2025 and carries the same two indications as Neulasta, first to reduce the incidence of infection as manifested by febrile neutropenia in patients with non-myeloid malignancy receiving myelosuppressive chemotherapy, and second, to increase survival in patients acutely exposed to myelosuppressive doses of radiation. Indications, limitations, warnings, dosage, and availability were given.

To note, none of the Neulasta biosimilars are currently FDA-designated as interchangeable.

Filkr8i was FDA-approved in January of 2026 and carries all of Neupogen's indication except for HPC mobilization. Indications, limitations, warnings, dosage, and availability were given.

Releuko received two additional indications in April of 2025. HPC mobilization and HSARS, making it approved for all Neupogen indications.

All biosimilars for Neupogen are also not FDA-designated as interchangeable.

In June 2025, Granix, 480-microgram per 1.6 ml injection vial was discontinued. All other dose formulation and strengths remain available.

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

Erythropoiesis Stimulating Agents (Green Class)

Utilization was 70.1 percent in line with PDL. Nina stated this was so low due to the low claim count.

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

ANNA BRECKHEISEN MOVED THAT THE DRUGS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Lipotropics, Other (Red Class)

JEFF BALDWIN, Amgen, spoke on Repatha. He stated, "I'll begin by highlighting that the updated indications for Repatha or Evolocumab now includes adults at increased risk for MACs, including CB death, MI, stroke, unstable angina requiring hospitalization, or coronary revascularization without the prior requirement for established cardiovascular disease. We have also recently reported new CV outcomes data from the Phase 3 Bacillus CV trial of approximately 12,000 patients that showed Repatha as the first and only PCSK9 inhibitor to reduce the risk of MACs in patients at high risk, at high CV risk without a prior MI or stroke. Of note in a pre-specified exploratory subgroup analysis of high-risk patients without known significant atherosclerosis and with diabetes, who comprised 30% of the overall study population, addition of Evolocumab to baseline lipid-lowering therapy resulted in a median LDL-C of 44 mg per deciliter compared to 105 mg per deciliter for placebo. There was a 31% relative risk reduction in both the 3-point and 4-point MACE endpoints and a 32% relative risk reduction in CV death, MI, or ischemic stroke. Reported serious adverse events were comparable between the two groups. The recently updated 2026 AHA-ACC guidelines on the management of dyslipidemia reestablished LDL-C goals and reinforced that earlier, more intensive LDL-C lowering is essential for reducing cardiovascular risk. The guideline recommends LDL-C goals of less than 70 mg per deciliter for primary prevention in high-risk adults and less than 55 mg per deciliter for secondary prevention in patients at very high risk, which is the majority of patients with clinical ASCBD. Additionally, coronary artery calcium or CAC scoring is utilized to help improve assessment and guide treatment decisions in patients with subclinical atherosclerosis. Please consider streamlining the PA criteria to a single high-intensity statin trial. This additional requirement may delay initiation of additional non-statin therapies that may help patients effectively achieve recommended LDL-C goals and reduce risk of a subsequent event. Additionally, given the reduction in MACE events seen in VESALIUS-CV, please consider Repatha to help support intensive LDL-C lowering also in patients at high CV risk without prior MIR stroke aligned with the

prescribing information. Thank you for your time today, and I'm happy to take any questions."

Robert Thompson asked, "If you had 1,000 patients in the Repatha group and another 1,000 in a non-Repatha group, how many would have fatal events in a year in each group? Actual numbers, not relative numbers."

Mr. Baldwin replied, "I don't have those numbers based on the 1,000 population. I can tell you the number needed to treat in the overall study population and then in the subgroup of patients that were diabetic. So for the four-point MACE endpoint, the NNT is 34 in the sub-analysis and 36 in the overall 12,000 patient population. That includes, like I said, the entire study population."

Nina gave the disease state description for dyslipidemia.

Data from the NHANES 2021 to 2023 shows that dyslipidemia remains widespread.

In July of 2025, the FDA updated the indication for LACVIO, allowing it to be used as monotherapy as it no longer requires concurrent statin therapy. The term primary hyperlipidemia also was revised to hypercholesterolemia to accurately reflect that glycerin is specifically targeting LDL reduction. The FDA-approved indication now states as an adjunct to diet and exercise to reduce LDL cholesterol in adults with hypercholesterolemia, including heterozygous FH. Indications, limitations, warnings, dosage, and availability were given.

Praluent expanded its MACE indication to include adults at increased risk of CV events. The FDA also updated the LDL-lowering indication to allow Praluent to be used as monotherapy as an adjunct to diet and exercise to lower LDL across three key groups, adults with hypercholesterolemia, adult with pediatric patients 8 years and older with heterozygous FH, and adults with homozygous FH. For MACE, Praluent does not have an outcomes trial in adults without established CV disease. Indications, limitations, warnings, dosage, and availability were given.

In December of 2025, the FDA-approved lerodalcibep-liga, marketed as Lerochol, is a new PCSK9 inhibitor indicated as an adjunct to diet and exercise to reduce LDL cholesterol in adults with hypercholesterolemia, including those with HEFH. Indications, limitations, warnings, dosage, and availability were given.

The FDA has expanded the indication of AFKESA to include use of pediatric patients 1 years and older as an adjunct to diet and exercise and other LDL-lowering therapies to reduce LDL in patients with homozygous FH. Indications, limitations, warnings, dosage, and availability were given.

In November of 2025, the FDA updated the indication for bempedoic acid related to cardiovascular risk reduction. The label now states that bempedoic acid is approved to reduce the risk of MACE, including cardiovascular death, MI, stroke, or coronary

revascularization. And this is approved in adults at increased risk for these events who are unable to take recommended statin therapy, including those not taking a statin at all. The LDL-lowering indication was also updated and now specifies that bempedoic acid should be used as an adjunct to diet and exercise, rather than diet alone, and that is indicated for adults with hypercholesterolemia, replacing the older terminology of primary hyperlipidemia, and the dosing and safety profile remains unchanged.

In December of 2020, or in February of 2026, the FDA expanded teplizumab-mzwv indication to now include pediatric patients 2 years and older with homozygous F8 as an adjunct to diet and exercise and other LDL-lowering therapies. Previously, it was only approved for adults. A new 2 milligram capsule was also approved to support the pediatric dosing. Indications, limitations, warnings, dosage, and availability were given.

Nina then gave the disease state description for familial chylomicronemia syndrome (FCS).

In 2024, the FDA approved TRYNGOLZA. More recently they have approved Redemplo. It is the first apolipoprotein C3 direct siRNA indicated as an adjunct to diet to reduce triglycerides in adults with FCS. Indications, limitations, warnings, dosage, and availability were given.

Utilization was 68.3 percent in line with PDL which is mainly due to the utilization on the phenol fibrate.

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

Platelet Aggregation Inhibitors (Green Class)

Utilization was 99.7 percent in line with PDL.

Previous motion Dr. Ryan moved that the drugs in the class were therapeutic alternatives to at least include clopidogrel. Seconded by Anna Brecheisen. The motion passed unanimously.

Pulmonary Arterial Hypertension (PAH) Agents (Blue Class)

RICHARD OLIVER, Liquidia Corporation, gave testimony on Yutrepia, a treprostinil inhalation dry powder. He stated, “it's the first and only dry powder formulation of treprostinil that comes that's enabled by our manufacturing process called print technology. This print utilizes advanced techniques that create drug particles with precise shape and size and chemical composition. This uniformity is designed to achieve enhanced deep lung delivery, ease of use with a low effort device that requires a minimal inspiratory effort for patients that is not position dependent and does not require refrigeration. And lastly, and very importantly, allowing specialists to titrate to higher

therapeutical doses. So this approach provides a new therapeutical option for patients with pulmonary hypertension, PAH, and PHILD. Offering potential benefits in terms of efficacy, tolerability, and ease of use.
In our inspired trial, our PH trial, patients that took Yutrepia were either transitioning from nebulized inhaled prostenol or were naive to prosthetic therapies. They were initiated then with Yutrepia. Patients were allowed to be in oral PH background therapy, what most of them were under a ERA and a PDE5. What the most common adverse events reported were cough, which is the main culprit of this continuation traditionally with these type of medications, headache and throat irritation. But in this case, we're all classified as mild to moderate. And very importantly, at a one-year time point, no patients in the transition group and only two patients in the naive group, this continued because of cough, showing the tolerability that Yutrepia offers to these patients. During the exploratory endpoints, 96% of them maintained or were able to improve functional class at two months. And those who transitioned saw an improvement of 19 meters in a six minute walk distance. Quality of life was measured as well in both groups at month two and four. And lastly, at the end of the trial, patients were able to reach doses above 79.5, that the long-term data shows that at one year, most of them were able to keep up titration, which is key to maintain or delay the progression of this disease. Given the payroll safety and tolerability of Yutrepia, along with the potential to titrate, we respectfully ask for consideration Yutrepia to be placed on the preferred drug list, or at least at a parity position, to other products like in products. I thank you for your time."

KIMBERLY SIMPSON, United Therapeutics Corporation gave testimony on Tyvaso DPI. She stated, "In May 2022, the FDA approved to have Tyvaso DPI for the treatment of patients with pulmonary arterial hypertension, or pH, and pulmonary hypertension due to interstitial lung disease or pHILD, to improve exercise ability. Types of Tvesa DPI is a new formulation in an inhalation device for Tyvaso and was the first dry powder inhaler approved by the FDA for use in both pH and pHILD. Tyvaso DPI was evaluated in the BREEZE Study. The primary objective was to evaluate the safety and tolerability of Tyvaso DPI during a three-week treatment phase and 51 pH patients on a stable regimen of types of inhalation solution who are then transitioned to Tyvaso DPI. Patients who transitioned from Tyvaso to Tyvaso DPI demonstrated safety and tolerance. 96% of patients completed the three-week treatment phase while two subjects discontinued due to treatment-related adverse events. Adverse events were consistent with studies of male patients and patients with pH and there were no study drug-related serious adverse events. Significant improvements in secondary study objectives are also observed that week three, including an increase in six minute walk distance of 11.5 meters compared to baseline. Overall patient satisfaction with the Tyvaso DPI inhaler. And improvements in the pH impact patient reported outcomes questionnaire in physical cognitive and emotional impacts. The 49 patients who completed the treatment phase of BREEZE opted to continue in an optional extension phase. Improvements in six minute walk distance compared to baseline were sustained through the data cutoff of up to 51 weeks. Given these findings, we ask that the committee consider making Tyvaso DPI preferred on the Alaska Medicaid PDL."

Nina gave the disease state description for pulmonary hypertension.

In May 2025, the FDA approved Yutrepia, a new dry powder inhalation formulation of treprostinil for the treatment of pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease to improve exercise ability. Indications, limitations, warnings, dosage, and availability were given.

Charcler tablets were discontinued in June of 2025. Generic Placentin remains available.

Utilization was 49.4 percent in line with PDL. Nina stated this was so low due to low claim count.

Previous motion Dr. Ryan moved that the drugs in the class were therapeutic alternatives to include one from each class plus one inhaled product. Seconded by Casey Gokey. The motion passed unanimously.

DR RYAN MOVED THAT THE DRUGS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE FROM EACH CLASS PLUS ONE INHALED PRODUCT. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

4-C. Genitourinary: Benign Prostatic Hypertension (BPH) Agents (Blue); Bladder Relaxant Preparations (Green); Uterine Disorder Treatments (Red)

Benign Prostatic Hypertension (BPH) Agents (Blue Class)

There was no one present who wished to give testimony.

In March 2025, the FDA approved the first generic for Entadfy. And then in April of 2025, the FDA issued a safety communication on compounded topical finasteride. First, there is no FDA approved topical finasteride. All products are compounded and unapproved. Between 2019 and 2024, the FDA received 32 adverse event reports with effects that mirror oral finasteride, including erectile dysfunction, low libido, anxiety, depression, brain fog, and testicular pain. Importantly, some symptoms persist even after discontinuation. The FDA also highlighted risk of transfer to female through skin contact and recommends healthcare providers educate patients on systemic risk and advice consultation before use.

Utilization was 98.1 percent in line with PDL.

Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternatives to include to include one alpha blocker and one androgen hormone inhibitor. Seconded by Casey Gokey. The motion passed unanimously.

DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE ALPHA BLOCKER AND ONE

ANDROGEN HORMONE INHIBITOR. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Bladder Relaxant Preparations (Green Class)

There is one new generic for bladder relaxant preparation. The FDA approved the first generic version of Myrbetriq Granules for oral suspension.

Utilization was 75 percent in line with PDL which is due to the utilization of generic.

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

Uterine Disorder Treatments (Red Class)

There was no one present who wished to give testimony.

Nina gave the disease state description for endometriosis and uterine leiomyomata. For endometriosis ACOG recommends medical suppression with oral contraceptives, progestin, or gonadotropin releasing hormone agonists. After failure of NSAIDs plus oral contraceptives a three-month trial of gonadotropin releasing hormone agonist is advised. For uterine leiomyomata combined oral contraceptives and progestin releasing IUDs help reduce heavy menstrual bleeding while tranexamic acid is a non-hormonal option. The gonadotropin releasing hormone agonist can be used short term to shrink fibroids or improve anemia but is limited by phytoestrogenic side effects.

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

4-D. **Anti-Infective:** Antifungals, Oral (Blue); Antifungals, Topical (Green); Antivirals, Influenza (Blue); Antivirals, General (Green); Hepatitis B Agents (Green); Hepatitis C Agents (Blue); Otic Antibiotics (Green)

Antifungals, Oral (Blue Class)

There was no one present who wished to give testimony.

Nina gave the disease state description for invasive aspergillosis.

According to the 2016 IDSA guidelines, aspergillosis is usually treated with voriconazole, given IV initially, then stepped down to oral therapy once patient is clinically stable. Alternative options for salvage therapy include other triazoles, livid formulation of amphotericin B, or echinocandins, depending on tolerance and resistance.

The FDA expanded Noxafil's indication for treatment of invasive aspergillosis to now include children 2 to less than 13 years old who weigh at least 40 kilograms for the delayed-release tablets, and for patients 2 years and older weighing 10 to 40 kilograms using the Noxafil powder mix delayed-release oral suspension. Previously, this indication was only approved for adults and pediatric patients 13 years and older. Indications, limitations, warnings, dosage, and availability were given.

There were two discontinuations in the past year, VFEN 50-milligram tablets and Sporanox 100-milligram capsules. All other VFEN formulations as well as generic Itraconazole products remain available.

Utilization was 98.8 percent in line with PDL.

Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternatives to include at least one fluconazole tablet, one oral terbinafine preparation, and one pediatric preparation. Seconded by Valerie Bixler. The motion passed unanimously.

DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE FLUCONAZOLE TABLET, ONE ORAL TERBINAFINE PREPARATION, AND ONE PEDIATRIC PREPARATION. SECONDED BY *. THE MOTION PASSED UNANIMOUSLY.

Antifungals, Topical (Green Class)

Utilization was 98.3 percent in line with PDL.

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

Antivirals, Influenza (Blue Class)

There was no one present who wished to give testimony.

Nina gave the disease state description for influenza.

Since 2010, the CDC's ACIP has recommended annual influenza vaccines for everyone aged 6 months and older without contraindications and ideally administered before the season begins. There are four FDA-approved antiviral drugs recommended by the CDC for the treatment of outpatient with suspected or confirmed uncomplicated influenza. These are Tamiflu, Relenza, Xofluza, and Rapivab. Empiric antiviral treatment is recommended as early as possible for any patients with confirmed or suspected influenza who has severe, complicated, or progressive illness, is hospitalized, or is at high risk for influenza complication. In addition, empiric antiviral treatment of non-high-risk outpatients with suspected influenza can be started based on clinical judgment without an office visit.

In June 2025, the FDA approved 30-milligram and 40-milligram packet presentation of Xofluza granules for oral suspension. Each packet is mixed with approximately 15 to 20 mL of water. This is a single-dose treatment recommended to be administered as soon as possible and within 48 hours of symptoms onset for acute uncomplicated influenza or following contact with an individual who has influenza. Indications, limitations, warnings, dosage, and availability were given.

Utilization was 97.1 percent in line with PDL.

Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternatives to include oseltamivir. Seconded by Casey Gokey. The motion passed unanimously.

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

Antivirals, General (Green Class)

Utilization was 87 percent in line with PDL.

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

Hepatitis B Agents (Green Class)

In August 2025, Spotex discontinued Adefovir 10 mg tablets leaving one generic product still on the market.

Utilization was 79.1 percent in line with PDL due to low claim counts.

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

Hepatitis C Agents (Blue Class)

There was no one present who wished to give testimony.

Nina gave the disease state description for Hepatitis C.

The 2023 AASLD IDSA Guidelines for Hepatitis C recommends a simplified treatment approach for most treatment-naive adults with cirrhosis or with compensated cirrhosis. This approach includes pangenotypic direct-acting antiviral regimens, such as a Mavyret or Epclusa, delivered in short course treatment durations.

In June of 2025, the FDA expanded Mavyret's indication to include the treatment of acute hepatitis C in patients 3 years and older. Previously, it was approved for chronic HCV genotype 1 through 6 in patients without cirrhosis or with compensated cirrhosis. With this update, Mavyret now covers both acute and chronic infections across all major patient populations. Dose remains unchanged. Indications, limitations, warnings, dosage, and availability were given.

Zepatier was discontinued in December of 2025.

Utilization was 100 percent in line with PDL.

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

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

Otic Antibiotics (Green Class)

In December 2025, the FDA approved the first generic of Cipro HC Otic Suspension.

Utilization was 98.7 percent in line with PDL.

Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternatives to include at least one otic glucocorticoid combination. Seconded by Dr. Casey Gokey. The motion passed unanimously.

4-E. Green Class Motion

DR. PHILLIPS MOVED THAT THEY APPROVE THE PREVIOUSLY ESTABILSHED MOTIONS. SECONDED BY DR. RYAN. 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 SEPTEMBER 18, 2026.