

**Washington State Pharmacy and Therapeutics Committee
Drug Utilization Review Board
Meeting Transcription
April 15, 2026**

Nonye Connor: Okay, the meeting has started.

Kevin Flynn: Okay.

Nonye Connor: Okay, and then give me a quick second and let me hit record and start recording. Wait -- stop recording. Sorry.

Kevin Flynn: Take your time.

Nonye Connor: Okay, it's recording. It's recording.

Kevin Flynn: Okay. All right. Good morning, everyone. We'll now convene the P&T/DUR Committee meeting. I am Kevin Flynn, the Chair of the P&T/DUR Committee. We have a new member this month, so Dr. Grubbs. And since this is our first meeting with you, I would like everyone to just give a brief introduction to themselves when I call your name. So I'll start just by introducing myself. I'm Kevin Flynn, the Chair of the Committee. And in practice, I practice at the University of Washington Medical Center, where I serve as the Director of Pharmacy Purchasing. I'll start with Dr. Grubbs.

Calvin Grubbs: Hello, I'm Calvin Grubbs. I'm a Family Physician practicing primary care with MultiCare. I'm super excited to be here.

Kevin Flynn: Awesome. Welcome. And then I don't think Matthew is Matthew Guindon is here. So Gregory Hudson.

Greg Hudson: Present. Yeah. So I'm navigating some technical issues. So working on getting my camera. Can you hear me?

Kevin Flynn: Yes.

Greg Hudson: Okay. Thank you. I'll work on getting my camera fixed here.

Kevin Flynn: Oh, just want to give a brief introduction?

- Greg Hudson: Yes, sorry. I'm Greg Hudson, navigating some technical issues this morning. I'm a Psychiatric Nurse Practitioner and DNP. I practice in Tacoma, Washington at Community Healthcare, a federally qualified healthcare center, as a psychiatric consultant in primary care.
- Kevin Flynn: Thank you. And then Matt, I'm sorry, I'm going to go back to you.
- Matt Guindon: Sorry about that. I also was having some challenges this morning. My name is Matt Guindon. I'm a Physician Assistant that works at University of Washington in Inpatient Hem-Onc.
- Kevin Flynn: All right. Bradley Pope.
- Brad Pope: Yeah, hi. I'm a Family Practitioner. I work in Spokane. I practice at the Kaiser Permanente Riverfront Medical Center in Spokane.
- Kevin Flynn: Great. Zoe Taylor.
- Zoe Taylor: Hi. I'm also a Family Doctor and also Addiction Medicine Doctor, and I live in Seattle. And I currently have like a few different like float per diem kind of jobs, but one of the places I work is at Health Point.
- Kevin Flynn: Thank you. Christy Weiland.
- Christy Weiland: Good morning. I'm a Pharmacist -- or I'm Vice Chair here, and then in my practice I am a Pharmacist. But I'm faculty with a family medicine residency with MultiCare, so East Pierce Family Medicine. It's nice to meet you.
- Kevin Flynn: And Laura Beste. You're on mute.
- Laura Beste: Sorry, different button to click for my mute. I'm Laura Beste. I am an Inpatient Pharmacist at Allenmore Hospital in Tacoma, Washington. It's part of MultiCare.
- Kevin Flynn: All right, I think I got everyone who is attending today. If I didn't, please speak up. And so I'm going to go and just call roll call for the Healthcare Authority members. Nonye?
- Nonye Connor: Hi, good morning.

Kevin Flynn: Amy Irwin.

Nonye Connor: She's not here. Right? She's not here today.

Kevin Flynn: Okay, Luke Dearden.

Ryan Pistorosi: Luke's not here today.

Kevin Flynn: Okay, Ryan Pistori.

Ryan Pistorosi: Morning.

Kevin Flynn: Elizabeth Punsulun.

Elizabeth Punsulun: Hi, good morning.

Kevin Flynn: Donna Sullivan.

Donna Sullivan: Hey, good morning.

Kevin Flynn: Ryan Takatomo.

Ryan Taketomo: Morning, I'm here.

Kevin Flynn: Joey Zarte.

Zoey Zarate: Good morning.

Kevin Flynn: And for Labor and Industry, Jamie Mai. Christy Pham. Doug Tuman. Hey.

Nonye Connor: Nothing here.

Kevin Flynn: None here. Okay. All right. For Prime, Nina.

Nina Huyhn: Good morning, here.

Kevin Flynn: All right. And then for our Managed Care Organization representatives, I'm just going to call off the names. Greg Simas, Heidi Goodrich, Petra

Eichelsdoerfer, Omar Daoud, and Jeffrey Natividad. All right, now I'll turn it over to Nonye to go over meeting logistics.

Nonye Connor: Okay. Yeah. Good morning again, everyone. So the committee and presenters can mute and unmute yourselves at any time. Please mute yourself when not speaking to limit background noises. Presenters, please share your webcams while presenting. Committee, please share your webcams during discussions and motion consideration. And for stakeholders participation, the share will read from the list of stakeholders who pre-registered to speak. When you hear your name called, please unmute yourself. Once all pre-registered speakers have been called, the Chair will then ask if there are any additional stakeholders. If there are, please raise your hands. We'll call on you and unmute you. You can also use the Q&A box to ask any questions. We'll address your questions during the stakeholder comments period. If you did not fill out a stakeholder conflict of interest form beforehand, please answer the questions that will be posted on the screen. And then your 3 minutes will start after you've answered those questions. Back to you, Kevin. Thank you.

Kevin Flynn: All right, we're going to start with our first, the Endocrine Metabolic Agents. So, Ryan.

Ryan Pistorosi: I will be sharing my screen in just a second. All right, let me know when you see the Endocrine and Metabolic Agents clinical policy on your screen.

Kevin Flynn: We can see.

Ryan Pistorosi: All right, great. So this is an update to an existing policy. The updates for this policy add in a number of newer products as well as a new ingredient, which is the Zelvysia that will be presented in this policy. and I will go ahead and present the clinical criteria. So as you are familiar with our other clinical policies, the medical necessity criteria is here at the top and explains if there are nonpreferred brand name products, that it does go through the non-clinical policy that is posted online. That's that NC-001. And so if you do have any questions about some of the nonpreferred brand that goes through that clinical policy -- or nonclinical policy, sorry. For this clinical policy, we are down here on this page. And for the clinical criteria, the preferred agents are the sapropterin, whereas the new product is located below with Criteria 4 and 5. And so for this, the clinical policy for the preferred products is largely the same. The diagnosis of PKU, the Phe levels cannot be maintained through dietary intervention alone. And then the documented average baseline Phe --

yeah, Phe is above 340 $\mu\text{mol/L}$ prior to initiating therapy. So this was consistent with the prior clinical policy. For the new criteria, we have that the patient would need to meet the basic diagnostic Criteria in 1-3 but also need to have a trial and failure of the preferred sapropterin products for a 3-month trial. And then if either of these criteria are met, the patient would be authorized for a 6-month period just to make sure that the combined use of the medicine and the dietary interventions can produce the results with the therapeutic Phe levels. So any questions, comments, thoughts on the initial clinical criteria up above? Okay, hearing none, the reauthorization criteria is located in the latter half of the box, and the authorization criteria -- sorry, reauthorization criteria is the same as in the prior clinical policy. So the patient is compliant with the appropriate diet and the Phe levels continue to be in that therapeutic level. And if they are able to demonstrate that, then the patient can continue on a 12-month period. So initially, that 6-month period to make sure that this is the right medication, that it's working, that the diet is still well, and then if they do meet that, then it goes to a 12-month approval. And then the rest of the clinical policy is just information about the different dosages available as well as some background and references. So if there are no questions or comments, I can move into the policy motion.

Kevin Flynn: Do we need to review the PDL first?

Ryan Pistorosi: Good question. I don't know if I actually had this class ready on the PDL. The PDL that I had put together for this DUR meeting was around Nina's. Give me a second and I can try to get this class up. So it will take me a moment.

Kevin Flynn: And while he's doing that, is there any questions about this review or policy? And then, Nonye, is there any stakeholders? Perhaps we can move on to that and then come back to the PDL.

Nonye Connor: Yes, we do. Let me pull a person up. So a pre-registered stakeholder I have is Lauren. And just give me a quick second. Lauren. Oops. Okay. Lauren, Warren, you can unmute yourself. And I'm just going to share my screen for the timer. Just give me a quick second. And then when you're ready, you can start.

Lauren Warren: Hi, I'm Lauren. I'm a Nurse Practitioner and Senior Medical Science Liaison at PTC Therapeutics, supporting Sephience. This was approved in July of 2025 for the treatment of PKU in patients 1 month and older. PKU is an inborn error of metabolism requiring management of phenylalanine (Phe) intake,

dietary protein restrictions to avoid elevated Phe, which is associated with significant neuro-cog, neuro-psych, behavioral, and physical manifestations of PKU. The goal of treatment is to maintain blood Phe levels in target range of less than 360, optimize neurocognitive development, promote normal growth in nutritional status, and support quality of life and psychosocial well-being. PKU was previously treated through the utilization of a Phe-restricted diet and amino acid formula. Updated evidence-based guidelines published by the American College of Medical Genetics now recommend managing PKU with any treatment that facilitates improvement in blood Phe levels, increased dietary Phe tolerance, or improvement in clinical symptoms. Sephience is differentiated through its dual mechanism of action. It has more effective bioavailability, utilizing an alternative biopterin pathway, leading to higher intracellular levels of BH4. Additionally, both BH4 and sepiapterin themselves work as independent pharmacological chaperone, supporting misfolded PAH enzymes. This dual mechanism of action offers a larger and more rapid onset of reductions in blood Phe in participants that were treated with sepiapterin compared to sepiapterin. Over 73% of participants responded to Sephience in a Phase III clinical trial, in which they saw a 63% reduction on average in their Phe levels. This included patients with both severe classical PKU and patients previously non-responsive to sapropterin. After 6 weeks of Sephience, 84% of patients achieved metabolic control and entered an extension study looking at the ability to increase their natural protein intake. 97% of patients with levels below 360 were able to increase their protein intake while maintaining metabolic control on Sephience, with 70% achieving their RDA for protein intake. I emphasize this cohort of patients who achieved significant increases in their dietary Phe tolerance began with levels below 360 and experienced additional benefit from Sephience by maintaining metabolic control while increasing their natural protein intake, showing that a policy restricting patients based on their phenylalanine level denies them the benefit of enhanced nutritional intake and optimized overall health. In a Phase 3 head-to-head trial, Sephience demonstrated statistically significant and meaningful superiority over sapropterin in the amount of PKU patients that were responsive. This study showed a 70% greater reduction in Phe levels when patients took Sephience for sapropterin. In summary, I ask that Washington Medicaid remove Criteria #1 -- or #2 and 3, as it punishes patients who adhere to their restrictive diet and does not allow them an opportunity to optimize their health and nutritional intake. I also ask for removal of Criteria 5, evidenced by Sephience demonstrating a superior treatment efficacy to sepiapterin in a head-to-head clinical trial. Additionally, there is no supporting evidence for a 3-month trial

of sepiapterin. These criteria further delays a patient's access to a more efficacious therapy that may allow them to meet their treatment goals. I thank this committee for working to create a fair prior authorization criteria reflecting the strong efficacy and safety data of Sephience. Thank you, guys. Happy to take questions, too.

Kevin Flynn: All right, thank you. Committee members, is there any questions? Bradley Pope?

Brad Pope: Yeah, I was just wondering, out of curiosity, what does this drug cost a month?

Laura Warren: What does this drug cost a month? It's weight-based dosing. So depending on the patient's weight.

Brad Pope: So per the 70 kg, what would it cost roughly? I just, just some idea.

Laura Warren: I don't know. I'm sorry, I'm on the scientific medical side. I don't know if one of my market access colleagues could be unmuted, but I'm on the science side.

Ryan Pistorosi: All right. And then I can bring up a copy of our Apple Health PDL with this drug class highlighted. And so this is the Apple Health PDL class for PKU Oral Agents. And as you can see, we do have all of the products listed here that were in the policy. These are all covered in the pharmacy and show that they are MCO carve-outs and that the preferred status right now is in, but that's because they're all on prior authorization as you saw in the policy. So I don't know if there was any specific NDCs or any specific ingredients to highlight with this PDL review.

Zoe Taylor: Could you go back to the policy for a second?

Ryan Pistorosi: Give me one second.

Zoe Taylor: Yeah.

Ryan Pistorosi: It should be coming up. Okay, so the policy is up again.

Zoe Taylor: So I think, I imagine that the Sephience is secondary to trying the other one because it's more expensive. But I think the other point that the stakeholder

was making is that perhaps it doesn't make sense for any of them to require a certain level. But I am not an expert enough to decide that, so we would need like a science review, I think, in order to, or some sort of expert in order to know if that's true.

Ryan Pistoresi: Yeah, again, the criteria up above is the same. So really, the only thing that we changed with this policy update was adding the new branded products. And again, as you had alluded to, I believe that there is a cost difference, which is why we are preferring the sepiapterin as a first-line agent before someone may be stepping into it, just in case if someone is able to meet the therapeutic goals with the first product that they don't need to then step I'll step into the second. Okay. If there are no other questions, I will bring up the motion.

Kevin Flynn: Do we have any more stakeholders? Just want to. Make sure before we move on.

Nonye Connor: I do not see any hands raised.

Kevin Flynn: Okay. Thank you.

Nonye Connor: Yeah.

Ryan Pistoresi: All right. And since this is the only clinical policy, this is the proposed motion for the DUR board.

Christy Weiland: [Cross-talk] This is Christy Weiland. I can make the motion. I move that Apple Health Medicaid Program implement the clinical criteria listed on policy 30.90.85-2 as recommended.

Zoe Taylor: This is Zoe Taylor. I can second.

Kevin Flynn: All right. All in favor, say aye.

Multiple Speakers: Aye. Aye. Aye. Aye. Aye.

Kevin Flynn: All opposed. All right. Thank you. Motion passes.

Ryan Pistoresi: Great. Thank you. And I believe we go to Nina next.

Kevin Flynn: Yes, Nina.

Nina Huynh: Thank you. I am sharing my screen. Let me know if you can see it.

Kevin Flynn: We can see.

Nina Huynh: All right. Thank you. Hello, DUR Board. This is Nina Huynh from Prime Therapeutics, and I'll be presenting today's drug class reviews. So for agenda topics, we will be going over the disease states, any new updates from the past year, including guidelines, indication, dosage, and formulations. So in purple on top is the prime therapeutic market basket, and below in blue is the AHPDL drug classes. So first we'll be reviewing Anticonvulsants. So acute repetitive seizures are also known as seizure clusters, and they are episodes where multiple seizures happen over a span of hours or days. What makes them stand out is that they often deviate from a patient's usual seizure pattern. Patients usually recover between episodes, but there's a real concern that these clusters may escalate into status epilepticus. The risk increase when seizures start lasting longer, happen closer together, or when the recovery between them worsens. Early recognition and treatment outside of the hospital setting can help prevent serious complications and reduce the need for emergency care. When it comes to rescue therapy, benzodiazepines are the cornerstone. Diazepam rectal gel as well as midazolam and diazepam nasal sprays, are approved rescue medication for treatment of seizure clusters. So in April of 2025, the FDA expanded the age indication for diazepam nasal spray, known by the brand name Valtoco. It's now approved for use in patients with epilepsy aged 2 years and older, a change from the previous age indication, which was limited to 6 years and older. Valtoco is indicated for the acute treatment of intermittent stereotypic episodes of frequent seizure activity, such as seizure clusters or acute repetitive seizures that are distinct from a patient's usual seizure pattern. For the newly included age group, 2 to 5 years old, the recommended dose is 0.5 mg/kg, administered as one spray into one nostril. If needed, a second dose may be given after at least four hours. No more than two doses should be used for a single episode, and treatment should not exceed one episode every 5 days or 5 episodes per month. Valtoco is available as a nasal spray in strengths of 5 mg, 7.5 mg, or 10 mg. And then the FDA recently approved Subvenite, which is the new oral suspension formulation of lamotrigine, and the strength of 10 mg/mL is indicated for three key uses. First, it can be used as an add-on therapy for epilepsy in patients as young as 2 years old, specifically for partial-onset seizures, primary generalized tonic-clonic seizures, and Lennox-Gastaut syndrome. Second, it's approved as

monotherapy for patients 6 years and older who have partial-onset seizures and have previously been on certain antileptic medication. And third is for maintenance treatment of bipolar I disorder in adults, specifically to help delay future mood episodes after the patient has been treated for acute mood episodes with standard therapy. Subvenite is not recommended for acute manic or mixed episodes, and its effectiveness in treating acute mood episodes have not been established. Dosing is dependent on concomitant medications, indication, and patient's age. Like other forms of lamotrigine, Subvenite carries a Boxed Warning for serious skin rash, so it's critical not to exceed the recommended initial or escalation doses. If therapy was stopped due to a rash, it should not be restarted unless the potential benefits clearly outweigh the risk. Dose adjustments are needed when starting or stopping estrogen-containing products. And if discontinuation is necessary, it should be tapered over at least 2 weeks. And then last year, Qudexy XR and Carbatrol tablets were discontinued. The generic version for both products remained available. And then in addition, the first generic of Fycompa was approved in July 2025, and the first generic of Briviact oral solution received approval in February of 2026. And this concludes the anticonvulsants section. I'm happy to take any questions.

- Kevin Flynn: All right, Committee members, are there any questions? Okay, there's none. Do we want to review the PDL?
- Ryan Pistorosi: All right, the PDL should be up. And as I had presented at the February meeting, each of these is kind of grouped into their individual drug subclasses and so you can see -- can zoom in just a little bit so you can see here on your screen each of the different drugs and whether they are preferred or nonpreferred with the colors in Column G. And we can scroll down whenever you're ready. So the Miscellaneous one is a bit long.
- Kevin Flynn: All right, committee members, any questions? All right, hearing none, can we bring up the motion?
- Nonye Connor: We do have a pre-registered stakeholder, Amanda.
- Kevin Flynn: Oh, sorry. Thank you for reminding me.
- Nonye Connor: Oh, no problem. You can unmute yourself whenever you're ready.[Cross-talk] Oh, just give me a quick second.

- Amanda Rendell: [Cross-talk] Hi. Thank you for your [cross-talk] -- oh, yeah.
- Nonye Connor: Okay. Let me know when you're ready. I can start the timer.
- Amanda Rendell: Yep, I'm ready. Thank you.
- Nonye Connor: Okay, yeah.
- Amanda Rendell: So I'll be brief. Hi, thank you for your time. My name is Amanda Rendell, and I'm a Senior Medical Science Liaison in the Department of Clinical Development and Medical Affairs at Norelis. I just wanted to -- just one quick correction of the dosing for Valtoco. Valtoco is the only intranasal rescue medication that allows for customized dosing based on age and weight, with 5 mg, 10 mg, 15 mg, and 20 mg doses available as optimal dose may be administered to pediatric and adult patients alike. As Nina mentioned, it's now approved for 2 years of age and older. But with that, I would like to thank you for your recommendation to maintain Valtoco go in a preferred position. And I'll give back my time to the Committee but will remain on the line to answer any questions you may have. Thank you.
- Kevin Flynn: All right. Committee members, any questions for the stakeholder? Okay. Hearing none, can we pull up the motion?
- Ryan Pistorosi: All right, it should be up now. So again, this is the Anticonvulsants class, and these were the five subclasses that were reviewed with the presentation. And the motion is now on your screen.
- Brad Pope: This is Brad Pope. I'll make the motion. I move that all products in the drug classes listed on Slide 2 are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in these classes may require prior authorization to determine medical necessity. All nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.
- Laura Beste: This is Laura Beste. I second the motion.
- Kevin Flynn: All right. All in favor, say aye.

Multiple Speakers: Aye. Aye. Aye. Aye. Aye.

Kevin Flynn: Any opposed? All right, motion carries. Antidementia Agents. Nina.

Nina Huynh: Okay. So next is Antidementia Agents. So Alzheimer's disease is a progressive neurodegenerative disorder. And what really defines it is the cognitive decline that starts to interfere with daily living. It's not just memory loss. It often comes with behavioral changes that really can be challenging for both patients and caregivers. Over time, we see a gradual loss of cognitive, analytical, and even physical functioning. There are 10 key Warning signs we look for. Things like memory loss that disrupt daily life, difficulty planning or solving problems, trouble completing familiar tasks, confusion with time or place, visual or spatial perception issues, new language difficulties, misplacing items, and inability to retrace steps, poor judgment, withdrawal from social or work activities, and mood or personality changes. The disease typically progresses through three key stages, early, middle, and late, and each stage is defined by how severe the symptoms are, how quickly they're progressing, and how much support the person needs with daily activities. In May of 2025, the Lumipulse G pTau217/beta-amyloid ratio test was cleared to help detect amyloid plaques in adults 55 years and older who show Alzheimer's type symptoms. And then in October of 2025, the Elecsys pTau181 blood test was cleared for use in primary care to evaluate cognitive decline in adults 55 years and older. It measures pTau181 and helps identify patients with early cognitive issues who may not yet show amyloid pathology. And here we have Leqembi, which had multiple updates in the past year. In January, the FDA approved an every 4-week IV maintenance dose. Then in August, the agency updated the MRI monitoring schedule and introduced a new subcutaneous formulation as a 360 mg/1.8 mL single-dose prefilled iQlik autoinjector. For the MRI schedule update, an additional MRI scan before the third infusion was added. This is to detect ARIA earlier and to help reduce the risk of serious complications. The starting dose remains the same. Patient starts with 10 mg/kg IV infusion over one hour once every 2 weeks for 18 months. After that, they can transition to one of three maintenance doses: so continue every 2-week IV dosing, switch to the every 4-week IV dosing, which again was approved in January, or move to the new subcutaneous option, which is the 360 mg once weekly using the iQlik autoinjector. And this concludes the Antidementia medications. I'm happy to take any questions.

Kevin Flynn: Committee members, any questions? All right, Ryan.

Ryan Pistorosi: All right, the PDL should be up on your screen showing the status for the two subclasses.

Kevin Flynn: So Ryan, if I'm reading this right, the autoinjector is now preferred with no PA criteria?

Ryan Pistorosi: Um, let's see the autoinjector. It looks like it's PA with -- it does have PA criteria here in Column H.

Kevin Flynn: Okay.

Ryan Pistorosi: Yep, PA. So yeah, it does have a prior authorization.

Kevin Flynn: Okay. And I would imagine that if, because all these patients would be transitioning from the IV, that the criteria would mostly be centered upon the fact that they got the IV, like, per the indications.

Ryan Pistorosi: Likely, yes, but I would have to double check and make sure that is correct. I have not looked at the PA criteria here.

Donna Sullivan: We don't have a specific policy for this class. This is Donna.

Kevin Flynn: Okay. It's just because a lot of these patients, I mean, before it's all on their medical side, but then, I mean, many would like to transition to getting it at home with the autoinjector just because [cross-talk] it's obviously way easier.

Donna Sullivan: It would be PA to label, so whatever it says in the label.

Kevin Flynn: Okay, perfect.

Donna Sullivan: And a lot of these, it does, you know, recommend or require that the first initial dose is provided in a, you know, professional setting.

Kevin Flynn: Understood. Committee members, any questions? All right, do we have any stakeholders?

Nonye Connor: We did have a pre-registered stakeholder, but I do not see that a person is in the meeting. So if there were any other stakeholders, please go ahead and raise your hands, and I can unmute you. Okay, so just give me -- Sam. Okay, Sam, I do not see that you pre-registered. Just give me a quick second. Let me share my screen. And if you can do me a favor and answer the question on the screen and then I can start your timer after that.

Greg Hudson: I think Sam's still muted, Nonye.

Sam Elsoki: Yeah. Can you hear me now?

Nonye Connor: Yes.

Sam Elsoki: Yeah, perfectly like. My name is Sam Elsoki, and yes, I'm speaking on behalf like [indistinct] Company. I'm not a provider in Washington, and I'm not a representing patient, and I don't have, like, any conflict of interest.

Nonye Connor: Okay.

Sam Elsoki: Okay. So just like, I just want to share, like, sorry. Greg, he wasn't available today. You know? But like, since all the major update have been already covered -- so we don't feel like a speaking session is necessary from our side. So I just want to give -- provide the time back to you guys.

Nonye Connor: Thank you.

Kevin Flynn: Thank you. Committee members, any questions for the stakeholder? All right, hearing none. Are there any other stakeholders?

Nonye Connor: No. No other hand raised.

Kevin Flynn: Okay. Can we pull up the motion?

Ryan Pistoresi: All right. The motion should be up. So these are the two subclasses that were presented and the motion is now before you.

Zoe Taylor: I can read the motion. This is Zoe Taylor. I move that all products in the drug classes listed on Slide 4 are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in these classes may

require prior authorization to determine medical necessity. All nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Greg Hudson: This is Greg Hudson. I second.

Kevin Flynn: All right. All in favor, say aye.

Multiple Speakers: Aye. Aye. Aye. Aye. Aye.

Kevin Flynn: All right. Any opposed? All right. Motion carries. Nina?

Nina Huynh: Next, we have Asthma and COPD Agents : Monoclonal Antibodies. So COPD is a complex and heterogeneous lung condition characterized by chronic respiratory symptoms such as dyspnea, cough, sputum production, and recurrent exacerbations. These symptoms result from persistent airway obstruction caused by structural changes in the airways and alveoli. COPD affects approximately 16 million people in the United States and remains one of the leading causes of death worldwide. The U.S. Prevention Service Task Force still recommends against routine screening in asymptomatic adults. And there are two main forms of COPD, chronic bronchitis marked by a long-lasting cough with mucus production, seen in about 3% to 7% of healthy adults and up to 74% of those with COPD. Pulmonary emphysema is characterized by progressive destruction of alveoli, leading to impaired breathing and reduced gas exchange. So GOLD 2026 maintains the definition of COPD as a post-bronchodilator FEV1 to FVC ratio of less than 0.7. It defines an exacerbation as worsening of shortness of breath, cough, or sputum within 14 days, often accompanied by rapid breathing, increased heart rate, and systemic inflammation, and that's typically triggered by infection or environmental pollutants. The classification now considers any patients with no exacerbations as group A or B, while those with one or more fall into group E. Treatment escalation moves from single bronchodilator to LABA/LAMA combination then triple therapy with inhaled corticosteroids. For ongoing exacerbations despite triple therapy, options include azithromycin for non-smokers, roflumilast for FEV1 less than 50% with chronic bronchitis and previous hospitalizations, and biologics like dupilumab or mepolizumab in cases with eosinophils 300 or higher. Inhaled corticosteroids should generally be maintained in high-eosinophil patients unless there's no benefit or Serious Adverse Reactions. So in May of 2025, the

FDA approved a new indication for mepolizumab, marketed as Nucala, as an add-on maintenance therapy for adults with inadequately controlled COPD with an eosinophilic phenotype. Nucala is not indicated for relief of acute bronchospasm or status asthmaticus. The recommended COPD dose is 100 mg subcutaneously every 4 weeks. The next disease state is chronic rhinosinusitis with nasal polyps, referred to as CRSwNP. This is a chronic inflammatory condition of the sinuses that significantly impacts quality of life. It affects approximately 1% to 2.6% of the population, and it's characterized by symptoms such as nasal polyps, nasal blockage, rhinorrhea or postnasal drip, facial pain or pressure, and loss of smell. The current standard of care begins with nasal saline irrigation combined with intranasal corticosteroids. Oral corticosteroids may also provide short-term relief but should not be used due to systemic side effects. Antibiotics are reserved for infectious exacerbation and have no proven effect on reducing polyp size. And then patient with Type 2 CRSwNP symptoms often are severe and recurrent, and standard therapy is frequently insufficient, leading to repeated surgeries and systemic steroid exposure. For these uncontrolled cases, biologic therapies such as dupilumab, mepolizumab, omalizumab, and tezepelumab offer targeted treatment options by addressing the underlying Type 2 inflammation. And then in October 2025, the FDA approved a new indication for Tezspire for add-on maintenance treatment of adults and pediatric patients 12 years and older with inadequately controlled CRSwNP. The recommended dose is 210 mg subcutaneously every 4 weeks. Okay, the next disease is Asthma, which remains a significant public concern in the United States. There are approximately 1 million emergency department visits related to asthma each year. Currently, an estimated 8.9% of adults and 6.7% of children are affected. Asthma is typically characterized by chronic airway inflammation and hyperresponsiveness. And diagnosis is based on a history of respiratory symptoms such as wheezing, shortness of breath, and cough, along with evidence of variable expiratory airflow limitation. So the 2025 GINA Guidelines for asthma continues to recommend the 2-track treatment approach. Track 1, which is the preferred route, and then Track 2 are other controller options. The main update from the 2024 guideline is seen on the right chart on Track 2, step 4, for patients aged 12 years and older. Previously, this step allowed medium to high doses of ICS/LABA combination, but now it specifies medium-dose ICS/LABA only. This change reflects GINA's ongoing emphasis on minimizing the risk associated with high-risk, high-dose inhaled corticosteroids. Within the current GINA guidelines, for severe Type 2 eosinophilic asthma, recommended biologic options include anti-IL5, anti-IL5 receptors, anti-IL4/alpha, and anti-TSLP.

therapies. So at this time, Exdensusur is not yet included in the GINA biologic framework. However, it recently received FDA approval in December of 2025 as an IL-5 antagonist for add-on maintenance treatment of severe asthma with eosinophilic phenotypes in patient 12 years and older. Exdensusur is not intended for acute bronchospasm or status asthmaticus. The recommended dose is 100 mg subcutaneously once every 6 months, administered by a healthcare provider in the upper arm, thigh, or abdomen. Key Precautions include the risk of hypersensitivity reactions, including anaphylaxis. So treatment should be stopped and managed immediately if that occurs. Patients should not abruptly discontinue corticosteroids. Any taper should be gradual. And because IL-5 therapies can affect parasite immunity, helminth infection should be treated before starting with discontinuation recommended if an infection develops and doesn't respond to therapy. Exdensusur comes as a 100 mg/mL single dose prefill pen or a single dose prefill syringe with a needle guard. And that concludes the Asthma and COPD : Monoclonal Antibodies. I'm happy to take any questions.

- Kevin Flynn: All right, Committee members, are there any questions? I'm going to look at the PDL.
- Ryan Pistorosi: All right. So the PDL for the asthma COPD Monoclonal Antibodies is up.
- Kevin Flynn: All right. Committee members, any questions? All right. Are there any stakeholders?
- Nonye Connor: Yes, I have Lisa Wilshaw.
- Lisa Wilshaw: Hello.
- Nonye Connor: Hi.
- Lisa Wilshaw: Hi. Thank you all.
- Nonye Connor: Let me know when you're ready.
- Lisa Wilshaw: I'm ready. So my name is Lisa Wilshaw. I'm a PharmD and Clinical Account Director at AstraZeneca. I just want to thank you for the opportunity to briefly present information on Fasenra benralizumab injection. Nina nicely went over this product and other products and the way that they are used. Fasenra is also indicated for EGPA or eosinophilic granulomatosis with

polyangiitis, which is a rare disease, but the dosing for this is the same 30 mg injection that is used for adult asthma, but it's every 4 weeks. So please refer to the Fasenra Prescribing Information for complete product information and Warning and Precautions. And I'll give most of my time back and just answer any questions. But in closing, AstraZeneca appreciates the Board continuing to have Fasenra listed as a preferred product on the PDL for Washington State Medicaid patients. So thank you.

Kevin Flynn: All right. Committee members, any questions for the stakeholder?

Lisa Wilshaw: Thank you.

Kevin Flynn: Okay. Is there any other stakeholders?

Nonye Connor: No, I do not see any other hand raised. Oh, wait, hold on.

Kevin Flynn: Looks like we got one.

Nonye Connor: Mm-hmm.

Shannon DiBartolo: Hi there. Thank you.

Nonye Connor: Yeah, no problem. If you just want to quickly answer the question on screen and let me know when you're ready, I can start the timer.

Shannon DiBartolo: Absolutely. My name is Shannon DiBartolo. I am speaking on behalf of Amgen today. I am a Washington State Licensed Pharmacist. And by means of conflicts of interest, yes, I'm an employee of Amgen.

Nonye Connor: Okay.

Shannon DiBartolo: All right, and I'll go ahead and I'll begin. So thank you so much. My name is Shannon DiBartolo. I'm a Medical Value and Access Liaison with Amgen's Medical Affairs. Thank you for this opportunity to provide testimony and respectfully request that Tezspire be added to the preferred drug list for the State of Washington with coverage aligned with its label. Tezspire is indicated as an add-on maintenance treatment for patients 12 and older with severe asthma and also an add-on maintenance treatment for adult and pediatric patients ages 12 and older with inadequately controlled chronic rhinosinusitis with nasal polyps. The efficacy of Tezspire and severe

uncontrolled asthma was studied in the PATHWAY and NAVIGATOR trials. The clinical program encompassed a broad, all-comer population in the multicenter, randomized, double-blind, placebo-controlled, 52-week studies. Overall, patients treated with Tezspire saw significant improvement in asthma exacerbation, lung function, asthma symptom control, and health-related quality of life. Reductions in annualized asthma exacerbation rates, while descriptive in nature, were observed across all biomarker levels and clinically relevant subgroups, including those with blood eosinophil levels and allergic status. In patients with CRSwNP, the efficacy of Tezspire was established by the WAYPOINT study. WAYPOINT was a multi-center, parallel group, double-blind, randomized, placebo-controlled 52-week trial in patients 18 and older who were on standard-of-care treatment with severe uncontrolled CRSwNP. The study results that treatment with Tezspire significantly reduced nasal polyp size, congestion, severity, and the need for systemic corticosteroids, and nasal polyp surgery and resulted in improved loss of smell versus placebo. Tezspire has an established safety profile. The most common reactions in severe asthma are pharyngitis, arthralgia, and back pain. And in CRSwNP patients, the most common Adverse Reactions are nasopharyngitis, upper respiratory tract infection, epistaxis, pharyngitis, back pain, influenza, injection site reaction, and arthralgia. With Tezspire's proven safety and efficacy profile, I respectfully request the Committee to add Tezspire with coverage aligned to its label on the state PDL. Thank you very much for your time, and I'll take any questions.

Kevin Flynn: All right, Committee members, is there any questions? All right, hearing none. There's no other stakeholders. Can we see the motion?

Ryan Pistorosi: All right. So the Asthma and COPD Agents, we just reviewed the monoclonal antibodies today. And so the motion is just for that one subclass.

Greg Hudson: And this is Greg Hudson. I can do the motion. I move that all products in the drug classes listed on Slide 6 are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of the HCA. Products in these classes may require prior authorization to determine medical necessity. All nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug class will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Brad Pope: This is Brad Pope. I'll second it.

Kevin Flynn: All right. All in favor, say aye.

Multiple Speakers: Aye. Aye. Aye. Aye. Aye.

Kevin Flynn: Any opposed? All right. Motion carries. We are a little ahead of schedule, so I think we should just move on to Atopic Dermatitis and then do our break after this one.

Nina Huynh: Okay. Atopic Dermatitis and Cytokine and CAM are combined. Just want to give that FYI, so it's going to be a large class. So again, it's going to cover Atopic Dermatitis therapies along with Cytokine and CAM Antagonists. Given the size of this category, the updates are grouped by indications instead of chronological order. So atopic dermatitis, commonly referred to as eczema, is a chronic, non-contagious, inflammatory skin disease caused by a combination of genetic and environmental factors. Approximately 70% of patients have a positive family history of atopic condition, such as asthma or allergic rhinitis. Atopic dermatitis affects an estimated 10% to 13% of children and about 7% of adults in the United States. And all those symptoms can develop at any age, roughly 60% of patients present within the first year of life and up to 90% before the age of five. The condition is characterized by extremely dry, itchy skin, most often on the inside of the elbows, behind the knees, on the face, hands, and feet. Persistent itching often triggers scratching, which further aggravates irritation and inflammation. As the epidermal layer loses moisture, the skin becomes increasingly dry and cracked, making it vulnerable to weeping, crusting, and scaling. This breakdown of the protective barrier not only worsens symptoms but also significantly raises the risk of secondary infections. Atopic dermatitis follows a chronic course with periods of remission and flare-ups, often triggered by irritants such as detergents, fumes, tobacco smoke, and alcohol-based skin products, as well as allergens like dust mites, pollen, and animal dander. Patients with asthma or food allergies tend to have more severe atopic dermatitis and the condition is associated with allergic rhinitis, anxiety, and depression. So the 2025 AAP Guidelines on Atopic Dermatitis For Pediatrics introduce updates regarding emerging systemic therapies and proactive treatment strategies to reduce flare frequency and improve quality of life, while maintaining core recommendations on skin care and topical treatments. Biologics such as dupilumab and tralokinumab is highlighted as an approved option for moderate-to-severe atopic dermatitis. JAK inhibitors are recognized as emerging treatment, with several newer topical and oral

options for refractory cases. The American Academy of Dermatology released a focus update to its adult atopic dermatitis guidelines. This update introduced strong recommendations for fully newly approved products from 2024. For adults with mild-to-moderate AD, the AAD now recommends roflumilast 0.15% cream. For those with moderate-to-severe disease, the recommended options include tapinarof 1% cream as well as the injectable biologics lebrikizumab and nemolizumab. Chronic hand eczema, or CHE, refers to eczema lesions on the hands and wrists, often accompanied by pain and itching. Beyond the physical discomfort, CHE carries a significant socioeconomic burden and is strongly associated with depression and anxiety. The condition includes several subtypes: atopic hand eczema, irritant contact dermatitis, allergic contact dermatitis, and protein contact dermatitis. Key risk factors include cirrhosis, a history of atopy, and occupational exposure such as hairdressing, healthcare, and metalwork. Management begins with skin protection and strict avoidance of irritants and allergens. Emollients are essential to restore the skin barrier and reduce dryness and pruritus. For acute flares, topical corticosteroids remain the cornerstone, though, prolonged use can lead to skin atrophy and irritation. Topical calcineurin inhibitors offer a steroid-sparing alternative, though they may cause burning or stinging. And in severe or refractory cases, systemic options include oral retinoids and immunosuppressants such as cyclosporine or methotrexate. The only FDA-approved medication specifically indicated for CHE is Anzupgo, a nonsteroidal JAK inhibitor which we will be reviewing on the next slide. So here is delgocitinib cream, marketed as Anzupgo. It is the first and only topical JAK inhibitor for the treatment of moderate-to-severe chronic hand eczema in adults who have had an inadequate response to or from whom topical corticosteroids are not advisable. Used in combination with other JAK inhibitors or potent immunosuppressants is not recommended. Anzupgo is available as a 2% cream and should be applied as a thin layer twice daily to affected areas on the hands and wrist only. And it should not exceed 30 grams per 2 weeks or 60 grams per month. Precautions include an increased risk of serious bacterial, viral, and fungal infections, so avoid use in patients with active infection and discontinue if one develops. There is also a risk of non-melanoma skin cancer, therefore periodic skin exams are recommended. Live vaccines should be avoided before, during, and shortly after treatment. In September of 2025, the FDA expanded the age indication for Opzelura, the topical JAK inhibitor, to include children as young as 2 years old for the short-term and noncontinuous chronic treatment of mild-to-moderate atopic dermatitis and non-immunocompromised patients whose disease isn't adequately controlled with topical prescription therapies

or when those therapies are not appropriate. Previously, Opzelura was limited to patients 12 years and older. The dosing remains the same. Apply a thin layer twice daily to affected areas up to 20% BSA, with a maximum recommended amount of 60 grams every 2 weeks for patients 2 to 11 years old. Okay. And then in March of 2025, Elidel 1% cream was discontinued. The generic remains available. The next disease state is chronic urticaria, which is defined as episodic or daily hives lasting for 6 weeks or more that impairs quality of life. Angioedema may occur separately or simultaneously. It affects about 0.5% to 5% of the general U.S. population, and the main subtypes are chronic spontaneous urticaria, or CSU, also referred to as chronic idiopathic urticaria and inducible physical urticaria. Chronic urticaria has a mixed inflammatory profile associated with infiltration of MAST cells, eosinophils, basophils, and cytokines. Treatment follows a step-by-step approach based on severity and prior response. First-line therapy is monotherapy with second-generation antihistamines and trigger avoidance. If symptoms persist, the dose can be increased or combined with other agents like antihistamines, H2 antagonists, or leukotriene receptor antagonists. For uncontrolled cases, stronger antihistamines such as hydroxyzine or doxepin can be used. And in refractory disease, biologics like omalizumab or immunosuppressants such as cyclosporine are considered. Other anti-inflammatory immunosuppressants or biologic agents may be considered. However, they do have a lower level of supporting evidence. The next disease state is bullous pemphigoid, which is a rare autoimmune blistering disorder in which the immune system attacks the fibers that connect the layers of the skin. This leads to formation of large, intense blisters, most commonly on the arms, legs, and torso. The condition is chronic, often lasting from months to years, and is not considered contagious. Bullous pemphigoid typically occurs in adults over the age of 60, and risk factors include older age, neurologic diseases, and certain medications, such as those used for diabetes and cancer. Treatment aims to relieve itching, reduce blister formation, and achieve remission. And high-potency topical corticosteroids are the first-line therapy, while systemic corticosteroids are reserved for widespread disease. For refractory cases or patients who cannot tolerate steroids, biologics such as dupilumab, omalizumab, and rituximab are options. Okay, and then allergic fungal rhinosinusitis or AFRS, is a unique subtype of chronic sinus disease that makes up about 5% to 10% of all chronic rhinosinitis. It is driven by an allergic response to non-invasive fungi and poorly draining sinuses, leading to accumulation of thick eosinophilic mucin without tissue invasion. Clinically, patients present much like those with chronic sinusitis and nasal polyps, such as nasal obstruction, mucopurulent drainage, facial pressure,

and reduced smell, with occasional proptosis or facial changes in more advanced disease. Diagnosis is often confirmed during endoscopic sinus surgery, which is the cornerstone of treatment. Surgery allows for removal of allergic mucin and polyps and improve access for post-operative medical therapy. Following surgery, systemic steroids for several weeks and long-term topical steroids are essential to reduce recurrence, which is otherwise common. And for patients with persistent or refractory nasal polyposis, dupilumab offers an additional therapeutic option. So Dupixent received three new indications in the past year. In April of 2025, it was approved for the treatment of patients 12 years and older with CSU, who remain symptomatic despite H1 antihistamines. It is not indicated for other forms of urticaria. In June of 2025, Dupixent was approved for adults with bolus pemphigoid in combination with the tapering course of oral corticosteroids. And then in February of 2026, it was approved for AFRS in patients 6 years and older with a history of sinus nasal surgery. The recommended dose for CSU in adults and adolescents weighing 60 kg or more is 600 mg loading dose, followed by a 300 mg every 2 weeks. For those weighing between 30 and 60 kg, the loading dose is 400 mg, followed by 200 mg every 2 weeks. For bolus pemphigoid, the approved dose is 600 mg initially, then 300 mg every other week. And for AFRS, adults receive 300 mg every 2 weeks, while pediatric dosing is weight-based, 300 mg every 2 weeks for those 60 kg or more, 200 mg every 2 weeks for those between 30 kg and 60 kg, and 300 mg every 4 weeks for children weighing between 15 kg and 30 kg. Okay, next is psoriasis, which is a chronic immune-mediated disease that affects approximately 3.2% of the U.S. population. Typical lesions are well-demarcated red plaque with a silvery scale, commonly found on the scalp, elbows, knees, and pre-sacral region. Severity is often assessed by body surface area involvement. Mild disease affects less than 3%. Moderate disease affects 3% to 10%, and severe disease involves more than 10% or includes critical areas such as the face, hands, feet, scalp, or genitals, or causes major emotional impact. Treatment for psoriasis typically begins with topical therapies, such as corticosteroids or emollients, with steroid-sparing options used as maintenance and long-term control. Next, is psoriatic arthritis, which is a chronic inflammatory musculoskeletal disease associated with psoriasis. It commonly presents with peripheral arthritis, dactylitis, enthesitis, and spondylitis, and nail involvement such as pitting and onycholysis. The incidence is approximately 6 per 100,000 per year, and prevalence is 1-2 per 1000, affecting men and women equally. Peripheral arthritis patterns include asymmetric oligoarthritis involving four or fewer joints, symmetric polyarthritis involving five or more joints, and distal

interphalangeal joint involvement, which can sometimes occur exclusively. Axial disease is present in up to 40% of cases, usually alongside peripheral arthritis. And the 2018 ACR and National Psoriasis Foundation Guidelines remains the most current official U.S. guidelines for psoriatic arthritis. Okay, next is inflammatory bowel disease, which is a group of chronic autoimmune conditions that causes inflammation of the GI tract. The two main types are ulcerative colitis and Crohn's disease. Ulcerative colitis is the most common, affecting the inner lining of the colon and rectum and leading to continuous mucosal damage. Patients often experience blood or mucus in the stool and an urgent need to empty their bowels. Severe complications can include dehydration, rectal bleeding, perforated colon, and toxic megacolon. Crohn's disease, on the other hand, can affect any part of the GI tract, from the mouth to the anus. It inflames areas of the intestinal walls, causing patches of damage that can reach the outer lining. People with this disease may experience mouth sores, non-bloody diarrhea, or malnutrition, and serious complications include abscesses, fistulas, and intestinal strictures or obstructions. The 2024 AGA Guidelines is the current standard for outpatient management of moderate-to-severe ulcerative colitis, emphasizing the early use of advanced therapies and immunomodulators through a tiered efficacy-based framework rather than the traditional step-up approach after 5-aminosalicylates failure. It supports TNF-immunomodulator combination therapy, remains neutral on combining non-TNF biologics, advises against withdrawing TNF therapy and steroid-free remission, and recommends discontinuing 5-immunosalicylate once patients escalate to advanced therapies. Similarly, the newly diagnosed 2025 AGA Living Guidelines for moderate-to-severe active Crohn's disease emphasize early initiation of advanced therapies rather than the traditional step-up approach, underscoring the need for rapid disease control. For first-line advanced therapy, it now recommends a broader set of high-efficacy agents, including infliximab, adalimumab, ustekinumab, risankizumab, mirikizumab, guselkumab, or upadacitinib over no treatment. For patients who are biologic-naïve and patients previously exposed to advanced therapies, the guidelines favor high or intermediate efficacy options over lower-efficacy choices. The guideline also reinforced combination therapy, where appropriate, suggesting infliximab with thiopurines over monotherapy. It also updates positions on immunomodulators, advising against thiopurine monotherapy for induction of remission while supporting its use for maintaining steroid-induced remission and recommended subcutaneous but not oral methotrexate for both induction and maintenance. When reviewing pregnancy management and IBD, a global panel of 39 IBD experts, along with

seven patient advocates from six continents, evaluated the available evidence to address the gaps in pregnancy data and variation we see in clinical practice. So the recommendations are straightforward. For the mother, biologics and thiopurines should be continued throughout both pregnancy and lactation, while small-molecule therapies, including corticosteroids, should be avoided during this period. They also advise starting low-dose aspirin between 12 and 16 weeks of gestation to help reduce the risk of preterm preeclampsia. For infants born to mothers with IBD, the guidance is to give all inactive vaccines on schedule, regardless of the mother's treatment. And then live vaccine should also be given on schedule with one exception. BCG should be delayed until after 6 months of age and infants who were exposed to biologics in utero. This slide shows Stelara and its approved biosimilars. So the reference product is highlighted in dark purple and the biosimilars are listed below that. Most Stelara biosimilars have received FDA approval within the past 2 years, with Starjemza being the most recent in May of 2025. All current approved biosimilars share the same indication as Stelara, which includes treatment of moderate-to-severe plaque psoriasis, active psoriatic arthritis, moderate-to-severely active Crohn's disease, and moderately to severely active ulcerative colitis in adults. as well as pediatric patients 6 years and older for plaque psoriasis and psoriatic arthritis. Regarding formulation, the biosimilar generally matched Stelara's dosage form and strengths. And all Stelara biosimilars have received interchangeable status except for in Imuldosa. Okay, and then Tremfya had multiple updates in the past year. In March of 2025, Tremfya received FDA approval for adults with moderate-to-severe active Crohn's disease. And along with that approval came the introduction of a new 100 mg/mL single dose prefill pen for subcutaneous use. Then in September of 2025, the FDA expanded Tremfya's induction option for ulcerative colitis, allowing patients to use subcutaneous induction dosing. Previously, you see induction could only be administered intravenously. Across both Crohn's disease and ulcerative colitis, the induction approaches now includes either the 200 mg IV infusion over at least an hour or 400 mg subcutaneous at weeks 0, 4, and 8. For maintenance, patient can continue with 100 mg subcutaneously at Week 16 and every 8 weeks thereafter, or 200 mg at Week 12 and every 4 weeks using the lowest effective dose that maintains clinical response. And then most recently in October of 2025, Tremfya expanded into pediatrics. It is now approved for a patient 6 years and older, weighing at least 40 kg with moderate-to-severe plaque psoriasis needing systemic therapy or phototherapy as well as for active psoriatic arthritis. Recommended pediatric dosing is 100 mg subcutaneously at Week 0, Week 4, and every 8 weeks

thereafter. For pediatric psoriatic arthritis, Tremfya can be used alone or in combination with conventional DMARDs. In July of 2025, the FDA expanded the indication for apremilast, marketed as Otezla, to include pediatric patients aged 6 years and older weighing at least 20 kg for the treatment of active psoriatic arthritis. Previously, this indication was limited to adults only. The following month, the FDA also approved Otezla XR, a 75 mg extended-release tablet for once-daily oral administration. Otezla XR is indicated for adults with active psoriatic arthritis, plaque psoriasis requiring systemic therapy or phototherapy, and oral ulcers associated with Behçet's disease. In pediatric patients, its use is limited to those 6 years and older who weigh at least 50 kg for the treatment of active psoriatic arthritis or moderate-to-severe plaque psoriasis. In children, treatment selection and dosing are weight-based and differ by formulation. Otezla immediate release is indicated for pediatric patients weighing 20 kg or more, while the Otezla XR is only indicated for those weighing at least 50 kg. So for patients weighing 50 kg or more, dosing options include Otezla 30 mg twice daily or Otezla XR 75 mg once daily, whereas children weighing 20 kg to less than 50 kg should receive the Otezla 20 mg twice daily. In patients with severe renal impairment, dose adjustment is recommended for the immediate release formulation, and use of the extended release Otezla XR formulation is not recommended. In October of 2025, Simponi received an expanded indication for ulcerative colitis to include both adults and pediatric patients weighing at least 15 kg. Previously, Simponi was limited to adults who were corticosteroid dependent or who had an inadequate response to or could not tolerate oral aminosalicylates, corticosteroids, azathioprine, or 6-mercaptopurine. For dosing, adult and pediatric patients weighing 40 kg or more now follows the same regimen, 200 mg subcutaneously at Week 0, 100 mg at Week 2, and 100 mg at Week 6, followed by 100 mg every 4 weeks. Pediatric patients weighing at least 15 kg but under 40 kg follow the same dosing schedule at half the dose. It's also important to note that pediatric patients should use the pre-filled syringe only. The SmartJect auto-injector is reserved for adults. And then in October of 2025, the FDA expanded the indication for Xeljanz to include pediatric patients aged 2 years and older for the treatment of active psoriatic arthritis and those who have had an inadequate response or intolerance to at least one TNF blocker. Previously, this indication was limited to adults only. They expanded age Indication applies to the immediate release tablets and oral solution form only and does not include Xeljanz XR formulation. Pediatric dosing is weight-based, ranging from 3.2 mg to 5 mg twice daily. Box Warning has also been revised to remove the statement that Epstein-Barr virus associated post-transplant

lymphoproliferative disorder has been observed at higher rate in renal transplant patients treated with Xeljanz and concomitant immunosuppressant agents. Okay. For Omvoh, the 200 mg/2 mL prefilled pen and prefilled syringe were approved for use in ulcerative colitis, which was previously available only for Crohn's disease. Following this, the 100 mg/mL single dose prefill pen and prefilled syringe will be discontinued, and the 200 mg/2 mL presentation will remain on the market. Okay, next is hidradenitis suppurativa (HS), which is a chronic inflammatory skin condition that affects hair follicles in areas with apocrine gland, such as the armpit, groin, perianal region, and under the breasts. It typically begins after puberty and is diagnosed clinically. The prevalence is estimated at 1 to 2% of the U.S. population, and symptoms include painful, deep nodules, abscesses, draining sinus tract, and scarring, and it can sometimes be associated with arthralgia. Historically, treatment guidelines focused on antibiotics, hormone therapy, and biologics like adalimumab. However, since these guidelines were published two additional biologics, Cosentyx and Bimzelx, have been FDA approved for HS. Uveitis refers to inflammation of the uvea and can involve different parts of the eye. The most severe and highly recurrent forms include non-infectious intermediate or posterior uveitis, which affects the intermediate and posterior segments, and panuveitis, which involves the anterior chamber, vitreous humor, and choroid or retina simultaneously. The incident is estimated at 25 to 52 cases per 100,000 patients per year, with anterior uveitis being the most common type. Initial treatment typically consists of topical corticosteroids. For cases that do not respond to initial therapy, adalimumab is an option. Other treatment includes systemic glucocorticoids, immunosuppressant agents, and intraocular implants. Okay. Here we have Humira and it's full FDA indications. There were no updates to the indication for Humira since our last review but wanted to list it here for reference. And then the next two slides are Humira and it's biosimilar. Since we last reviewed, the Humira interchange biosimilar (Amjevita, Cyltezo, Hyrimoz, Simlandi, Yuflyma, and Idacio) received FDA approval for two expanded indications, which are seen in bold. Indication for treatment of moderate-to-severe HS has been expanded to include patients at least 12 years old, and indication for treatment of non-infectious intermediate posterior and panuveitis have been expanded to include patients 2 years and older. Both of these indications were previously approved for adults only. There were also updates on available dosage form and strengths of Humira as biosimilar. Current available products are listed on the slide. And here is the remainder of the Humira biosimilars. And again, in bold, you can see the updates for HS and uveitis. Giant cell arteritis, also called GCA or temporal

arteritis, is a systemic inflammatory vasculitis of unknown cause. It is classified as a large vessel vasculitis but can also involve small and medium arteries. Commonly affected vessels include the temporal, occipital, ophthalmic, posterior ciliary, and proximal vertebral arteries. Incidence ranges from 0.5 to 27 cases per 100,000 people aged 50 years or older, with higher rates in northern U.S. regions. The condition primarily affects older adults and can lead to vision losses and systemic complications. High-dose corticosteroid dosing protocols are the primary treatment, though evidence of optimal dosing is limited. And therapy is generally continued until symptoms resolve, followed by a slow taper to the lowest effective dose. So in April of 2025, the FDA approved a new indication for Rinvoq for the treatment of adult with GCA. The recommended dose is 15 mg once daily with a corticosteroid taper, and Rinvoq may be continued as monotherapy once corticosteroids are discontinued. Then in October of 2025, the ulcerative colitis and Crohn's disease indications were updated to specify that TNF blocker are inadvisable. Patients should receive at least one other approved systemic therapy before initiating Rinvoq. Okay, next disease state is cytokine releasing syndrome, or CRS. This is a potentially life-threatening condition caused by a rapid surge of cytokines following certain immunotherapies. Clinical symptoms include fever, nausea, headache, rash, tachycardia, hypotension, and dyspnea. The FDA has approved tocilizumab and its biosimilar, Actemra, Tyenne, and Avtozma for the treatment of severe or life-threatening CRS associated with CAR T-cell therapy in patients 2 years and older. So here we have Actemra and it's biosimilar. We'll go line by line so it's easier to follow. So for Actemra, In August of 2025, the FDA expanded the age indication for treatment of COVID-19 to include pediatric patients 2 years and older. Previously, this indication was limited to adults only. The recommended dose is weight-based for patients weighing less than 30 kg, the dose is a single 60-minute IV infusion of 12 mg/kg. And for patients weighing 30 kg or more, the dose is 8 mg/kg, with the option for one additional infusion at least eight hours later if symptoms worsen or do not improve. Avtozma, the third biosimilar to Actemra, received additional FDA approval in July for severe or life-threatening cytokine-releasing syndrome associated with CAR T-cell therapy in patients 2 years and older. It is available in both IV and subcutaneous formulations and have interchangeable status. In May of 2025, the FDA approved Tyenne 162 mg/0.9 mL in a single dose pre-filled syringe and auto-injector for subcutaneous use, aligning it with the same dose and formulation as Actemra. And then there were no updates for Tofidence in the past year. And our last update for this class, the FDA approved a new 300 mg/2 mL single dose prefill syringe of Spevigo for

subcutaneous injection. And that concludes the cytokine and camp antagonist section. I'm happy to take any questions.

- Kevin Flynn: Nina, thank you for that very comprehensive review of all the different updates in this class. Do any of the Committee members have any questions? If not, can we take a look at the PDL?
- Ryan Pistoiresi: All right. So for this, we are going to split it into two different motions. So the first will just be what is in our Atopic Dermatitis class. So these were the agents that were presented at the beginning of Nina's. And then once we finish with the motion and stakeholders for this one, then we will go into the Cytokine and CAMs. So for now, we are just looking at this subset.
- Kevin Flynn: Okay. Any questions? All right, are there any stakeholders for this specific class? I would imagine most of them are for the other class.
- Nonye Connor: Yes, they are. Sorry, I was trying to [cross-talk] unmute myself. Give me a quick second. Let me pull my timer and pull my list. Okay, so -- the Cytokine and Cam, we have [cross-talk] --
- Ryan Pistoiresi: [Cross-talk] Oh, no, Nonye, [cross-talk] --
- Nonye Connor: [Cross-talk] Oh, I'm sorry.
- Ryan Pistoiresi: [Cross-talk] we're not doing Cytokine and CAMs. We're just doing Atopic Dermatitis right now.
- Nonye Connor: [Cross-talk] Oh, atopic -- yes, I'm sorry. Thank you. Atopic, we have first have Carla. Let me unmute you. Hey, Carla. You can unmute yourself whenever you're ready. And I'm going to turn on a timer when you're ready. Just let me know.
- Carla McSpadden: Can I just clarify first? Nemluvio is not a topical, so it didn't look like it was part of this particular motion. Do you want the testimony now or right before the other motion?
- Kevin Flynn: Yeah, Ryan. That was my question. It looked like all those agents were topical ones that we were looking at now.

- Ryan Pistoiresi: Yes. So I would say let's hold off until after we finish the atopic dermatitis motions. So this section is just for what was presented on the PDL prior. So like the tacrolimus --
- Kevin Flynn: Tacrolimus. Okay.
- Nonye Connor: Okay. Um, next, let me see. Valerie. And it's going to be -- Valerie.
- Valerie Ng: Yeah. Hi, Nonye. So I may have may be on the same boat too. I do have Anzupgo, which is a topical JAK inhibitor, but it is not for atopic dermatitis. It's for chronic hand eczema. And I have Adbry as well. It is for atopic dermatitis, but it is a biologic injectable.
- Nonye Connor: Okay.
- Ryan Pistoiresi: Right. And so that would not be part of what we were currently reviewing.
- Valerie Ng: Yeah. Thank you.
- Nonye Connor: Let's see, Adam. Just give me a quick second. Adam.
- Adam Furman: Yeah, I'm in a similar situation to others. [Cross-talk] -- I'll be presenting [cross-talk] I kind of figured all the topical [indistinct] inhibitors wouldn't [cross-talk] --
- Nonye Connor: [Cross-talk] One more.
- Kevin Flynn: Is there any other? Yeah, Crystal. I have a feeling on the same. Crystal.
- Crystal Mill: So Zoryve is a topical. Okay. It is a topical phosphodiesterase 4 inhibitor, so it does fall under the category of atopic dermatitis. [Cross-talk] But within the PDL list that was shown, I believe we're listed under antipsoriatics, although we do have an indication for atopic dermatitis.
- Ryan Pistoiresi: Yeah. And right now it's only for Eucrisa. So thank you for clarifying.
- Crystal Mill: Yeah, of course. But I'm happy to testify now if that works for everyone.

Ryan Pistoiresi: If you're -- if you don't have any products in the Cytokine and CAMs, then now might be an appropriate time for you to, even though your product's not part of this class.

Crystal Mill: Yeah, it's not listed within the slides, but the product is a PDE4 inhibitor under the topical. So I'm happy to start now if that works. Okay. [Cross-talk] Okay, thank you. Okay, thank you. All right, so hi, my name is Crystal Mill and I'm the Director of Medical Values and Outcomes employed by Arcutis Biotherapeutics, speaking to Zoryve, also known as roflumilast topical. And as I mentioned, Zoryve is a steroid-free, highly-potent phosphodiesterase 4 inhibitor that is approved for the treatment of multiple inflammatory dermatoses with no label restrictions. And currently, older generic topicals, such as topical corticosteroids, are typically twice daily dosing and have limitations on continuous use due to safety. There are several strengths of Zoryve, with the 0.15% cream being indicated for the treatment of mild-to-moderate atopic dermatitis in patients 6 years of age and older. And most recently approved in October 2025 is Zoryve's 0.05% cream, which is indicated for patients with mild-to-moderate atopic dermatitis 2 to 5 years of age. Zoryve 0.05% and 0.15% cream were studied in pivotal trials where a specifically significant greater proportion of patients achieved the primary endpoint of a validated investigator global assessment of clear, almost clear, plus a 2-grade improvement from baseline at Week 4. And recently published open-label extension data through 56 weeks have shown that both 0.05% and 0.15% had a consistent safety profile as observed in Week 4 in the pivotal trials. Additionally, durable effectiveness in improving the signs and symptoms of atopic dermatitis were observed in eligible patients that switched to twice weekly maintenance application, who were able to maintain disease control for about 8 to 9 months. Zoryve 0.15% and 0.05% cream are topical options for adult and pediatric patients with mild-to-moderate atopic dermatitis. That is a once-daily steroid-free option with no label restrictions on duration of use, particularly in a chronic inflammatory disease such as atopic dermatitis, where long-term steroid [audio cuts out] use is not recommended. Additionally, the AAD 2025 focused guideline update lists roflumilast or Zoryve cream, as mentioned earlier in the slides, with a strong recommendation with high certainty for patients with mild-to-moderate atopic dermatitis. And with that, we respectfully request the committee to have Zoryve 0.15% and 0.05% cream to be on the PDL as preferred with a single step through, a topical corticosteroid for no more than 28 days. And with that, thank you to the Committee for your time and

consideration, and I will open it up for any questions that the committee may have. Thank you.

Kevin Flynn: Committee members, is there any questions? Hearing none, can we see the motion?

Ryan Pistoresi: All right. So as I had mentioned, we are just doing these two drug classes as they are on the PDL for this motion. And then after this, we will go into the Cytokine and CAMs. So I'll jump into the PDL next.

Nonye Connor: I'm so sorry. We have Brian with a hand raised. So, Brian, you can unmute yourself.

Brian Sherwood: Thank you so much. I also just wanted to jump in in this section as well. My name is Brian Sherwood. I'm with Organon supporting VTAMA or tapinarof, also a topical nonsteroidal for atopic dermatitis. I was just hoping to provide testimony as well.

Nonye Connor: Okay, whenever you're ready.

Brian Sherwood: Thank you. So despite available therapies to treat atopic dermatitis, some current therapeutic options have potential limitations in terms of overall efficacy, safety, and tolerability. VTAMA, or tapinarof cream, 1%, is a once-daily prescription, steroid-free, first-in-class, aryl hydrocarbon receptor agonist that's indicated for the topical treatment of atopic dermatitis in patients down to 2 years of age as well as for the treatment of plaque psoriasis in adults. VTAMA Cream was evaluated in two randomized, double-blind, multi-center, vehicle-controlled 8-week pivotal trials, the ADORING-1 and 2 trials, which included 813 patients down to 2 years of age with moderate-to-severe atopic dermatitis. These pivotal trials were followed by a 48-week open-label long-term extension trial called ADORING-3, which included 728 patients with mild, moderate, and severe atopic dermatitis. In the pivotal trials, the primary efficacy endpoint of vIGA-AD treatment success. So vIGA-AD score of 0-1, clear or almost clear, with at least a 2-grade improvement from baseline, was achieved by a statistically significant higher proportion of patients in the VTAMA cream group versus the vehicle group in ADORING-1 and ADORING-2. Patients treated with VTAMA cream experienced an improvement in itch within 24 hours after first application, with statistical significance observed by day 2. In ADORING-3, 52% of patients entered the trial or achieved complete disease clearance at least

once during the trial and experienced a mean first treatment-free interval of approximately 80 consecutive days off of therapy. 82% of patients entered with or achieved clear or almost clear skin at least once during ADORING-3. The most common Adverse Reactions reported in at least 1% of patients in ADORING-1 and 2 included upper respiratory tract infection, folliculitis, lower respiratory tract infection, headache, asthma, vomiting, ear infection, pain in extremity, and abdominal pain. VTAMA cream demonstrated consistent safety and tolerability in the pivotal trials and open-label extension trial ADORING-1, 2, and 3. So, in summary, VTAMA cream offers adults and children, down to 2 years of age, an efficacious, safe, well-tolerated, nonsteroidal topical that can be used to treat atopic dermatitis without restrictions on the severity of disease treated, duration of use, total body surface area treated, or sites of application. VTAMA cream also offers patients the potential to achieve complete disease clearance and experience a treatment-free interval of around 2-1/2 months, as demonstrated in the 48-week open-label long-term extension study. So therefore, we respectfully ask the Committee to consider adding VTAMA cream to the preferred drug list in the Atopic Dermatitis : Topical Agents Class. Thank you so much for your time today.

Kevin Flynn: All right. Committee members, is there any questions for the stakeholder? All right. Can we see the motion?

Ryan Pistorosi: All right. The motion is up. And just a reminder, it was for the two subclasses that were shown on the PDL previously.

Laura Beste: This is Laura Beste. I make a motion that I move that all products in the drug classes listed on Slide 8 are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at discretion of HCA. Products in these classes may require prior authorization to determine medical necessity. All nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Christy Weiland: This is Christy Weiland, I can second.

Kevin Flynn: All right. All in favor, say aye.

Multiple Speakers: Aye. Aye. Aye. Aye.

- Kevin Flynn: Any opposed? All right, motion carries.
- Ryan Pistoresi: All right, and then I will bring up the PDL for the Cytokine and CAMs. So it'll be this page. Okay. And like the anticonvulsants, this is going to be multiple pages. So these are by subgroups. And so I'll just start with this first one and then scroll down to the next few. So this is going to be the largest of the drug classes that we look at just given the number of products.
- Kevin Flynn: Just it looks like multiple biosimilars are approved are preferred in.
- Ryan Pistoresi: Yes. And that's one of the things that you'll see is that we do have, I mean, just given the amount of ustekinumabs here, you can see that we've got them by their biosimilar name here, and then you can have the four letter suffix here as well. And so just given the size of these classes, again, it will take multiple pages to go through all of them.
- Kevin Flynn: Yeah, makes sense.
- Ryan Pistoresi: And I'll go through the TNFs just because this is the largest one and with the most biosimilars. As you can see, it's really the adalimumab and the Enbrel. Okay. And then it sounds like we do have a lot of stakeholders, so I will transition that back over to Nonye.
- Nonye Connor: Okay. I'm going to go ahead and share my screen. Put a timer. So pre-registered first again. Carla.
- Carla McSpadden: Yeah, I'm here. Can you hear me?
- Nonye Connor: Yes.
- Carla McSpadden: Okay, perfect. Yeah, again, my name is Carla McSpadden. I am a pharmacist employed by Galderma and appreciate the opportunity to speak about Nimluvio, generic name nemolizumab. Nimluvio is indicated for two skin diseases, actually, prurigo nodularis, but in the case of today, moderate-to-severe atopic dermatitis in adults and pediatric patients 12 and older. It's the first drug to target IL-31, which is a cytokine that's been implicated in itch, inflammation, and skin barrier issues. In the atopic dermatitis trials, Nimluvio significantly improved skin lesions and disease severity, but it also demonstrated significant itch relief and sleep improvement within a week

after the first dose and significant skin clearance within 4 weeks. It's been well tolerated in the trials. It has no Warnings or lab monitoring requirements in the PI. It is self-administered subcutaneous using an auto-injector pen that has a long shelf life after removal from the fridge, 90 days. And it's the first atopic dermatitis treatment dosed every 4 weeks, with maintenance dosing extended to every 8 weeks for responders. Nimluvio has been strongly recommended in the 2025 update of the American Academy of Dermatology Guidelines in combination with topical therapy. And lastly, we recently presented a positive Phase 2 study in the 2- to 11-year-old AD population that showed similar PK and safety as adolescents and adults and clinically meaningful improvements in lesions and itch. So Galderma is respectfully requesting that Nimluvio be added as preferred on the PDL. And the rationale is first to have a unique mechanism of action to offer something different than just an IL-4/IL-13 in the case of Dupixent. Second would be the clinical benefits in itch, skin, and sleep that it offers. And last, the potential value of those responders extending the dosing interval to every 8 weeks as recommended in the PI, which would equal 6 to 7 pins per year for maintenance. So I'm happy to answer any questions.

Kevin Flynn: All right. Committee members, any questions for the stakeholder? Hearing none, thank you.

Nonye Connor: Next is Valerie.

Valerie Ng: Hi, Nonye. Can you hear me okay?

Nonye Connor: Yes.

Valerie Ng: Okay, great. Nonye and Ryan, before I start, I do have two products. Do I have 6 minutes? I'm not going to use all of that, but I was just curious if [cross-talk] --

Nonye Connor: [Cross-talk] Sure, yeah.

Valerie Ng: -- I just have three or six.

Nonye Connor: Mm-hmm. You have 3 minutes for each one.

Valerie Ng: Perfect. Thank you.

Nonye Connor: Uh-huh.

Valerie Ng: Well, good morning, everyone. I'm Valerie Ng. I'm a Pharmacist with the Field Medical Affairs at Leo Pharma. First, I'm speaking on Anzupgo or delgocitinib. It is the first and only FDA-approved treatment for moderate-to-severe chronic hand eczema, or CHE, for adults with inadequate response to topical corticosteroids or for whom the topical corticosteroids are not advisable. CHE is really not just atopic dermatitis of the hands. It encompasses a lot more, such as, but not limited to, allergic contact dermatitis, irritant contact dermatitis, hyperkeratotic, and dyshidrotic hand eczema. It is a distinct, high-burden disease, as Nina mentioned earlier. It is defined by persistent itch and pain. addresses this heterogeneous disease by uniquely blocking all four members of the JAK family, targeting that specific pathophysiology of CHE. In two robust Phase 3 trials, Anzupgo achieved statistically significant improvements over cream vehicle in all primary and secondary endpoints. Itch reduction was observed as early as Day 1 and pain reduction by Day 3. Long-term data, also very important, right, since this is a chronic disease, also confirmed its sustained efficacy out to one year. And Anzupgo has a safety profile well suited for chronic management as well as it does not have a Boxed Warning. Given the proven safety and efficacy data of Anzupgo or delgocitinib as the only medication approved for this high unmet need like CHE, we respectfully request that Anzupgo/delgocitinib be made available as a preferred agent and not require patients to step through off-label, unproven atopic dermatitis agents, to help Washington Medicaid members with CHE perhaps return to work and return their daily function. And the next one I have, Nonye, is on Adbry or tralokinumab. I'll start by saying we respectfully request Adbry be added as a preferred drug to the PDL. This ensures that Washington Medicaid patients can realize that proven safety, that proven efficacy of Adbry or tralokinumab, while both the state and patients benefit from that distinct economic value associated in the monthly dosing and eligible patients suffering from moderate-to-severe atopic dermatitis. I'd like to highlight a significant label update just last year, end of last year, regarding long-term safety. While we often see new Warnings, right, emerge with long-term data with these new label updates on safety, Adbry's update reinforces the opposite. It reinforced the safety and remained consistent over 6 years, with no increase in Adverse Events or no neutralizing antibodies. Furthermore, new data demonstrates robust efficacy in hard-to-treat areas (atopic dermatitis areas), specifically the head, the neck, the hands, the feet, where patients suffer most visibly. And from an economic perspective, as mentioned earlier, real-world evidence continues

to show approximately a third of patients successfully switch to that every 4 weeks or monthly dosing. Thank you all for your time, and I'm happy to answer any questions you may have.

Kevin Flynn: All right. Committee members, any questions from the stakeholder? All right. Thank you. All right. Next stakeholder.

Nonye Connor: Next. Adam.

Adam Furman: Yep, I'm here. Can you hear me?

Nonye Connor: Yes.

Adam Furman: Perfect. So thank you all for taking the time to hear from me. My name is Adam Furman, and I'm a Pharmacist on the Medical Value and Outcomes Team at Sanofi. And today I'd like to discuss dupilumab, also known by the brand name of Dupixent. So while the focus of this testimony is going to be on dupilumab and atopic dermatitis, I would like to call out some quick aspects that are important for dupilumab. It's now approved in nine indications, including most recently allergic fungal rhinosinusitis. In addition, a published head-to-head Phase 4 clinical trial, the EVEREST trial, which evaluates omalizumab versus dupilumab in patients with severe CRS with MP and comorbid asthma, is now available. So dupilumab is a fully human monoclonal antibody that blocks the IL-4 receptor alpha subunit. So it simultaneously inhibits IL-4 and IL-13, which are central drivers to Type 2 inflammation and are associated with numerous inflammatory conditions that we've already discussed today. So this unique mechanism explains its efficacy across nine conditions spanning dermatology, GI, and respiratory. And once you take into account the percentage of AD patients that have additional type 2 comorbidities, the clinical value of dupilumab becomes even more clear. The FDA approvals include three indications, bolus pemphigoid, EOE, and AFRS, in which there's no alternate biologics with FDA approval. And even NAD, in which there are alternative biologics indicated, there are currently no other biologics approved for ages 6 months through 11 years of age, making dupilumab an important therapy for Washington residents and physicians to have access. In the AD space, there are six pivotal trials and numerous other supporting trials demonstrating the safety and efficacy of dupilumab, which have previously been reviewed by this committee. So instead, I'll focus on the longer-term data. So there is published open-label extension information available for dupilumab and AD.

The LIBERTY AD OLE followed adult patients for up to 5 years. And at that 5-week mark, 88.9% of patients achieved EASI-75 and 76.2% achieved EASI-90, meaning near clear skin, and that was sustained over that full 5-year period. And then itch responses were similarly durable. In the pediatric open-label extension, efficacy was also demonstrated across both the younger children population, so 6 months to 5 years, and 6 to 11, with EASI-75 being 79.3 and 81.7%, respectively. And there's also robust real-world evidence available for dupilumab in both the pediatric and adult population demonstrating durable efficacy. From a safety perspective, dupilumab has a well-established and consistent safety profile after 9 years on the market, with no laboratory monitoring required during dupilumab treatment. Serious Adverse Events are uncommon, and important safety considerations and Warnings and a full list of Adverse Events can be found in the Prescribing Information. So taken together across trials, registries, geographies, and age groups, it's confirmed that dupilumab delivers durable, meaningful disease control both in the clinical trial setting and the real world setting and to remain an accessible and preferred treatment option for Washington residents on the PDL. And with that, I'll open myself up for questions.

Kevin Flynn: All right, Committee members, any questions? All right. Thank you. Next stakeholder.

Nonye Connor: Irene. I hope I'm pronouncing your name correctly.

Irene Luy: That's correct. I'm ready.

Nonye Connor: Yay. Thank you.

Irene Luy: Thank you. Okay. Hi, everyone. My name's Irene Luy. I'm -- I don't know if the timer started yet. I just want to make sure. Okay. My name is Irene Luy. I'm a pharmacist and health outcomes liaison at Eli Lilly. I'll be providing comments on mirikizumab, brand name Omvoh. Mirikizumab is an IL-23 antagonist that's indicated for the treatment of moderately to severely active ulcerative colitis and moderately to severely active Crohn's disease in adults. Dosing for both indications includes an IV induction dose at weeks 0, 4, and 8, 300 mg over 30 minutes for ulcerative colitis and 900 mg over 90 minutes for Crohn's disease. The maintenance dose in ulcerative colitis is 200 mg administered by subcutaneous injection at Week 12 and every 4 weeks thereafter. Originally, this was to be administered as two consecutive 100 mg

subcutaneous injections. But as Nina mentioned, a single injection of 200 mg was recently approved. The Prescribing Information includes both dosing options, and the 100 mg pens or syringes will be phased out after patients have been transitioned to the new 200 mg injection. In Crohn's disease, the maintenance dose is 300 mg administered as two consecutive injections of 100 mg and 200 mg in any order. These are packaged together in a 300 mg carton. Mirikizumab has demonstrated significant efficacy in ulcerative colitis, achieving high rates of clinical remission and endoscopic improvement compared to placebo in both induction and maintenance phases. We do have long-term data from the LUCENT-3 maintenance study supporting sustained efficacy and consistent safety with treatment of mirikizumab for ulcerative colitis over 4 years. Similarly, mirikizumab significantly improved clinical remission and endoscopic response in Crohn's disease, with high maintenance rates and consistent safety profile observed after 2 years of mirikizumab therapy in the VIVID-2 extension study. Please consult the prescribing label for Full Safety Information. Mirikizumab is contraindicated in patients with a history of serious hypersensitivity reactions. It carries Warnings for hypersensitivity infections, tuberculosis, hepatotoxicity, and immunizations. The most common Adverse Reactions include upper respiratory tract infections, arthralgia, injection site reactions, rash, headache, herpes viral infection, and elevated liver tests. Thank you for the opportunity to provide comments on Omvoh. We would appreciate consideration for Omvoh as a preferred agent on the Washington Medicaid PDL. And I'd be happy to take any questions.

Kevin Flynn: All right, thank you. Committee members, any questions? All right, thank you. Next stakeholder.

Nonye Connor: Nirmal? I am so sorry if I'm pronouncing that incorrectly.

Nirmal Ghuman: No worries.

Nonye Connor: Let me know when you're ready.

Nirmal Ghuman: Oh, okay. I'm ready to go if you want me to answer these questions here.

Nonye Connor: Oh yes, please.

- Nirmal Ghuman: Sure. As you said, my name is Nirmal Ghuman, and I'm speaking on behalf of Johnson & Johnson. I am not a provider, I'm not a patient, and I don't have any other conflicts of interest to report.
- Nonye Connor: Okay.
- Nirmal Ghuman: And hello, everyone. My name is Nirmal Ghuman, and I'm a Pharmacist and Regional Account Director with Johnson & Johnson Innovative Medicine. Thank you for the opportunity to speak to you about two products today, the first one being Icotyde, icotrokinra. On March 18, 2026, Johnson & Johnson announced that the FDA had approved Icotyde for the treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 12 years of age and older who weigh at least 40 kg who are candidates for systemic therapy or phototherapy. Icotyde is an oral peptide that selectively binds to the IL-23 receptor and antagonizes the binding of IL-23. The recommended dosage of Icotyde is 200 mg administered orally once daily. Please refer to the Full Prescribing Information for complete information. In adults and pediatric patients 12 years of age and greater, who weigh at least 40 kg with moderate-to-severe plaque psoriasis. Icotyde demonstrated significant improvements in IGA0/1 and PASI 90 versus placebo at Week 16. and deucravacitinib at Week 24. These findings were also observed in patients with psoriasis involving high-impact sites, such as the scalp. Long-term data with Icotyde through 52 weeks has also been evaluated. Response patterns in adolescents were generally consistent with those observed in adults, although data were more limited due to smaller sample sizes. The overall safety of Icotyde observed across studies remained consistent over time. Most common Adverse Reactions are headache, nausea, cough, fungal infection, and fatigue. For these reasons, please consider adding Icotyde to the Washington Medicaid Preferred Drug List. I would also like to thank you for the opportunity to speak to you about Tremfya, guselkumab. The FDA approved, as Nina had shared, Tremfya for the treatment of multiple immune-mediated disease states, including adults and pediatric patients 6 years of age and older, who also weigh at least 40 kg, with moderate-to-severe plaque psoriasis in July 2017 and September 2025, respectively. as well as adults and pediatric patients 6 years of age and older, who also weigh at least 40 kg with active psoriatic arthritis in July 2020 and September 2025, respectively. Additionally, Tremfya was approved for the treatment of adult patients with moderately to severely active ulcerative colitis on September 2024 and adults with moderately to severely active Crohn's disease on March 2025. Please refer to the Full Prescribing Information for complete

information. The recommended dosage for adult ulcerative colitis and Crohn's disease for induction is 200 mg administered by IV infusion over at least one hour at Weeks 0, 4, and 8, or 100 -- or sorry, or 400 mg administered by subcutaneous injection. I would like to respectfully request that you consider updating the policy to reflect the pediatric indications for Tremfya, as well as the availability of subq induction for ulcerative colitis and Crohn's disease. Thank you for your time and consideration today. I'm happy to answer any questions.

Kevin Flynn: Thank you. Committee members, any questions? All right, hearing none, next stakeholder.

Nonye Connor: That's it for pre-registered stakeholders. I don't know if any other stakeholder would like to raise their hands now. Do you have? Okay. Let me see. Anne?

Anna Allen: Hi, can you hear me?

Nonye Connor: [Cross-talk] Yes. [Cross-talk] If you just want to quickly [cross-talk] --

Anna Allen: [Cross-talk] Oh, sorry, go ahead.

Nonye Connor: No, I was going to say if you want to do me a favor and answer the questions on your screen and then let me know when you're ready, I can start the timer.

Anna Allen: Yeah, definitely. My name is Anna Allen. I am speaking on behalf of UCB. I did fill out a conflict of interest form and registered and had received approval for speaking. And I am not a patient or representing a patient and for conflicts of interest, I do work for UCB.

Nonye Connor: Okay, go ahead.

Anna Allen: Thank you. So again, my name's Anna Allen. I am a PharmD Medical Outcomes Liaison for UCB. Grateful to be here with you all engaged in this scientific exchange. And thank you for the time to share clinical information about bimekizumab or brand name Bimzelx. Bimzelx is the first and only approved humanized monoclonal IgG1 antibody that selectively inhibits both IL-17A and IL-17F. It has five indications, which are the treatment of adult patients with plaque psoriasis, psoriatic arthritis, non-radiographic axial

spondyloarthritis, ankylosing spondylitis and moderate-to-severe hidradenitis suppurativa, (HS), and Bimzelx is available as a prefilled syringe or auto-injector. Looking at psoriasis there are four different Phase 3 trials in which Bimzelx achieved superiority versus all active comparators. In these studies treatment with Bimzelx produced rapid, complete, and durable response. PASI 90, which is a measure of 90% improvement in psoriasis area and severity, was significantly improved compared to placebo, Humira, and Stelara. Clearance of skin disease is the ultimate goal for psoriasis, but patients often feel frustrated, feeling like they have suboptimal disease management or higher relapse rates. And in clinical trials, PASI 100, which indicates complete skin resolution, was significantly improved with Bimzelx versus placebo and versus Cosentyx. There's also long-term data that shows more than 3 years of maintained response regardless of the disease characteristics or prior exposure to biologics. Looking at the rheumatology indications, In Phase 3 studies, treatment with Bimzelx produced rapid, deep and sustained response. For psoriatic arthritis, ACR50 responses at Week 16 were significantly improved versus placebo for both DMARD-naïve and TNF-inadequate responders. And for nr-axSpA the ASAS40 responses at Week 16 were significantly improved versus placebo. Finally, for HS, In Phase 3 studies, treatment with Bimzelx produced rapid sustained and maintained responses, where high score 50 responses at Week 16 were significantly improved with Bimzelx 320 mg every 2 weeks versus placebo. And patients treated with Bimzelx had a rapid response compared to placebo as early as Week 4. Taking a look at safety there are no Contraindications, Boxed Warnings, or REMS programs for Bimzelx. The most common Adverse Effects were upper respiratory tract infection, oral candidiasis, and headache. And it may increase the risk of suicidal ideation, but this risk has not been associated as causal. And patients should be evaluated for TB or have liver function monitoring at baseline and periodically during therapy. So, with this information, we kindly ask today that Washington Medicaid maintain a single-step [indistinct] for nonpreferred cytokines in support of Washington Medicaid patients with hidradenitis suppurativa. And I'm happy to field any questions. Thank you.

Kevin Flynn: All right. Thank you. Committee members, any questions? Hearing none. Is there any other stakeholders?

Nonye Connor: I do not see any other hand raised.

Kevin Flynn: Okay. Can we see the motion then?

- Nonye Connor: Yes. And I just wanted to do a gentle reminder, please, Committee members, share your camera when you are making a motion, please. Thank you so much. Turn on your camera. Sorry, not share your camera. Turn on your camera. Sorry. Thank you.
- Ryan Pistorosi: All right. And as you saw from the PDL review, there are a lot of subclasses just given how the different drugs in this class target different interleukins or different aspects of, you know, our system. So that is what is at stake for this motion.
- Brad Pope: Brad Pope, I move that all products in the drug classes listed on Slide 10 are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in these classes may require prior authorization to determine medical necessity. All nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not medically appropriate, or only one product is preferred.
- Laura Beste: This is Laura Beste. I second the motion.
- Kevin Flynn: All right. All in favor, say aye.
- Multiple Speakers: Aye. Aye. Aye. Aye.
- Kevin Flynn: Any opposed? All right, with that motion carries. I think with that, we're scheduled for our well-deserved break. So Nonye, if it's okay, we'll say 11:25.
- Nonye Connor: Okay. Thank you. We're back at 11:25.
- Kevin Flynn: Okay. Thank you.
- Nonye Connor: Great. Thank you.
- [break]
- Kevin Flynn: All right, if I could have the Committee members just turn their cameras back on so we can see that everyone is here.

Nonye Connor: Okay, we are at quorum.

Kevin Flynn: Okay. All right, Nina.

Nina Huyhn: Next is Gaucher disease. Gaucher disease is an autosomal recessive lysosomal storage disorder due to GBA1 mutation-induced glucocerebrosidase deficiency. GD results in accumulation of glycolipids within the lysosomes of macrophages in the spleen, liver, bone marrow, bone, and other tissues or organs, and leads to the manifestation of the disease. Gaucher disease can be classified as Type 1, Type 2, or Type 3, and these subtypes are primarily differentiated by the presence or absence of progressive neurodegenerative involvement. Type 1, or GD1, is the most common form in the United States. It is non-neuronopathic and typically presents with visceral and skeletal manifestations. Type 2, or GD2, is the acute neuronopathic form characterized by rapid and severe neurodegenerative and is almost always fatal within the first 2 to 3 years of life. Type 3, or GD3, represents the chronic or subacute neuronopathic subtype with slowly progressive neurologic decline along with systemic features. From a treatment standpoint, GD1 is managed with enzyme replacement therapy as first line, with substrate reduction therapy such as eliglustat or miglustat as alternatives. And then for GD2, care remains fully supportive and palliative because no disease-modifying therapy exists. And then for GD3, ERT or SRT can address systemic non-CNS symptoms. And as of 2026, imiglucerase is FDA approved for treating the non-CNS manifestations of GD3. Neurologic disease still requires supportive care, as there's no approved therapies currently modifying CNS progression. So in January 2026, the FDA expanded imiglucerase, marketed as Cerezyme, to include treatment of Type 3 Gaucher disease in both adults and pediatric patients and to extend its Type 1 indication to pediatric patients under 2 years of age. Previously, it was approved only for adults and children 2 years and older with Type 1 Gaucher disease, presenting with anemia, thrombocytopenia, bone disease, hepatomegaly, and splenomegaly. The recommended dosing ranges from 2.5 units/kg three times weekly to 60 units/kg every 2 weeks. This is administered intravenously and titrated based on disease severity and therapeutic goals. Treatment must be initiated in a healthcare setting with appropriate monitoring and the capability to manage hypersensitivity reactions, including anaphylaxis. Okay. And then next is the granulocyte colony-stimulating factors. When we think about supportive care in oncology, chemotherapy-induced neutropenia, and febrile neutropenia remain some of the most significant dose-limiting toxicities. These

complications can lead to hospitalization, the need for broad-spectrum antibiotics, and ultimately chemotherapy dose delays or reductions. Neutropenia is defined as having fewer than 500 neutrophils/ μL or fewer than 1000 neutrophils/ μL with a predicted decline to 500/ μL or less. Febrile neutropenia is characterized by a single oral temperature of 38.3 degrees Celsius or higher or 38 degrees Celsius sustained for over an hour in a patient with neutropenia. This is where colony-stimulating factors play an important role. CSFs help reduce the severity, duration, and overall risk of febrile neutropenia by preventing neutropenia-related complications. They lower infection-related hospitalization and help patients stay on full-dose, on-schedule chemotherapy, which is often critical for achieving optimal outcomes. The 2025 NCCN Hematopoietic Growth Factor Guidelines provide updated recommendations on the use of granulocyte colony-stimulating factors and patients receiving myelosuppressive chemotherapy for solid tumors and lymphoid cancers. The guidelines reaffirm that all current available G-CSF agents have comparable safety profiles, and subcutaneous administration remains the preferred route. The NCCN also notes that there's still insufficient evidence to declare clinical superiority of G-CSFs over GM-CSFs, so agent selection should continue to focus on availability, cost, dose inconvenience, 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 FN, defined as 20% or greater. Primary prophylaxis with the G-CSF is a Category 1 recommendation. And the intermediate risk range 10% to 20% prophylaxis should be considered based on individual risk factor, such as age 65 or older, significant comorbidities, organ dysfunction, or a history of prior febrile neutropenia. And then in low-risk regimens with the FN risk under 10%, routine prophylaxis is not recommended. The guidelines also reinforced caution when using G-CSFs in the setting of concurrent chemoradiation, as prophylaxis use can amplify toxicity in this context, so you should be highly selected. Finally, regarding the therapeutic use for established febrile neutropenia, the NCCN states that no new evidence supports 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, so they are not recommended as standard therapy. Okay, this slide shows Neulasta and its approved biosimilar. In November of 2025, the FDA approved Armlupeg, which carries the same two indications as Neulasta. First, it is approved to decrease the incident of infection as manifested by febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy. And second, it is approved to increase survival in patients

acutely exposed to myelosuppressive doses of radiation. Armlupeg will be supplied as a 6 mg/0.6 mL subcutaneous injection in a single-dose prefilled syringe. Fylnetra, which is the fourth product listed, received the radiation exposure indication in April of 2025. And then to note, none of the Neulasta biosimilars are currently FDA designated as interchangeable. Okay, Neupogen had no updates to its FDA indication. But for context, it's indicated for chemotherapy-induced neutropenia, acute myeloid leukemia during induction and consolidation, bone marrow transplant, hematopoietic progenitor cell mobilization, severe chronic neutropenia, and radiation-induced myelosuppression, referred to as hematopoietic syndrome of acute radiation syndrome, or HSARS. So here we have neutropenia and it's biosimilar. Filkri was FDA approved in January of 2026 and carries all of Neupogen's indication except for HPC mobilization. It will be available as a 300 mcg/0.5 mL and 480 mcg/per 0.8 mL single-dose prefilled syringe. Releuko, 4th product listed, received two additional indications in April of 2025. HPC mobilization and HSARS, making it approved for all Neupogen indications. And all biosimilar for Neupogen are also not FDA designated as interchangeable. Okay, and then Granix was discontinued in June of 2025. And this concludes the Hematopoietic Agents. I'm happy to take any questions.

Kevin Flynn: Thank you. Are there any questions? All right, so review the PDL.

Ryan Pistorresi: For the Hematopoietic Agents, we have the two subclasses.

Kevin Flynn: [Cross-talk] Is there [cross-talk] --

Ryan Pistorresi: [Cross-talk] Are there no questions?

Ryan Pistorresi: Go ahead.

Kevin Flynn: Oh, is pegfilgrastim not on the -- or one of the biosimilars?

Ryan Pistorresi: Um. [Cross-talk] So we do have pegfilgrastim [cross-talk] --

Kevin Flynn: [Cross-talk] I guess that would be like clinic administered, so it doesn't matter.

Ryan Pistorresi: Yeah, I think they would still have to go through a PA. But I do believe that there is a pathway to coverage. I think it's just for the PDL, the Neupogen

here, and then the Granix here are the preferred options. But the other ones, yes, they would have this PA criteria here that applies to the entire colony-stimulating factor subclass.

Kevin Flynn: All right. Any other questions? Are there any stakeholders?

Nonye Connor: None that pre-registered, and I do not see any hands raised.

Kevin Flynn: All right. Let's see the motion.

Ryan Pistorosi: All right. So again, for the Hematopoietics, these are the two subclasses for the motion.

Laura Beste: This is Laura Beste. I move that all products in the drug classes listed on Slide 12 are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in these classes may require prior authorization to determine medical necessity. All nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Greg Hudson: This is Greg Hudson, I second.

Kevin Flynn: All in favor.

Multiple Speakers: Aye. Aye. Aye. Aye.

Kevin Flynn: Any opposed? All right. Motion carries. All right. Corticosteroids.

Nina Huyhn: Okay. Next is Oral Glucocorticoids. So adrenal insufficiency is a serious endocrine disorder caused by damaged or dysfunction of the adrenal cortex, leading to inadequate cortisol production and, in many cases, low aldosterone. Patients can have a life-threatening adrenal crisis during physical stress, and long-term use of higher than [cross-talk] -- thank you for muting. Patients can have a life-threatening adrenal crisis during physical stress, and long-term use of higher-than-needed steroid doses can cause serious problems such as osteoporosis, heart and metabolic disease, and mental health side effects. Most cases stem from autoimmune destruction, as

seen in Addison's disease, or from medication-induced suppression. This is especially concerning during rapid steroid tapering or in patients exposed to interacting agents like opioids, antifungals, antiretrovirals, and immune checkpoint inhibitors. Symptoms are often nonspecific, such as fatigue, weakness, weight loss, GI disturbances, orthostasis, salt craving, and hyperpigmentation. Laboratory abnormalities, such as hyponatremia, hyperkalemia, and hypoglycemia help clarify the picture. And then in pediatric patients, red flags include faltering growth and prolonged neonatal jaundice. Populations at highest risk includes individuals recently discontinuing long-term steroids, current steroid users experiencing infection, surgery or trauma, and patients with autoimmune endocrine disorders, or prior cranial pituitary radiation. Primary adrenal insufficiency is treated with physiologic glucocorticoid replacement, most commonly hydrocortisone in divided doses. Doses should be increased during illness, stress, or surgery with immediate parenteral glucocorticoids administered if adrenal crisis is suspected. So the FDA has approved Khindivi, the first hydrocortisone oral solution formulated specifically for pediatric patients 5 years and older with adrenal cortical insufficiency who require chronic replacement therapy. Khindivi comes as a ready-to-use 1 mg/mL solution, offering a practical alternative for children who may struggle with tablets. The recommended starting dose is 8 mg to 10 mg per square meter per day, divided into three doses given throughout the day. Older patients may be able to switch to twice-daily regimens. Doses may be titrated up based on age and clinical symptoms, while some patients with residual cortisol production may require less. It's important to note that Khindivi is not approved for stress dosing during illness or acute events. Instead, clinicians should use another hydrocortisone-containing product for that purpose. And finally, the formulation includes PEG 400, propylene glycol, and glycerin, which carries toxicity risks such as metabolic acidosis, hyperosmolarity, hypoglycemia, and potential CNS or hepatorenal injury. And this concludes the Oral Glucocorticoids. I'm happy to take any questions.

Kevin Flynn: All right, any questions from the Committee members? All right, PDL.

Ryan Pistorosi: All right. So I did zoom out a bit so that way everything could fit on the screen at once. So no scrolling for this class, but these are the drugs within this class that was just reviewed.

Kevin Flynn: Just as a question, is this class limited to just oral? Because some of these patients also have like pumps where they get like hydrocortisone.

- Ryan Pistorosi: That's a great question. Yes. So this is limited to just the oral products in this class. And so you can see we've got a few different types of oral dosage forms. So we've got different capsules, drops, elixirs, oral concentrates, suspensions, tablets. So yes, all just the orals.
- Kevin Flynn: Okay. All right. Any questions? And I don't believe there is any stakeholders for this one pre-signed up. But is there any in the waiting room?
- Nonye Connor: There are no hands raised.
- Kevin Flynn: All right. Let me see [cross-talk] --
- Ryan Pistorosi: [Cross-talk] And the motion should be up on your screen.
- Kevin Flynn: All right. This is Kevin Flynn, and I move that all products in the drug classes listed on Slide 14 are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in these classes may require prior authorization to determine medical necessity. All nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.
- Zoe Taylor: This is Zoe Taylor. I can second.
- Kevin Flynn: All right. All in favor.
- Multiple Speakers: Aye. Aye. Aye. Aye.
- Kevin Flynn: Any opposed? All right. Motion carries. We're still a little bit ahead of time, so the Neuromuscular Agents doesn't look like it will take that long. So I'd like to just proceed with that one and then we can go to lunch after that. So, Nina.
- Nina Huyhn: Okay. So next, we have the Muscular Dystrophy Agents. So Duchenne muscular dystrophy is a rare X-linked genetic disorder that involves progressive muscle weakness from degeneration of muscle tissues, leading to loss of ambulation, osteoporosis, cardiac and respiratory failure, and death typically by 30 years old. This wasting away of muscle is the result of genetic mutations that lead to the inability to produce dystrophin, a protein which is

essential for keeping muscle cells intact. The most common mutation responsible for DMD is a deletion over one or more exons presenting in 60% to 70% of cases, and exon duplications account for 10% to 15%. The disease affects approximately one in 3600 to 6000 male births and has a prevalence of approximately one in every 7250 males aged 5 to 24 years. Boys typically present with symptoms such as abnormal gait and proximal weakness between the ages of three and 5 years old. Without treatment, ambulation is usually lost by 12 years old. In 2025, the AAN emphasized that delandistrogene moxeparvovec remains an evolving therapy with uncertain clinical benefits. While the treatment reliably increased microdystrophin expression, the large placebo-controlled trial failed to show improvement in NSAA functional scores at one year, leaving real-world benefit unclear. A major challenge in interpreting outcomes is a requirement for high-dose corticosteroids, which independently -- improves strength and motor performance, making it difficult to isolate any true effect to the gene itself. From a safety standpoint, clinicians must be prepared for acute infusion reactions, including rare cases of anaphylaxis necessitating close monitoring during and after the infusion. Beyond that, the therapy requires significant infrastructure, specialized expertise, and ongoing clinical and laboratory follow-up to ensure patient safety over time. Ultimately, key questions persist regarding its durability, long-term safety profile, and how best to integrate therapy in the context of chronic steroid use. So in November 2025, the FDA updated the label for Elevidys after reports of acute liver failure in certain patients. The indication is now limited to ambulatory patients 4 years and older with Duchenne muscular dystrophy who have a confirmed DMD gene mutation. So it removed the non-ambulatory patients from eligibility. The label now includes a Boxed Warning for the risk of serious liver injury and acute liver failure. It also adds guidance to avoid use in patients with pre-existing liver impairment, active hepatic viral infection, recent vaccination within 4 weeks, or active recent infection, as these factors may increase safety risks or affect immune response to therapy. And then next we have the Spinal Muscular Atrophy Agents. So spinal muscular atrophy is an inherited neuromuscular disease that causes degeneration of the spinal motor neurons, leading to progressive muscle weakness and atrophy. Without treatment, Type 1 SMA is fatal before 2 years of age, primarily due to severe weakness and respiratory failure. The disease is caused by a mutation in the SMN1 gene, which results in a low level of SMN protein, an essential protein for motor neuron survival. The SMN2 gene acts as a backup and produces a small amount of the functional SMN protein, so patients with more SMN2 copies generally have a milder phenotype. Our gene therapy option,

onasemnogene abeparvovec, delivers a functional SMN gene using an AAV9 vector to increase SMN protein production. So in November of 2025, the FDA approved Itvisma, an adeno-associated virus-based intrathecal gene therapy for both adults and children 2 years and older with spinal muscular atrophy and a confirmed SMN1 gene mutation. Itvisma is given as a one-time fixed dose of 1.2×10^{14} vg delivered as a rapid intrathecal bolus over 1 to 2 minutes. The product is supplied as a single-dose vial containing 3 mL of suspension at a concentration of 4×10^{13} vg/mL. Treatment includes a structured corticosteroid regimen beginning with prednisolone 1 mg/kg/day, starting one day before therapy and continued for 30 days. After that period, steroid may be tapered over 28 days if liver tests are normal or continue until normalization if abnormalities persist. Itvisma carries a Boxed Warning for serious liver injury. So patients require baseline labs, including LFTs, coagulation studies, albumin, CBC, creatinine, and anti-AAV9 antibodies, and requires ongoing monitoring as well. The label advises against -- the label advises avoiding treatment during active or recurrent infections and ensuring routine vaccinations are up-to-date with consideration of RSV prophylaxis. Finally, Itvisma should not be used in patients who previously received IV Zolgensma, and re-administration is not recommended. And this concludes the Neuromuscular Agents. I'm happy to take any questions.

Kevin Flynn: All right. Any questions? Can we see the PDL?

Ryan Pistorosi: All right. And so as you see with this, we've got the two different disease states. The Duchenne Muscular Dystrophy agents are all in that top one, whereas the bottom two subclasses are for the spinal muscular atrophy, and then split between the gene therapies and the other agents.

Kevin Flynn: And so for -- I mean, most of these are all given, like, in a clinic setting. I mean, Spinraza has to be given intrathecally, so I'm [cross-talk] --

Ryan Pistorosi: Yes.

Kevin Flynn: These would never be really given outpatient, so.

Ryan Pistorosi: Usually, so for these agents, the reason that you see so many X's is that these are not available through the point of sale pharmacy system. These would have to be billed through a outpatient hospital claim type or professional claim type, so that's the reason. But given that these are all on the PDL, they

are part of our, you know, DUR review process. So that's why they're here today.

Kevin Flynn: Okay. Any questions? All right. We have stakeholders. Looks like we have three.

Nonye Connor: Yes. Yeah. Let me see. First one was Roslind. I'm so sorry if I'm pronouncing your name incorrectly, but I do not see a person on my list. If you're here, please go ahead and raise your hands. But I do have Armen. Okay, hold on. Let's see. Armen, go ahead and unmute you. Oops. Okay.

Armen Khachaturian: Thank you. Can you hear me?

Nonye Connor: Yes.

Armen Khachaturian: Awesome.

Nonye Connor: Let me go ahead and share my screen. And let me know when you're ready. I can start the timer.

Armen Khachaturian: Absolutely. I'm ready. Go ahead.

Nonye Connor: Okay. Thank you.

Armen Khachaturian: Hello, everybody. My name is Armen Khachaturian. I'm the Director of Medical Managed Care representing Sarepta Therapeutics Medical Affairs Team. I'm not going to take the whole three minutes. I just wanted to provide some additional information for the committee regarding delandistrogene moxeparvovec, the gene therapy for Duchenne muscular dystrophy. Likely at this point, the review of evidence seemingly didn't -- probably didn't include the recently published 2-year functional data post the EMBARC pivotal trial readouts. And within that second, that 2-year data, which just recently read out at the beginning of this year and was recently published in journals, we saw significant functional improvements across all measures when compared to external controls or functional stability and mitigation of decline when compared against matched external controls at the year two time horizon. And additionally, 3 years worth of data has since been presented at the recent Muscular Dystrophy Association Conference in March of this year, which showed even more profound separation of functional benefit compared to matched natural history and the decline within those

untreated patient populations. With that being said, not enough time to cover all of that, obviously within this three minute time horizon. So I would make myself available at any time in the near future to provide a more expansive and robust conversation and evaluation of that data with the Committee. And with that, I'll yield back my time to answer any questions.

Kevin Flynn: All right. Any questions?

Brad Pope: So that three-year follow-up, that was just after one administration?

Armen Khachaturian: Correct. Patients were infused one time at their initial infusion site time, and then 3 years later those patients have been followed on. Again, one of the challenges with these trials is, you know, we can't run a placebo-controlled trial for 3 years. Patients want to enroll in the Duchenne populations. We have this big challenge. So we were optimistic and confident that the results would materialize with more time to present to see those changes occur. So we're very happy with the three-year data, and happy to present them in more detail at any time.

Brad Pope: So it doesn't sound like you have, you know, a real long-term data, but is the anticipation that it is just a once-in-a-lifetime treatment?

Armen Khachaturian: So with regard to the first comment, long-term data, we do have 5 years worth of data for our initial first four patients. This is more confirmatory of the results we saw in those initial four patients that were dosed. So this is just adding to that body of evidence. So I agree with you, long term, technically no, but we do have up to 5 years and this seems to be reinforcing that trend that was observed in those initial four patients. And then what was the second question you asked?

Brad Pope: Well, so is the intention that this would always be just a once in a lifetime treatment?

Armen Khachaturian: The intent -- well, I mean, currently, physiologically, it is a one-time treatment. Antibodies would materialize after that initial infusion, and so the patients would not be able to receive a second infusion with gene therapy at this time. And so that's generally at this point in time, we're looking to provide that one-time infusion, give the cells the cellular capacity to create that microdystrophin to help stabilize muscle. So one time.

Brad Pope: Wow. Okay, thanks. Sounds like science fiction, but here we are.

Kevin Flynn: All right. Any other questions? If not, our next stakeholder.

Nonye Connor: Robert.

Rob Connop: Yeah, hello. Can you hear me?

Nonye Connor: Yes.

Rob Connop: All right. I am going to be brief also. So my name is Rob Connop. I'm a Pharmacist by training. I work as an MSL for Novartis Gene Therapies. And today, I'm going to be talking about Itvisma, which you already went over, did a pretty good job. It's a one-time intrathecal gene therapy administration. So you may be familiar with Zolgensma. It's the same construct, same SMN1 gene replaces the missing SMN1 gene that SMA patients have. The difference between this and Zolgensma is it's administered intrathecally, so we get to use a lower dose of 1.2×10^{14} vg. It's not per kg dose. And it's indicated for patients 2 years and older. So patients that have not received Zolgensma, essentially. It was approved based off of two studies. One, the STEER study, showed statistically significant differences in comparison to a sham control at end of 52 weeks of Hammersmith increase of 2.39 points versus -- well, it totaled versus 0.51, which was a total 1.88 difference in Hammersmith. If you look at the strength outcomes, we did see -- from a safety standpoint, in both steer and strength, we saw very consistent Adverse Events, things we were expecting based off of our experience with Zolgensma. And I'll just leave it at that. I'll yield back my time for any questions.

Kevin Flynn: All right, any questions? Hearing none. Next stakeholder.

Nonye Connor: Lynda. Lynda?

Lynda Finch: Yeah, hi, this is Lynda Finch. I did fill out a conflict of interest form. I think you had it under my legal name, which is Rosalind.

Nonye Connor: Oh, okay. Okay.

Lynda Finch: Yeah, so sorry. I'm here.

Nonye Connor: Let me know when you want. Okay, let me know when you want me to start the timer.

Lynda Finch: Yeah, you can go ahead and start. So good afternoon. I'm Lynda Finch. I'm a Medical Account Director for Biogen. We're the manufacturer of nusinersen or Spinraza. So on March 30th, the FDA approved a new higher dose regimen of Spinraza. And I understand that you may not be evaluating the new high-dose formulation today, but I'd like to share some information for your future consideration. So Spinraza has shown clinically meaningful and sustained efficacy across the SMA spectrum with a well-established safety profile of the lower-dose 12 mg regimen with more than 10 years of clinical trial and real-world experience in over 14,000 individuals. So recognizing the remaining unmet need in SMA that still exists despite available therapies, a higher-dose regimen was evaluated in two clinical trials. So the DEVOTE study, which included participants that were naive to SMA treatment and participants who were previously on Spinraza for at least one year. And these studies included individuals with both infantile onset and later onset of SMA of all ages. These patients are now being followed for up to 5 years in a long-term extension study called ONWARD. So the DEVOTE study met the pre-specified primary endpoint and led to clinical and significant improvements in motor function, survival, and all other outcomes relative to the infantile onset matched sham group. Trends favored the high-dose group over the 12 mg dosing group across nearly all secondary measures of efficacy in the infantile onset group. And then later onset participants, trends on the Hammersmith Functional Motor Scale and the revised upper limb module favored the high-dose group over the low-dose group in DEVOTE and in the matched low-dose and sham groups from CHERISH, our previous clinical trial in this patient group. We also saw clinically meaningful improvement in functional outcomes. The Hammersmith Functional Motor Scale and the revised upper limb module in previously treated participants who'd been on the 12 mg regimen of Spinraza for a median of 3.9 years when they were transitioned to the high-dose regimen and treated for one year. So these improvements would not be expected in patients who've already been on treatment for this period of time. They're generally stable, or in some cases, they may be declining by this point. But these improvements were observed across phenotypes, functional status, and age, and the most common AEs occurring in greater than 15% were pneumonia, respiratory failure, pyrexia, COVID-19, upper respiratory tract infection, procedural pain from the intrathecal injection, and headache. But overall, the high-dose regimen provides clinical benefit with a generally well-tolerated safety profile. So I'm

requesting today that the high-dose formulation be made available as an option for individuals with SMA. There is high unmet need still and so request that this be made available in the interim before you're awaiting review. So thank you for your time today, and please let me know if I can answer any questions for you.

Kevin Flynn: All right, thank you. Committee members, any questions? All right. Are there any other stakeholders?

Nonye Connor: No pre-registered, and I do not see any hands raised.

Kevin Flynn: All right, can we bring up the motion?

Ryan Pistorosi: Okay. And again, this motion does encompass both the DMD and the Spinal Muscular Atrophy Agents.

Christy Weiland: This is Christy Weiland. I move that all products in the drug class listed on Slide 16 are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in these classes may require prior authorization to determine medical necessity. All nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Laura Beste: This is Laura Beste. I second the motion.

Kevin Flynn: All right. All in favor, say aye.

Multiple Speakers: Aye. Aye. Aye. Aye.

Kevin Flynn: Any opposed? All right. Motion passes. All right, with that, it looks like we're right on schedule for lunch. So we will return at 12:40.

Nonye Connor: Okay. I will put that up. Thank you.

Kevin Flynn: Thank you. Great.

Ryan Pistorosi: Thank you.

Nonye Connor: Thank you.

[break]

Kevin Flynn: All right, welcome back. I can ask the Committee members to turn on their cameras so we can take attendance.

Nonye Connor: Okay, we are -- we have a quorum. Thank you.

Kevin Flynn: All right. I think our next topic is Oncology Agents. Thank you.

Nina Huyhn: Thank you. So this is Nina. Next is Oncology Agents. So first, we'll go over Marginal Zone Lymphoma, or MZL, which is a group of indolent B-cell non-Hodgkin's lymphomas that primarily affects adults around the age of 60 and tends to follow a slow chronic course. We typically divide MZL into three major subtypes. The most common is extranodal MZL, often referred to as MALT lymphoma, which arises in mucosal-associated lymphoid tissues. Less commonly, we see nodule MZL, a primary nodule lymphoma without extra nodule or splenic involvement. And the third subtype is splenic MZL, a distinct entity characterized by involvement of the spleen, bone marrow, and peripheral blood. Biologically, these lymphomas share a characteristic immune phenotype and many cases are linked to chronic antigenic stimulation, whether from infections like *H. pylori* or underlying autoimmune disease. While the clinical behavior is generally indolent, we remain mindful of the potential for histologic transformation, most commonly to diffuse large B-cell lymphoma, which carries different management considerations. So, for relapse or refractory MZL, the 2026 NCCN Guidelines outline several systemic treatment options. First, we look at the Bruton Tyrosine Kinase inhibitors, which remain central in the setting. Zanubrutinib is the preferred BTK inhibitor based on its strong efficacy and tolerability profile across MZL subtypes. Acalabrutinib is another BTK option for appropriate patients, and pirtobrutinib is reserved specifically for those who have already been treated with a covalent BTK inhibitor. On BTK inhibitors, other systemic regimens remain important. One option is bendamustine combined with obinutuzumab, which offers acidotic plus anti-CD20 approach for patients who may benefit from deeper disease control. Immunomodulatory-based therapy is also included, with lenalidomide plus rituximab, or lenalidomide paired with obinutuzumab as alternatives depending on patient characteristic and prior therapy. And then finally, for patients who progresses through multiple lines of therapy, the NCCN

includes CD19-directed CAR T-cell therapy, such as lisocabtagene maraleucel as the third-line option. Okay. Follicular Lymphoma, or FL, is the most common subtype of indolent non-Hodgkin's lymphoma and accounts for roughly 22% of all new NHL diagnoses. It typically presents in older adults with the median age around 60 and is often diagnosed at an advanced stage due to its slow and clinically subtle progression. Biologically, FL has a classic immunophenotype, which helps distinguish it from other lymphomas. A hallmark abnormality is the t(14;18) translocation, leading to BCL2 overexpression and contributing to its indolent behavior. Although the disease is generally slow-growing, it follows a chronic relapsing course and remains incurable with current therapies. Importantly, FL carries a 2% to 3% per year risk of histologic transformation, most commonly to diffuse large B-cell lymphoma, which has significant impact -- implications for prognosis and treatment strategies. So for relapse or refractory follicular lymphoma, the 2026 NCCN Guidelines outline a variety of second-line and later-line treatment options. So starting with second-line therapy, patients who haven't previously received chemoimmunotherapy can still be treated with those combinations, but much of the focus in the setting shifts towards immunotherapy and targeted option, most notably the lenalidomide-based regimens with either lenalidomide plus rituximab or the newer triplet approaches that pair lenalidomide with a CD20 or CD3/CD20-directed agents. For patients progressing beyond this, third-line and later therapy is anchored by T-cell-mediated strategies. Preferred options include both the bispecific antibodies and the CD19-directed CAR T-cell therapies, which provide meaningful activity in multiple relapse disease. So in December of 2025, the FDA approved Breyanzi for adults with relapse or refractory MZL after at least two prior lines of systemic therapy. This marks the first CAR T-cell therapy available for relapse or refractory MZL. The recommended dose is 90 to 110 million CAR-positive viable T-cells delivered as a balanced 1:1 ratio of CD4 and CD8 components. And then in February of 2026, the indication for adults with relapse or refractory follicular lymphoma after at least two prior line-of-therapy was converted from accelerated approval to full approval. In October of 2025, the FDA added a Box Warning to Carvykti for immune effector cell-associated enterocolitis, which has caused severe diarrhea, abdominal pain, weight loss, and in rare cases, GI perforation and sepsis. Despite this, the FDA stated that benefits still outweigh risks and added updated CARTITUDE-4 data showing improved overall survival. The label also now includes risk of GI T-cell lymphoma and GI perforation. Then in February of 2026, the FDA issued a safety update for capecitabine, Warning about serious toxicity in patients with DPD deficiency. The agency

now recommends DPYD genetic testing before treatment. And then in the past year, we have two new generics that were approved. The first generic version of Purixan 20 mg/mL oral suspension, and a new generic of Gleostine oral capsule. In addition, in October of 2025, a new 10 mg tablet strength of Xpovio was approved, expanding the available dosing options. And this concludes the Oncology section. I'm happy to take any questions.

Kevin Flynn: All right. Are there any questions? All right. Can we look at the PDL?

Ryan Pistorresi: One second, I'm bringing that up. Okay, that should be on the screen now. If there are no questions, I'll hand it over to Nonye.

Kevin Flynn: Okay. It didn't look like there was any stakeholders that were signed up.

Nonye Connor: No. There were no pre-registered stakeholders, and there are no hands raised.

Kevin Flynn: Okay, look at the motion.

Ryan Pistorresi: All right. So the motion is for these subclasses.

Greg Hudson: This is Greg Hudson. I can do the motion. I move that all products in the drug classes listed on Slide 18 are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of the HCA. Products in these classes may require prior authorization to determine medical necessity. All nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Brad Pope: This is Brad Pope. I'll second that.

Kevin Flynn: All right. All in favor.

Multiple Speakers: Aye. Aye. Aye. Aye.

Kevin Flynn: Any opposed? All right. The motion carries. All right. Asthma and COPD Agents.

- Nina Huyhn: Okay, and this is my last class that I will be reviewing today and is Inhaled Glucocorticosteroids with one minor update. So in June of 2025, AirDuo RespiClick was discontinued. The generics remain available. And that concludes my portion of the meeting. I'm happy to take any final questions. All right. Thank you, everyone.
- Kevin Flynn: Thank you. And then the PDL.
- Ryan Pistorosi: All right. So the PDL should be up for the Inhaled Corticosteroids and the Inhaled Corticosteroids Combinations. So the combinations like Advair are up top, and then the solo products are below.
- Kevin Flynn: Are there any questions? Are there any stakeholders?
- Nonye Connor: Lisa, I had you registered for this drug class. Is that correct?
- Lisa Wilshaw: Yes.
- Nonye Connor: Okay, perfect. Just give me a quick second. Let me put the timer up. And it's coming. Sorry about that. There we go.
- Lisa Wilshaw: Perfect. Thank you. I'm ready. Hello, my name is Lisa Wilshaw and I'm a PharmD and Clinical Account Director at AstraZeneca. Thank you again for the opportunity to present some information on Breztri Aerosphere inhaler today. So Breztri is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease or COPD. Breztri is not indicated for the relief of acute bronchospasm or the treatment of asthma yet. Breztri contains 160 mcg of budesonide, which is the inhaled corticosteroid, 9 mcg of the LAMA glycopyrrolate and 4.8 mcg of the LABA formoterol fumarate per actuation. So it's two actuations for one dose, and it is dose b.i.d. So Breztri is the only ICS/LAMA/LABA combination inhaler product available in a pressurized meter-dosed inhaler, which is important for patients options in treating COPD. Nina did a really great job earlier in the day of covering updates for the GOLD, so I'm not going to go through all the COPD 2026 GOLD Report updates. But it does specifically recommend triple therapy as an option for initial pharmacologic treatment among appropriate COPD patients. And it states that beneficial response with that ICS/LABA/LAMA combination is observed when you are treating patients with eosinophil counts greater than or equal to 100 cells/ μ L. The GOLD Report also states that even the patient that is currently not suffering from exacerbations, that

triple therapy is recommended for patients on a current ICS/LABA combination with high symptom load. And finally, triple therapy is recognized in GOLD as the only pharmacologic therapy with a treatment effect on mortality. So I'll refer you to the Breztri Prescribing Information for the other additional information regarding Warnings and Precautions. But based on some of the information she shared on COPD epidemiology, the GOLD 2026 update for recommendations, and especially round triple, AstraZeneca respectfully requests that Breztri be added on your preferred drug list without a step-through to other preferred inhaler agents in this inhaled corticosteroid combination drug class for Washington Medicaid patients. Thank you, and I'll address any questions.

- Kevin Flynn: All right, thank you. Is there any questions from the Committee? All right, hearing none. Are there any other stakeholders?
- Nonye Connor: Sorry, I was speaking when muted. I was saying I did not see any hand raised.
- Kevin Flynn: All right. Can we see the motion?
- Ryan Pistorresi: All right. And so the motion is for these two subclasses.
- Kevin Flynn: I can make the motion. I move that all products in the drug classes listed on Slide 20 are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in these classes may require prior authorization to determine medical necessity. All nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.
- Laura Beste: This is Laura Beste. I'll second the motion.
- Kevin Flynn: All right. All in favor, say aye.
- Multiple Speakers: Aye. Aye. Aye. Aye. Aye.
- Kevin Flynn: Any opposed? All right. Motion carries.
- Ryan Pistorresi: Great. And then as Nina had mentioned, she does not have any other class updates. And so for my portion, I'm just highlighting that these are the

remainder of the drug classes that were reviewed today with all of the subclasses that have no clinical updates either from HCA or from Prime. So as you remember, you know, we did Asthma/COPD earlier. We did the Hematopoietic Agents, you know, earlier this morning. After lunch, we started with the Oncology. So this is just showing the rest of the subclasses that were part of the larger drug classes that were reviewed today but do not have any clinical updates. With that said, I am going to the PDL to show you what are the drugs within each of these different drug classes. So that way you are aware of the rest of the drugs. So in case you were wondering if we were going to talk about the Anticholinergics or the Long-Acting Muscarinic Agents. There are no clinical updates, but they are part of the review today. And I apologize when I was doing some of the formatting, you do get some extra lines in here. So like in the Anticholinergics, it's not saying that these are the different ones. So you do kind of have to look at these. So I'm sorry for some of the erratic extra lines in here. And so moving on from the Asthma/COPD, I'll just scroll down to the top of the Hematopoietic Agents. And then I'll scroll down to the top of the Oncology Agents, which is going to be the largest of these. Actually, one second. There. So that way you can see all the Oncology together now on your screen. Okay? If there are no questions on this, I will switch back to the motion.

Kevin Flynn: Do we [cross-talk] --

Ryan Pistorresi: [Cross-talk] Unless we have stakeholders.

Kevin Flynn: Yeah, we still can have stakeholders, correct?

Nonye Connor: Yeah, let's see. I have Jalan. I'm so sorry if I mispronounced your name.

Jalan Hamoud: Yeah, hi. This is Jalan.

Nonye Connor: Yes. Let me go ahead and share my screen. Give me a quick second and so that you can -- I'll start the timer whenever you're ready.

Jalan Hamoud: Yeah, I am.

Nonye Connor: Perfect.

Jalan Hamoud: Well, thank you for this opportunity. My name is Jalan Hamoud. I am MSL here at Medunik, and I am presenting Siklos as a treatment option for sickle

cell anemia patient. Siklos is the first FDA-approved hydroxyurea indicated for patient 2 years of age and older with sickle cell anemia. Hydroxyurea remained the GOLD standard disease-modifying treatment for sickle cell anemia patients because of its safety and efficacy shown in several clinical trials. However, during those trials, the dose was always precisely adjusted to the patient's body weight, which is not the case in rare practice. With some of the current formulation, a prescriber must either use a higher dosing or lower dosing of capsules or dose for every other day, which is not an optimal treatment, especially for a child with rapidly changing weight, and especially with actual situation where there are some shortages of capsules and compounding hydroxyurea. And the film-coated Siklos oral tablets are available as 100 mg scored tablets and 1000 mg triple-scored tablet, which offers a variety of strength from 50 mg to 1000 mg to help the physicians to titrate correctly and precisely each patient based on his weight. And for patients who are not able to swallow the tablets, these can be dissolved in a small quantity of water on a teaspoon. In a prospective and observational clinical study in almost 2000 pediatric patients that had been treated with Siklos for one year, there was a highly significant decrease in painful crisis, in acute chest syndrome, in hospitalization, and in blood transfusions. The NIH guidelines recommend starting hydroxyurea at 9 months of age. In fact, Siklos has been studied in pediatric patients less than 2 years of age, with published data demonstrating its efficacy and safety compared to placebo in this patient population. And the label change request is submitted to the FDA to include patients under 2 years of age. However, please note that the indication is currently limited to patients 2 years of age and older. So for important safety information on Siklos, I refer you to Siklos Prescribing Information. Thank you, and I respectfully request that Siklos remain within the preferred drug list. And I'm happy to take any question you might have. Thank you.

Kevin Flynn: Thank you. Are there any questions for the stakeholder? All right, hearing none. I think we had one more stakeholder preregistered.

Nonye Connor: Yeah. Let me see if Anna is still here. Anna Allen, if you're here, please raise your hand. I am not seeing her. I'm not seeing her here.

Kevin Flynn: All right. Are there any other stakeholders who didn't pre-register?

Nonye Connor: I do not see any other hand raised.

Kevin Flynn: Okay. We can move on to the motion then.

Ryan Pistorosi: All right. So just a reminder, these are the drug classes for the final motion of the meeting.

Laura Beste: [Cross-talk] This is Laura Beste [cross-talk] --

Brad Pope: [Cross-talk] This is Brad Pope. [cross-talk] --

Laura Beste: Go ahead.

Brad Pope: Go ahead.

Laura Beste: Okay. I move that all products in the drug classes listed on Slide 22 are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of the HCA. Products in these classes may require prior authorization to determine medical necessity. All nonpreferred products require trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Brad Pope: And this is Brad Pope. I'll second it.

Kevin Flynn: All right. All in favor, say aye.

Multiple Speakers: Aye. Aye. Aye. Aye.

Kevin Flynn: Any opposed? All right. Motion carries. All right, that -- at this time that concludes our agenda. So thank you to all the Committee members and everyone from the Health Care Authority. Did I forget something?

Nonye Connor: Sorry, if you could just -- I know we finished and, but if we can just adjourn the DUR Board, please?

Kevin Flynn: Oh, yes, this officially adjourns the DUR board.

Nonye Connor: I know. Thank you so much. I appreciate it.

Kevin Flynn: All right.

Nonye Connor: Well, that's it, everyone. Enjoy the rest of your day. Thank you again, everyone. Thank you. Thank you.

Ryan Pistoiresi: Bye-bye. Thank you.

[end of audio]