

**Washington State Pharmacy and Therapeutics Committee
Drug Utilization Review Board
Meeting Transcription
February 18, 2026**

Nonye Connor: Okay, perfect. Laura?

Laura Beste: Good morning. Welcome to the February 18th P&T Committee DUR Board meeting. And we will now convene the P&T/DUR Committee meeting. I'm Laura Beste, the Vice Chair of the P&T/DUR Committee. And I will now read off the names of participating attendees. Please say "here" when I call your name. P&T Committee members, Hope Barnes.

Hope Barnes: Present.

Laura Beste: Kevin Flynn.

Kevin Flynn: Present.

Laura Beste: Matthew Guindon.

Matthew Guindon: Yeah, that's right. Here.

Laura Beste: Gregory Hudson.

Greg Hudson: Good morning. Here.

Laura Beste: Alex Park.

Alex Park: Morning. Present.

Laura Beste: Bradley Pope.

Bradley Pope: Present.

Laura Beste: Zoe Taylor.

Zoe Taylor: Here.

Laura Beste: And Christy Weiland.

Christy Weiland: Good morning. Here.

Laura Beste: Morning. For Health Care Authority members, we have Nonye Connor.

Nonye Connor: Morning.

Laura Beste: Amy Irwin.

Nonye Connor: I don't know if she's here yet.

Laura Beste: Okay. Luke Dearden.

Luke Dearden: Good morning.

Laura Beste: Morning. Ryan Pistorosi.

Ryan Pistorosi: Good morning.

Laura Beste: Elizabeth Punsalan.

Elizabeth Punsalan: Here.

Laura Beste: Donna Sullivan -- maybe not here yet.

Nonye Connor: Let me see. Maybe not here yet.

Laura Beste: Okay. Ryan Taketomo.

Ryan Taketomo: Good morning, I'm here.

Laura Beste: Morning. Joey Zarate.

Joey Zarate: Good morning.

Laura Beste: Morning. For Labor and Industry members, we have Jaymie Mai.

Jaymie Mai: Here.

- Laura Beste: Christy Pham.
- Christy Pham: Not here.
- Laura Beste: Okay. And then we have Drug Effectiveness Review Project, the DERP presenters, Jennifer Lyon [cross-talk] --
- Nonye Connor: [Cross-talk] I don't see her here.
- Laura Beste: [Cross-talk] And Nina Huynh.
- Nina Huynh: Good morning, here.
- Laura Beste: Good morning. And for Managed Care Organization representatives, I'm just going to read off the names. No need to stay here. We have Greg Simas from Molina Healthcare, Heidi Goodrich from Molina Healthcare, Petra Eichelsdoerfer from United Healthcare, Omar Daoud from Community Health Plan of Washington, and Jeffrey Natividad from Community Health Plan of Washington. And now I will give it back to Nonye for going over meeting logistics.
- Nonye Connor: Okay. Thank you, Laura. So the Committee and presenters can mute and unmute themselves at any time. So please mute yourself when not speaking to limit background noises. Presenters, please share your web cameras when presenting. Committee, please share your web cameras during discussions and motion consideration. For stakeholder participation, the Chair will read from the list of stakeholders who pre-registered to speak. When your name is called, we will unmute you. Once all pre-registered speakers have been called, the Chair would then ask -- or Vice Chair in this instance -- will then ask if there are any additional stakeholders. If there are, please raise your hand. We'll call on you and unmute you. You can also use the question and answer box. We'll answer your questions during the stakeholder comments period. If you did not fill out the stakeholder conflict of interest form, please answer the questions that will be posted on the screen, and then your three minutes will start after you've answered those questions.
- Laura Beste: So next, I believe we're voting on committee vote on the new Chair and Vice Chair. Is that correct?

- Nonye Connor: Yes, that is correct. So sorry, we do have to vote for a new committee member for this coming year. As you may have noticed, our previous committee member Dr. Barkett has finished his term, and so now we need to vote for a new person. So if we want to go ahead and want to start putting our hands up or start, I'll just leave it up to you guys to decide on who you want to start who wants to be your Chair.
- Laura Beste: This is Laura Beste. I would vote for Alex Park, 4as he did a phenomenal job when I first started and has a lot of good insight to always offer. And as Vice Chair, I was going to recommend Gregory Hudson also having good insight all the time.
- Nonye Connor: Okay. So we have Alex Park for our Chair and Gregory Hudson for our Vice Chair. Alex, I see your hand is raised.
- Alex Park: Yes. Thank you, Nonye. Thank you, Laura, for the vote of confidence. Before the votes start running away in that direction, let me also put in my words here. First of all, I just wanted to say thank you to Dr. Barkett. I know he's not with us, but I thought he did a fabulous job as Chair, and to you as well, Laura, for doing a fabulous job as Vice Chair. I would love to put some votes in the copper here for Kevin Flynn as Chair and Christy Weiland as Vice Chair. I've really valued both of your insights over the years, and I've learned a lot from you by participating on this committee with you.
- Nonye Connor: Thank you. Any other vote?
- Christy Weiland: This is Christy Weiland. I um -- I think Alex Park or Kevin Flynn would both be fantastic and have held a lot of value on this. Is there -- or I guess I'm wondering is there interest in both -- for both of you? Because I think either one of you would lead lovely.
- Alex Park: To answer your question, Christy, I, you know I've done it before, and it's a lot of fun, and it's a great honor. I don't want to usurp the position in any way. I've had my chance, and we've got a lot of great people here. And so if it falls that way, I'll take it. But I really want to encourage all of you to think about the other committee members because we've got a richness of knowledge and expertise here outside of me and my big mouth. So please consider that. Thanks.

- Kevin Flynn: If it's the Committee's decision that they'd like me to be Chair, I'd be happy to take on the roll.
- Nonye Connor: Hope?
- Greg Hudson: Oh, I was -- I was just going to say for Laura, thank you. I appreciate the nomination as Vice Chair. I again, I think -- I agree with Alex that we have a wealth of experience, and I think both Kevin and Alex would be excellent Chairs. And I guess I just wanted to ask Christy if she had any -- I don't know if she had any thoughts on the position of Vice Chair or, um, I guess the same question you posed to Kevin and Alex.
- Christy Weiland: Sorry, Hope. I know you've had your hand up. Do you want to go, and then I'll answer Greg?
- Hope Barnes: Absolutely. Good morning, everyone. I am new to this committee, and I have been astonishingly impressed with everyone on the Committee. I really appreciate the insight. I happen to know Laura and Christy very well, and I think they're both amazing. And I have interacted with Kevin as well outside of our organization. And I also really appreciate Zoe. I think she's on the call today. She has a lot of great insight. My question is, is there anyone really interested in the position? As a person I am not. I just joined the team, and I'm still learning the ropes. But there is a lot of great candidates as you all tend to echo here in your comments.
- Christy Weiland: Great. Thanks for asking. I am happy to serve but also don't feel like I need to at all. And so if you -- I think you would be fantastic. And if you are ambitious to do that, that is, yeah, I'm happy with that, too. Not a great answer. I'm sorry.
- Greg Hudson: I feel about the same, and I'll leave it up to the Committee, I think, because I...
- Laura Beste: So, Nonye, how is this usually handled? So it sounds like we have two candidates for Chair and two candidates for Vice Chair. Do we just raise hands? Do we go through and just vote then?
- Nonye Connor: Yes. Okay [cross-talk] --
- Laura Beste: [Cross-talk] Is that led by you, or am I supposed to leave that?

Nonye Connor: You can leave that, please.

Laura Beste: Okay. So for Chair, we have a nomination for Alex Park and Kevin Flynn. So if anybody wants to put up their hand to vote for Alex Park. So [cross-talk] looks like we have one, two. Okay. So we have two. [cross-talk] That's it?

Nonye Connor: [Cross-talk] three hands. We have three hands [cross-talk] for Alex Park.

Laura Beste: [Cross-talk] For Alex, okay.

Nonye Connor: Yep.

Laura Beste: Maybe I can't see. Okay.

Zoe Taylor: Well, one of them is yours, Laura.

Laura Beste: Oh. [laughter] Okay. And then for a Vice Chair, we have Christy Weiland and Greg Hudson. So let's go with Greg Hudson first if anybody would like to put up their hand. So it looks like we have four?

Nonye Connor: Yes.

Laura Beste: Okay. And [cross-talk] --

Nonye Connor: [Cross-talk] I think we. [cross-talk] I'm sorry, [cross-talk] go ahead, go ahead, go ahead, go ahead.

Laura Beste: I mean do you just want to go forward with that?

Nonye Connor: We didn't vote for Kevin, so yeah.

Laura Beste: Oh [cross-talk].

Nonye Connor: Yeah.

Laura Beste: Sorry.

Nonye Connor: No, that's okay.

Laura Beste: Sorry, let me go back. So hands for Kevin, please, for Chair. Okay. So it looks like we have five hands. So our new Chair, congratulations, is Kevin Flynn.

Nonye Connor: Yes. [Cross-talk] And then --

Laura Beste: [Cross-talk] And -- go ahead.

Nonye Connor: Sorry. No, go ahead. We didn't vote for Christy for Vice Chair.

Laura Beste: Right, I know. I was coming back to it [cross-talk] --

Nonye Connor: [Cross-talk] Okay.

Laura Beste: And then for Vice Chair, we raised our hand already for Greg Hudson, and we had four hands. So for Christy Weiland, we have -- please raise your hand. So we have five hands, so it looks like our new Chair is Kevin Flynn with Christy Weiland as our Vice Chair. Congratulations. Looking forward to this next year in P&T with you.

Nonye Connor: Thank you. Thank you, everyone. I appreciate that.

Kevin Flynn: Thank you, both, for doing this for us.

Nonye Connor: [Laughter]. Congratulations, congratulations. Thank you, Kevin and Christy. Thank you. Okay. So next, we're going to go -- I'm sorry, Laura, it's -- I am so sorry. You are.

Laura Beste: That's okay. So next, we will have the P&T and DUR Overview by Donna Sullivan.

Donna Sullivan: Hey, good morning. This is Donna. [cough] I'm not going to be on camera this morning. I have a cold, and I'm just not camera ready. So can you get the slides up, Nonye?

Nonye Connor: Yes. Oh, sorry. Can you guys see my screen?

Donna Sullivan: Yeah.

Nonye Connor: Okay, thank you.

Donna Sullivan: Okay, so every year, usually in February, we go over just kind of an overview of the P&T Committee and the DUR Board just to let you know what the functionalities are and the little nuances between the two committees. So I first wanted to introduce the staff that will usually support the Committee and the DUR Board. I'm Donna Sullivan, I'm the Chief Pharmacy Officer. My role in HCA is pretty much everything prescription drugs and prescription drug purchasing. We oversee our Medicaid program, which we call Apple Health, as well as the programs, the benefits, health benefits for our public employees and school employees. That's PEB and SEB. We also have a drug price transparency program and it's Prescription Drug Affordability Board. And we are part of ArrayRx, which is -- used to be called the Northwest Prescription Drug Purchasing Consortium. So all of that really falls under my hat for my responsibilities. And then the rest of my team, part of my team, Ryan Pistori, he is the Assistant Chief Pharmacy Officer. He's primarily overseeing our PEB and SEB Pharmacy Benefit Program. He also oversees some of the clinical policy development and is our representative on the Drug Effectiveness Review Project. He was on the Governance Board previously. I think his term is up, but he has represented us before. We also have Amy Irwin, who is our Medicaid Pharmacy Operations Manager. I don't think she's with us today. She really oversees the Medicaid Fee-For-Service pharmacy program, primarily the operations. We manage everything in-house, so we do all of our prior authorizations in-house. We do all of the programming of our system in-house. So she manages that team that keeps our system up and running and answers a lot of questions from providers and clients. And then she also helps with the cost analysis for the Washington PDL. The next slide. And then we have Nonye Conner, who's our Pharmacy Program Project Manager. Her role here is really the logistics of the P&T Committee meetings. If there's any travel or getting your pay, that's all done through Nonye. We have Marissa Tabile, who is our Apple Health PDL and Drug Utilization Review Manager. Marissa is out on family leave. She had a baby last year, and she will be back, I believe, in May. So we're really excited for her. We also have Luke Deardan, who is a Clinical Pharmacist. He works primarily with Ryan over the PEB and SEB program. Luke also works -- does a lot of work on the clinical policies with us at -- for Apple Health. We have Ryan Taketomo, another Clinical Pharmacist. Ryan is really our kind of pipeline manager and trying to review the pipeline. Unfortunately, we have been inundated with requests for GLP-1s for weight loss, primarily for the obstructive sleep apnea, the MACE and the masks. So Ryan's really been focusing on doing those authorizations and trying to keep us -- keep us on task. So he does -- is really working hard on those. And then he also does

work on the clinical policies as well. We've split them between the three pharmacists. We also have Joey Zarate, who is our Apple Health PDL coordinator. Joey manages the new drugs to market or our new drug report that comes out. Every week there are new NDCs and new drugs that get published in First Data Bank, which is our drug reference file that we use, and Joey coordinates with the pharmacists to make the decisions on how those drugs are going to be covered as they come out to market. Next slide. We then have Labor and Industries also participates in the P&T -- the Washington P&T Committee. We have Jaymie Mai, who is the Pharmacy Director for Labor and Industries, and she's also a representative to the prescription drug program. She sits on the Steering Committee for ArrayRx as well. We have Doug Tuman, who's a pharmacist. He's a backup for the prescription drug program. And then Christy Pham, also a pharmacist, and she's responsible for implementing the PDL changes for Labor and Industries. So our history is back in 2003, the legislature created the Washington State Prescription Drug Program, and it was a coordinated effort at that time with the Health Care Authority's Uniform Medical Plan, the Medicaid Fee-for-Service Program, which at that time was in the Department of Health and Social Services, and then as well as the Labor and Industries Program. So it was like a consolidating -- consolidated purchasing initiative, really, that was passed by the legislature. They also created an evidence-based prescription drug program, which evolved into our Washington State Preferred Drug List. And the Washington Preferred Drug List is a subset of each program's overall formulary or drug list. And the goal really was to have -- was getting towards evidence-based medicine and really looking to control prescription drug costs without reducing the quality of care. And back in 2003, we were worried about Lipitor and Crestor breaking the bank and Prilosec and Nexium and all those coming out, so the landscape has really changed. So if you're looking at what's really on the Washington Preferred Drug List, it's not necessarily the really expensive drugs that we see that are coming to market now. So we've evolved over time. There are about 30 classes, I think, on the drug list. So next slide. I'm probably getting ahead of myself. So there are components of the Washington Prescription Drug Program. It's the Pharmacy and Therapeutics Committee that was established by the legislature, the Washington Preferred Drug List. There's an endorsing practitioner Therapeutic Interchange Program. ArrayRx was really a piece -- a part of that. And then we have the Apple Health Pharmacy Program as well. Next. So the P&T Committee has 10 members. The membership we made based on the federal requirements for the Drug Utilization Review Board, which basically says you can't have more

pharmacists or more physicians on the Committee, or more than 51% pharmacists or 51% physicians, I believe, is what the statute says. So what we did is we chose to go with four physicians, four pharmacists, a physician assistant, and an advanced registered nurse practitioner. And we've maintained those positions in order to make it so that there's not a 50%, either pharmacist or physicians on the Committee. We used to meet six times a year, every even month. But our goal is to meet at least four times a year. Due to the budget constraints is one of the reasons why we have reduced it down to just four times a year. Plus it gives the team more time between some meetings in order to get our policies in up to speed and ready for presenting to the Committee or to the DUR Board. And then the Committee -- so the difference between the Committee and the DUR Board is the Committee is making decisions for the Washington Preferred Drug List, which is not the same as the Apple Health Preferred Drug List. So the Washington Preferred Drug List impacts Labor and Industries and Uniform Medical Plan, which are not part of the Medicaid program. So next slide, please. So the roles and responsibilities. You just elected the new Chair and Vice Chair, so congratulations to both of you. The Chair really manages the meetings and makes sure that we're following the business rules of voting on making a motion, getting it seconded, getting a vote. And the Vice Chair will perform the duties of the Chair when the Chair is not here. Each year, we do ask that the Committee members fill out a Conflict of Interest form. The Committee also will review the reports that are prepared by the Drug Effectiveness Review Project, or also known as DERP, and compare the evidence of the drug safety and efficacy and use in special populations is really the challenge of what you're being asked to do and then determine whether or not these drugs are safe and efficacious and also to see if they could be interchanged. And I'll go into the interchange program a little bit in the next few slides. So next slide, Nonye. So the P&T Committee really needs to consider the overall quality of the evidence provided. And we really rely on only the Drug Effectiveness Review Project reports for the Committee to review. And we want you to review it from the provider and the patient perspectives. But it's limited to the -- these DERP reports because it is, we think, unbiased -- or to the most part unbiased. The Drug Effectiveness Review Project, they've been around since, I think, about 2002. We've contracted with Oregon Health Science University for many years, and they do a pretty in-depth literature search and then put the data together in a way that's understandable. They'll grade the data high, medium, and low, and present it to the Committee. And so we're really wanting to consider the HARMS and benefits of the drugs that you review. And at some times we'll

pick -- there might be a drug that is found to be safer or more harmful or more effective than others, and the Committee has the opportunity then to make recommendations based on that evidence. Next slide. So the Drug Effectiveness Review Project, it is 12 states and mostly Medicaid agencies and some of the public pharmacy programs like the employers or L&I will also use these reports. The 12 states are listed on the slide. I'm not going to read through them all. The membership does change. We've had as many as 16 states some times. There's also the Med Project and Medicaid Evidence Decision-making group, and many of the states are members of both programs. But like I said, the membership has waxed and waned, but there are pretty much the core states. Idaho, Washington, and Oregon have really been the founding states of the DERP program and have been with the DERP program since its beginning. So next slide. So the type of DERP reviews. So we mentioned that we do rely on the drugs that are reviewed by the Drug Effectiveness Review Project. So in order to be considered in a class on the Washington PDL, the drug has to have been reviewed in a DERP report. And there are several different types of reports that have evolved over time as well as the landscape has changed. And I do see, Brad, you have a question. So sorry, I didn't notice.

Bradley Pope: Yeah, I was just curious. When DERP had a larger number, why did some -- what were the reasons for some of the states dropping out?

Donna Sullivan: You know, it's varied over the state. I think over time, I think mostly it's money. When a state is in a budget shortfall or something, it's about \$100,000 a year to participate in DERP. Sometimes in the very beginning, the reports that were published by DERP, we actually made them public. And so it got to the point where if it's a public report and your state's paying \$100,000, why should I pay \$100,000 when I can just wait for it to be posted online and get it for free, right? So at some point in time, and I don't remember exactly when the DERP, the governing board, which is made-up of representatives from all of the states, chose and voted to no longer make the reports available publicly. So that would encourage states to join. But some states may not get exactly what they need out of the program as well. It is a challenge when you have that many different states that each use the DERP reports differently. For us, we want to be able to review all of the classes on the Washington Preferred Drug List every year. And in order to do that, we're spending collectively the money from the entire group to do those reports. And it might not be the priority of other states to review a drug class that has been on the market for five or 10 years, and they're not -- it's not their

primary focus. So there are many different reasons, I think, why states have come and gone.

Bradley Pope: That helps me. Thank you. Thank you for your response.

Donna Sullivan: And it has evolved over time, too. You know, we used to do these scan reports, which would just scan the literature. And so I won't get too long because I'm probably going to run over my time. But anyways, it has evolved. The drugs do have to be reviewed by DERP. And primarily, there will be a new class review, which is how kind of the drugs get initiated into the program. And then we'll have an update to an existing class review. If a new drug comes out and we don't want to do a full class review because maybe the cost is too high, but we want to be able to add a drug to the PDL, we can do a single drug addendum. And so that would just review that drug, and that's not included in the existing class review. And it basically what it does is it updates the class to allow that drug to be included. And then we have topic briefs. So each year, the states will put forth topics of like drugs that they want reviewed or policy decisions or policy items that they would like reviewed and DERP will create a topic brief. And for a drug, what that really means is they'll look to see at the evidence, and they'll compile some -- they'll summarize the evidence. They don't actually go in and evaluate the evidence, but they'll let us know how many -- if there are any head-to-head trials, if it's all placebo-controlled trials, and things like that. And then the DERP will actually vote to see if they want to move forward with a full on review of the drug or policy that was the subject of that topic brief. Surveillance reports for an existing drug where new drugs are not eligible for inclusion on the PDL, it summarizes the availability of new evidence in the class. So we'll do these surveillance reports, which really just when we have an existing drug class, the surveillance report is looking to see what new information is out there. Maybe there's new head-to-head trials that were published since the last report that weren't available before. And again, they'll summarize that evidence. They'll identify any new drugs within that class that have come out. If there's new INDICATIONS, new BLACK BOX WARNINGS or anything like that. And then, again, as part of our annual decision making at the DERP level, we decide what reports are going to be -- what reports are going to be funded for that year going forward. So the surveillance report might come to you just as an update where the Committee can then approve it as an adequate update. Or if they feel like there's too much new evidence out there, they might request an updated class review that the state would have to probably pay for ourselves, if it wasn't voted on by the entire by the DERP

collaborative. So the next slide. So the PDL process is the P&T Committee makes the recommendation based on the evidence. We do an actuarial analysis. We pull our data with Labor and Industries when L&I is using that drug class. And then there's a work group that reviews the cost analysis made-up of the L&I and HCA staff. They'll make recommendations to the agency directors, who then will usually approve those recommendations. Then we send out a notice of what the PDL changes were, if any. And then the agencies will implement the PDL usually on the first day of the next quarter, or it might be, depending on where we are in the existing quarter, it might be two quarters away. We do need to give notification to patients and providers if there's a negative change that's going to be made. So next slide. So we've been using this preferred drug list since 2004. I'm just going to go quickly through this. Currently, only Uniform Medical Plan with the -- and the Department of Labor and Industries uses the Washington PDL. Medicaid used to use it, but in 2018, we were directed to use -- to create a single preferred drug list, which is the Apple Health PDL. And so I'll get into that later. But the Washington PDL has about 30 drug classes, and then we have the interchange program as well. So next slide. Did you skip one, Nonye?

Nonye Connor: Sorry about that. Let me see. Okay. This is the next slide.

Donna Sullivan: Okay.

Nonye Connor: There we go.

Donna Sullivan: Okay, thank you. So I've talked about the Therapeutic Interchange Program. So part of the evidence-based review program was that if the drugs were equally safe and efficacious, then why not just use the least expensive one? And instead of requiring pharmacists to call doctors and get a new prescription to switch from one -- the non-preferred drug that they prescribed to the preferred drug, the legislature gave pharmacists the authority to actually make an interchange without having to get the doctor's - - a new prescription from the prescriber. And they created what we call this endorsing practitioner program. So if a doctor agrees with the Washington PDL and what is considered preferred and non-preferred, they can endorse the list, and there's a -- you can go online and sign up to become an endorsing provider. And then what would happen then is the pharmacist at the point of sale would get a message instructing them that this drug is non-preferred, and that they should interchange the preferred drug, which they could do. And they were just required to then notify the prescriber of what was

actually dispensed. There were some stipulations around this. There is what we call a refill protection. So certain drug classes felt -- it was felt that you wouldn't really want just to do an interchange at the point of sale without further clinical evaluation. So the legislature prohibited the interchange of antipsychotics, antidepressants, antiepileptics, chemotherapy, HIV medications, immunosuppressive treatment for hepatitis C, or immunosuppressive -- yeah, it was actually immunosuppressive drugs, I think, for the treatment of hepatitis C is how that is supposed to read. Also, it was felt -- strongly felt that if the practitioner wrote Dispense As Written on the prescription for the nonpreferred drug, it would also prohibit not just a generic substitution, but it would also prohibit any therapeutic interchange as well. So there are about 7200 endorsing practitioners. The list kind of waxes and wanes. It's hard to get a sense of how many there really are or what percentage of all prescribers have endorsed the list because we get our -- we get the file from the Department of Health of all licensed prescribers in the state, and we don't know who's actually still practicing in the state or if they've retired and are just maintaining their license. So we get asked that question a lot, but it's really not something that we can answer easily. So the next slide. So the status of drugs on the PDL are either preferred, and TIP doesn't apply, something is preferred on the Washington PDL. Non-preferred drugs are subject to therapeutic interchange when they're included in the class. If they're not in one of the refill protected classes, if the Committee also allows therapeutic interchange, we have left it up to the Committee in their clinical discretion to decide whether or not a drug should be interchanged or not. And then also substitution has to be allowed by the endorsing practitioner. The next slide. So, status of the drugs, if it's in a PDL class but not included in the report, it's covered according to the program benefit design, meaning that Uniform Medical Plan or L&I can treat it however they want to, but it's not really part of the -- it's not considered part of the class. But if they want to make it preferred, they can, or they can leave it non-preferred. TIP does not apply. The therapeutic interchange does not apply to a drug that's not officially included in the class. And then the Dispense As Written provisions do not apply other than a generic requesting that a generic substitution not be made. But that doesn't override the preferred status of a drug if it's not on the PDL. Drug classes not on the PDL are also covered according to the program benefit design. Excuse me, next slide. We also then have started to archive drug classes, usually as a result of when a drug class has been on the market for a very long time. Mostly, they are generic. There's not a lot of new information coming out. And it's not likely to be reviewed by DERP again. We will try to get that drug class archived. The

Committee then will review a final surveillance report, and vote whether or not it's appropriate. They'll determine if therapeutic interchange and DAW rules should still apply and then direct the agencies to change to preferred status, or allow us to, based on cost when appropriate, without additional review by the Committee. The archived drug classes actually do remain on the PDL, but they won't be coming back to the Committee on a regular basis for review. At any time, either the Committee or the prescription drug program work group may reactivate an archived class. Generally, if there were significant changes that were made, or maybe there's a new drug class that another drug class that comes out where it might be -- we might be using first-line therapy or something. That might be a reason why we would bring a drug class back. I don't think to this time that we have actually reactivated any of those classes that have been archived. Next slide. So then we have the DUR Board, and the primarily difference between the P&T Committee and the DUR Board is the program where you're governing the selection of the preferred drugs. So for the Washington PDL, when you have the P&T Committee hat on, you are making decisions for the Washington PDL. And you'll notice we don't do clinical policy for the Washington PDL. We don't decide on first-line therapy, step therapy, prior authorization, or not prior authorization. What you're really doing is selecting whether or not the drugs are safe and efficacious and if they can be interchanged. If you think one drug is more appropriate, then you can direct that it needs to be preferred. Or if you think -- feel it's less safe, you can direct it to be non-preferred. But that's really the limits on what the P&T Committee does. The Drug Utilization Review Board -- and so that's why we do have like a formal adjourning and reconvening as the two different bodies. So the DUR Board only impacts our Medicaid program, and it is federally required by the Social Security Act as part of the Medicaid program. And so it's really advising the Apple Health Preferred Drug List or the Medicaid Preferred Drug List and what we do for our utilization controls. So the DUR Board would recommend programs or interventions based on data provided by Apple Health or our Chief Medical Officer, review and approve DUR programs proposed by Apple Health, such as our clinical programs, and then engage in provider education activities when appropriate. And primarily, in the past, that's been around opioid prescribing. We haven't had a lot of provider education activities probably in the last five years or so. Next slide. And so on January 1st, we were directed to have a single preferred drug list, which is to be used by all the managed care plans within Medicaid as well as our fee-for-service program. We are a member of, it's called the Optimal PDL Solution or the TOPS Supplemental Rebate Pool, which is administered by Prime Therapeutics. So Nina is here,

and she will -- from Prime -- and that's their role is to also provide us with some clinical review of more drug classes than what are on the PDL. The Apple Health PDL is a very comprehensive preferred drug list. It has over 700 preferred drug classes on it at the time. We try to review many -- as many as we can as frequently as we can. Some of the ones that are really, really dated classes where we just have to have something preferred, and we've we put them in a class just for comprehensiveness. They don't necessarily come to the Committee for review, especially if they're all generic. So the next slide. So the Apple Health PDL process, the clinical is, again, Prime will review each drug class on the -- on its clinical merits. They look at the published peer-reviewed clinical trials and are the primary source of the information for those drug classes that are not reviewed by the DERP program. They also present some of the data and efficacy. They'll go over the ADVERSE EFFECTS and all of the INDICATIONS, many for each of those drug classes. And then the DUR Board will then determine if they're, again, if the drugs are safe and effective. We don't really do interchange anymore within the Apple Health PDL program, at least not on an automated basis. But we will look at the different alternatives within a class and have the Board approve. And we usually we'll have the Board also say how many preferred drugs someone might have to try before a non-preferred drug would be authorized by the state. And that's part of our motion template. Next slide. So each -- twice a year, Prime puts out bids for supplemental rebates on the drug classes that they manage. They are split between a January -- for Prime, it's for January 1st implementation or a July 1st implementation due to our timing and our notification requirements to the managed care plans of significant changes, that usually means an October implementation and an April implementation for Washington of those drug classes. But Prime will put in -- will get those bids, and we give them our data every month. They will look at that and provide us with cost sheets with an analysis of shifting assumptions that might help us determine if we're going to make any changes to a preferred drug based on the cost or the net cost after considering all of the rebates. And that comes after we follow the decisions that the Board has made regarding if something needs to be preferred or non-preferred on the PDL. We will follow those decisions as well that are made by both the P&T Committee and the DUR Board as well, but it is the Health Care Authority that makes the final selection of what is preferred or non-preferred on the Apple Health PDL. Next slide. Okay, so that was -- I did speed up there. That was really quick. So just for your -- and I think these are in both packets that you get each meeting is all of the acronyms. You know, as a state agency, we love our acronyms. I try not to speak to them as much as I can, but sometimes we do.

But I think there are two pages. I'm not going to go through them all, but they're just here for your reference. If you ever have a question about what the heck are we saying when we're just speaking with all these random letters rather than using words? So any questions? All right. Back to you then.

Laura Beste: Okay. Thank you very much for that nice overview. And before we move on to our new meeting minutes, I believe that Greg had a question following up on the Ingrezza topic from last committee, if you'd like to speak to that.

Greg Hudson: Yeah, less of a question and more -- I just -- if the Committee remembers, there was a number of stakeholders that talked at the very end of our DUR Board meeting, and we weren't able to sufficiently cover the requested topic. And so I think my request for, I believe, would be during the DUR Board, that we could take back up that topic on Ingrezza and the prescribing of Ingrezza to patients with tardive dyskinesia and maybe a request, Nonye, if the stakeholders had any written statements that were submitted at the last meeting, maybe if those could be sent to the DUR Board members prior to that discussion. And maybe -- I don't know -- maybe we could take it up at the beginning of the DUR -- as the DUR Board convenes so that it doesn't get pushed to the end of the meeting.

Laura Beste: So this is Laura. So Nonye, is it best to put it there, or would it be best to move it maybe to the next meeting so people had time to review before the discussion?

Donna Sullivan: Um, Laura, this is Donna Sullivan. I can give you an update of what we've done since that last meeting that might make your decision different. But again, I think we do, like Greg said, probably need to take it up as the DUR Board portion of the meeting. But I'll give you an update, and we can do that in the very beginning. It shouldn't take long, and we haven't -- I don't know if we've gotten the new policy posted yet, but I will let you know when that -- when we can get that done. But like I said, I can give you an update when we do convene as the DUR Board.

Laura Beste: Okay, that sounds like a plan. So we'll look forward to that discussion. So next, good job being on time. We have Asthma and COPD Controller Review by Jennifer Lyon of DERP.

Jennifer Lyon: Okay. Can everyone hear me?

- Laura Beste: Yes.
- Jennifer Lyon: Yes. Okay. I'm going to try to share my screen. Oh, there it is. Okay. Can everyone see the presentation?
- Greg Hudson: Yes.
- Jennifer Lyon: Yes. Okay, great. Great. So, this is a surveillance report on Single Inhaler Triple Therapies for Asthma and COPD. So I have no conflict of interest disclosures and no funding issues to report. So this is what we'll go through, the History and Background, the PICOs and Key Questions, Methods, Findings, both Clinical and Research, and then I'll summarize. So first, some abbreviations. This has a lot of drugs and drug categories involved in it. The single inhaler triple therapies (SIT), as you'll see on the slides, have three drugs involved, and they include one drug from each of the categories: the inhaled corticosteroids, the long-acting beta-2 agonist (LABA), and the long-acting muscarinic agonist (LAMA). So our previous review on this was an individual topic report in December of 2022, which covered databases up through September 16, 2022, and we picked up after that. The 2022 review included 12 randomized controlled trials that compared these single inhaler triple therapies with either another SIT or other standard of care therapies. One of the RCTs was in adult asthma patients, and the remaining 11 were in COPD patients. I think most of you are probably familiar with asthma and COPD. So asthma is a chronic inflammation of the lungs, causing narrowed airways and difficulty breathing, affecting about one in 13 people in the US. And there are a lot of different management strategies for it, including monitoring, medication, and avoiding triggers such as pollen and allergens that may set it off. COPD is a chronic progressive lung disease where damage leads to airway inflammation and blockage. So symptoms include severe cough and extensive mucus production. It's a progressive disease that includes emphysema and chronic bronchitis, affecting over 14 million adults in the U.S. And again, you have multiple management options for this lifestyle changes, oxygen therapy, pulmonary rehabilitation, and the medication that we'll be talking about. So medications for asthma and COPD include those three categories, and they may be prescribed individually or in combination, so the ICS, the LABA, and the LAMA. These triple therapies combine three therapies and one inhaler dose. So those are separate from multi-inhalers, where you may take more than one inhaler at the same time even, and/or different drugs at different times during the day. So we have two that are FDA-approved, Trelegy and Breztri. You can see the drugs that are involved

in them, one approved in 2017 and one approved in 2020, the first one for asthma and COPD and the second one just for COPD. Here's another look at those interventions in our PICO's. So you'll see the two FDA-approved therapies. And remember, breast cheese is FDA-approved for COPD. It is in pipeline for asthma. And then we have the new one, Trimbrow, which is in pipeline for both COPD and asthma. And you can see the drug combinations that are involved in those. So our comparisons here were another listed intervention. So a head-to-head comparison or a standard of care, which might include a monotherapy, a dual therapy, or a multiple-inhaler triple therapy. Outcomes that we look for are things like forced expiratory volume, severe exacerbations and symptom control, use of rescue medications, quality of life using validated scales, all-cause ED visits or hospital admissions, mortality, and various ADVERSE EVENTS, and study designs with specifically RCTs. So our Key Questions, we looked at the Efficacy and HARMS of these SITs for COPD and asthma, variation of the EFFECTIVENESS and HARMS by subgroup, and ongoing studies of these triple therapies for COPD and asthma. We go into Methods. All searches covered September 2022 through to July 2025. We searched for registered clinical trials using ClinicalTrials.gov and ScanMedicine. researched our relevant DERP evidence sources like Ovid MEDLINE and Google Scholar using trial identifiers, and researched sources for FDA actions, specifically IPD Analytics and the FDA website. Look at the clinical landscape. So we found that some inhaler manufacturers are replacing the hydrofluoroalkane or HFA propellants with alternatives due to environmental concerns that includes for these drugs. So specifically Breztri Aerosphere, which uses a hydrofluoroolefin or HFO propellant is in phase 3 testing. That's the one that is in pipeline. And we did not include but did see some studies that compare HFA versus HFO propellants, so that is an issue upcoming. And Breztri Aerosphere that uses that HFO-type propellant is approved in the EU and the UK in 2025. And time of the US approval is unclear at this time. We did not find any new pipeline agents in Phase 3. And we did not identify any new INDICATIONS, SERIOUS HARMS, or WARNINGS since 2022. And if we go into our Findings in terms of new published studies and ongoing studies, we did not identify any newly published RCTs since the search is in the rapid review, but we identified 17 ongoing studies that will be eligible if published. So 12 for COPD and 5 for asthma. You can see the interventions there by individual drug, 6 for Brez -- for the combinations, Breztri at 6, Trimbrow 3, Trelegy 3, and then non-named but similar drug combinations. You can see that the fluticasone with its combinations for 4, and that's budesonide in combinations for 2. Completion dates, 2022 to 2028, and 2 international trials did not report an

expected completion date. For comparisons, there was 1 head-to-head trial. The others had various comparators, including single or double drug therapies or the multiple-inhaler therapies. You'll see that most of these trials were adults only. We had two that were adolescents and adults and one that was adolescents only. One in the U.S., 6 that were multinational, including U.S., and 10 in other countries. Note that we limited to countries that were very high on the Human Development Index. So to summarize since our last review, we identified no new INDICATIONS or WARNINGS, no new drugs, formulations, or SERIOUS HARMS, no new RCTs, but 17 ongoing studies, including 1 head-to-head study, 12 in COPD, and 5 in asthma. And this just gives you sort of our summary in terms of whether we decided to do -- that an update would be necessary. In this particular case, we decided that it would probably not be necessary. That's the only thing I have on this topic. Do you have any questions?

Laura Beste: Thank you, Jenny, for that thorough review. And did anyone have any questions before she moves -- before we move on? No? Okay. So, Nonye, can you remind me, do we vote on anything here or have a motion to accept the information as provided?

Nonye Connor: Yes. I'm pulling up the motion for you guys to review right now. And I do not see any stakeholder hand raised, and they were none that pre-registered for this particular topic. So just give me a quick second, I'm pulling it up. Share my screen. Sorry about that. Share screen. Where is -- share screen.

Laura Beste: Okay, so if we can all take a moment to read through the motion. And then when you're done if anybody would like to make a motion to accept?

Alex Park: Laura, it's Alex Park here. I have a question for DHA. Sorry. DHA is the agency I work for, DHCA. Thank you very much, Jenny. As always, you guys do an amazing job with these things. It looks like there's not much that's new in the field, but there's some information that's going to come down the pipeline at some point. Was there a reason that this particular surveillance was convened? Is this a class that we should be worried about? And should the Committee be thinking about making a recommendation to have another surveillance when some of those studies that you cited come to fruition?

Ryan Pistorosi: Yes. So this is Ryan from Health Care Authority. One of the reasons that the states voted for this was that -- it had been a while since we last reviewed it. In fact, if you look at the slide, the last time that we reviewed it as a P&T

Committee was at the end of 2022. So it's been a few years. We were curious about whether there were any studies that further recommended the use of these triple therapies or if there was any evidence that dual or single or other types of therapies were still appropriate. So really, it was more that we hadn't looked at it for a while and that we wanted to see if there was any change in the evidence in which you saw that maybe not yet but maybe soon.

Alex Park: Yeah. And do you -- I mean, will -- is there a standard cadence whereby, HCA will ask for another surveillance? Because it sounds like there are over 10 or 15, say at least one of them head-to-head that would be really interesting to look at down the line.

Ryan Pistorresi: So this is Ryan again. And yes, we do have our annual meeting in the spring coming up, where we do discuss different topics as they are being voted from topic briefs into full reports. This one is not since it was just reviewed, and the states did determine that there was not enough yet. But we will likely be bringing this up again later this year at our fall conference where we are doing a lot of the initial brainstorming for classes that can either be updated or new classes for different types of drugs that states would be interested in. So we probably won't know until maybe around October-ish if this would be something that we would re-review in the near future -- well, near future as in 2027. But we probably won't know for a little while based off of the cadence that we have as states.

Alex Park: Thank you, Ryan, for that context.

Ryan Pistorresi: Sure thing.

Alex Park: Laura, I will make a motion to accept the surveillance as adequate.

Laura Beste: Okay, we had our motion, and do all in -- wait, no, we need a second.

Kevin Flynn: this is Kevin Flynn, I second.

Laura Beste: Okay. And with that, all in favor, say aye.

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

Laura Beste: Any opposed or abstained? Okay, the motion passes.

Nonye Connor: So we have to do the motion now.

Laura Beste: Oh.

Nonye Connor: Yeah. Yeah, Dr. Park accepted the surveillance. Now we have to do the motion part.

Laura Beste: Okay.

Alex Park: And Laura -- Alex Park, I'm also happy to make the motion to reiterate the [cross-talk] prior motion on the basis of basically no new information unearthed in the very well-prepared surveillance review.

Laura Beste: Does it need to be read out?

Nonye Connor: Yes, please.

Alex Park: Oh. You guys are going to make me work today, huh?

Laura Beste: Yep.

Alex Park: Okay. I move that the ICS/LABA/LAMA combinations; after considering the evidence of safety, efficacy, and special populations for the treatment of asthma and COPD, I move that budesonide/glycopyrrolate/formoterol furoate and fluticasone/umeclidinium/vilanterol are safe and efficacious for the treatment of their approved INDICATIONS. Long-acting beta-agonist combination with ICS and LAMA products can be subject to therapeutic interchange in the Washington Preferred Drug List if the preferred drug is approved for the condition being treated.

Bradley Pope: Boy, that was an excellent enunciation.

Laura Beste: And now we need a second.

Greg Hudson: This is Greg Hudson. I second.

Laura Beste: Okay. All in favor, say aye.

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

Laura Beste: Any opposed or abstained? Okay. Now with that, motion passes.

Nonye Connor: Okay, I'm gonna stop sharing.

Laura Beste: Okay. So next on our agenda, we will be covering biologics for non-asthma conditions. And once again, we welcome Jennifer Lyon from DERP.

Jennifer Lyon: Okay. This particular surveillance is on Biologic Drugs for Non-Asthma Indications. So again, no conflict of interest, funding, or support disclosures. And again, the same structure for this report, our History and Background, PICOS and Key Questions, Methods, Findings, Clinical, and Research Landscapes, and a Summary. Let's move into the Background. So here are some abbreviations. Some of these conditions that we are looking at here have long names, so we have the abbreviations for those listed here. And we'll talk about each of the conditions briefly in the background. And so there's not quite as many here as in the previous report. So, in this case, the last systematic review update was done in October of 2024, covering January 21 to August 24, so we included October 24 and up for the surveillance. This is the overview of what was in the 2024 systematic review update. You'll see that most of the trials were placebo-controlled, 31 of those, and one head-to-head. One head-to-head was in patients with eosinophilic granulomatosis -- benralizumab versus mepolizumab. And then with the others, you can see for the different conditions we had anywhere from 1 to about 15 trials per condition for each of those, and you can see those here. So I'm going to go into the background just briefly. Biologic drugs are human-made complex molecules that target parts of the immune system responsible for inflammation. Treatment options. These are treatment options for a variety of therapeutically challenging diseases and illnesses, including the ones that we're gonna talk about here. And I know it's kind of an alphabet soup, but we'll go into each one. Next. CRS is Chronic Rhinosinusitis with or without Nasal Polyps. Primarily with nasal polyps is the way we will be looking at it. It's a chronic inflammatory disease in the nasal sinuses defined as lasting at least 12 weeks, affects about 5 to 12% of the global population, and then about 25% to 30% of the CRS patients have the nasal polyps, which are non-cancerous growths. Treatment options for this include oral and nasal spray corticosteroids, the surgery, and its biologics. Urticaria or Chronic Spontaneous Urticaria (CSU) on these slides. It is known colloquially as hives and defined as lasting at least 6 weeks. These are raised bumps on the skin often with swelling, itching, burning sensations. And then you have multiple treatment options, including antihistamine, these biologics, or

corticosteroids, cyclosporine, and phototherapy. The eosinophilic granulomatosis with polyangiitis, or EGPA, and it's probably the last time you'll hear me refer to it as anything other than EGPA. It is a rare immune disease that affects blood vessels primarily in the lungs. It involves high levels of eosinophils, which are an inflammatory response blood cells, granulomas, which are small masses of immune cells and polyangiitis, which is an inflammation of the blood vessels. There are multiple symptoms depending on the stage of the disease. And our treatment options include high-dose corticosteroids, immunosuppressants, and these biologics. Hypo-eosinophilic Syndrome, or HES, is a rare condition involving organ damage or dysfunction caused by an excess of eosinophils, defined as at least 1500 per mL of blood. It can affect any body tissue, and the symptoms depend on which organ or organs are affected. This can make it difficult to diagnose because the symptoms can be so variable. Treatment options include corticosteroids, human therapy drugs, immunotherapy, and biologics. Prurigo Nodularis is a localized chronic skin condition with hard raised bumps. You can see the photo there. It's often dry and crusty, extremely itchy, and can occur anywhere on the body. Here you see it on the hands. It affects about 72 per 100,000 people in the U.S., and is more common in African Americans, women, and adults aged 40 to 69 years. Treatment options include corticosteroids, topical antihistamines, cryotherapy, phototherapy, and these biologics. So our populations for adults age 18 and older with one of these five conditions, CRS with or without nasal polyps, urticaria, EGPA, HES, or prurigo. We also included children with one of these non-asthma conditions, so adults or children with these conditions. So here are our interventions. First, the FDA-approved therapies, so we have dupilumab, brand name Dupixent. Mepolizumab, brand named Nucala, and omalizumab, brand named Xolair. You can see that the date of first approval for these drugs, but that's not necessarily for these conditions, that's for any condition. And you'll see that they vary a little bit as to which condition they've been approved for. So dupilumab for rhinosinusitis and prurigo, mepolizumab for EGPA, HES, and rhinosinusitis, and omalizumab for urticaria, and adults with nasal polyps that don't respond well to nasal corticosteroids. We also have some pipeline therapies. Benralizumab, brand name Fasenra, which to date has been only FDA approved for asthma, is under consideration for some of these. depemokimab, lirentelimab, and tezepelumab, brand name Tezspire, again, has been FDA approved for asthma and is now being looked at for some of these non-asthma conditions. So for comparators, it was again another listed intervention for head-to-head studies, topical prescription therapies, standard of care, and placebo. We

looked at a variety of outcomes, condition-specific outcomes, and you can see in the box there that for each of the different drugs there were different scales. FEV1 was common. You had the urticaria scores, remission rates and relapse rates, reduction in use of steroids, nasal polyps scores and nasal congestion scores, and an itch rating scale for prurigo, and quality of life, exacerbations, hospital admissions and mortality, and ADVERSE EVENTS and SERIOUS ADVERSE EVENTS. For our study designs, we looked specifically at RCTs from countries that are very high on the UN HDI. Our Key Questions, which are pretty standard, are the EFFECTIVENESS and HARMS of these drugs for these conditions of interest with variation by patient characteristics, characteristics of ongoing studies, and characteristics of any new identified pipeline therapies. Moving to our Methods, again, these are pretty standard DERP Methods for surveillance. In this case, all searches covered August 2024 through September 4, 2025. We used ct.gov, and since ScanMedicine was down, we used the World Health Organization's ICTRP, the International Clinical Trials Registry. Research revealed that DERP evidence sources for using trial identifiers, and we looked at IPD Analytics and the FDA website for the FDA actions. Let's look at the clinical landscape. We identified four newly approved agents, including one newly approved biosimilar. We did not identify any new formulations. To look at these, benralizumab for adults with EGPA, which was based on the MANDARA trial. Nemolizumab or Nemluvio for prurigo nodularis, and that was based on the OLYMPIA 1 and 2 trials. Tezepelumab for adolescents with rhinosinusitis with nasal polyps based on the WAYPOINT trial, and omalizumab biosimilar Omlyclo for all omalizumab INDICATIONS, and that includes rhinosinusitis and urticaria. That was based on a comparative clinical trial done specifically in urticaria patients. We identified 14 pipeline agents in Phase 3 testing, including one with a 2025 PDUFA date, in this case, December 2025. So it should be through that by now, and that drug is depemokimab for chronic rhinosinusitis with or without nasal polyps. That is with nasal polyps. So we've got, again, benralizumab remaining in phase 3, itepekimab and lebrikizumab for CRS, barzolvolimab, dupilumab for CSU, depemokimab for EGPA. Some familiar drug names, benralizumab, depemokimab, and mepolizumab for HES. And for prurigo, we have dupilumab, povorcitinib, rocatinlimab, and ruxolitinib, other drugs there. And the -citinibs certainly should be a JAK inhibitor. So we identified one new indication and one expanded indication for the drug dupilumab. It was newly approved for adolescents and adults with CSU who remain symptomatic despite histamine-1 antihistamine treatment. And approval expanded to include add-on maintenance treatment for adolescent patients 12 to 17 years of age who

have inadequately controlled rhinosinusitis with nasal polyps. We identified, again, for dupilumab, four new WARNINGS and two changes to WARNINGS. So WARNINGS affecting eosinophilic conditions, psoriasis, and psoriatic arthritis were added to the describing label for dupilumab in April of 2025. A WARNING for hypersensitivity was added in June of 2025. And changes to the WARNINGS for conjunctivitis and keratitis were added in June of 2025 as well. If you go into the research landscape, looking at new and ongoing studies, we found four RCTs represented by three publications since the recent systematic review update. So one publication included two RCTs. There was one head-to-head comparison of omalizumab with tezepelumab for urticaria, and three placebo-controlled trials, those two of depemokimab versus placebo for rhinosinusitis, and one trial of tezepelumab versus placebo, again, for rhinosinusitis, both with nasal polyps. We'll take a quick look at those three publications. The INCEPTION trial, adults with CSU, 183 patients, so over 16 weeks, that head-to-head comparison of omalizumab to tezepelumab doses and placebo. The ANCOR-1 and ANCOR-2 trials were published together in the closely related trials, both looking at depemokimab versus placebo in adults with rhinosinusitis with nasal polyps. In both of them, about 275 patients over 52 weeks. And then the WAYPOINT trial, the one that was involved in tezepelumab being approved for rhinosinusitis with nasal polyps, 416 patients over 52 weeks. For ongoing studies, we identified 20 ongoing RCTs, and you'll see them divided out in various categories here by condition. You'll see that the largest number were for rhinosinusitis with nasal polyps. When combined -- two trials combined that with asthma. Three looked at the rhinosinusitis without nasal polyps. And then you'll see the others, one for urticaria, 3 for EGPA, 2 for HES, and one that looked at its triad of disease, which was the rhinosinusitis, asthma, and NSAID-exacerbated respiratory disease. It was kind of an unusual trial, but we did want to include it here. So for interventions, you can see by individual drug, the most for dupilumab was 9, mepolizumab falling with 7, and so on down, benralizumab with 3. And you can see the numbers there. For the trials, these ongoing RCTs are head-to-head: 1 uses a surgery comparator, and the remaining 15 use placebo as the comparison. 19 of the trials are adults only, and 1 is in adolescence. The completion dates range from January of 2024 to estimated February of 2030, 3 of them take place in the U.S., 7 are multinational, including the U.S., and 10 are in other countries. So to summarize, since the last review, there's quite a bit of activity here. We identified 4 new drugs, including 1 biosimilar. No new formulations. 14 new pipeline agents, including 1 with a 2025 PDUFA date, 1 new indication and expanded indication, 4 new WARNINGS and 2 changes to WARNINGS. The

INDICATIONS and the WARNINGS were all for the drug dupilumab. 4 new RCTs, a head-to-head trial, and three placebo-controlled, and 20 ongoing studies, 4 head-to-head, 15 placebo-controlled, and 1 with a surgical comparator. So if you look -- in our summary, you'll see that there is quite a bit of activity here. So pretty much everything was a yes, leaning towards doing a review sometime in the future. I don't believe it's been set yet, but this was our conclusion for this particular surveillance report. And you'll see, for example, that we included some options when we discussed this with the states, including things like looking at, for example, the WAYPOINT trial, which was important for approval of the tezepelumab for CRS with nasal polyps and looking at the head-to-head trials. So I think that that's everything for the surveillance. If you have any questions, I'd be happy to try and answer them.

Laura Beste: I don't see any hands up or any questions from anyone. Thank you, Jenny, for that thorough review of that surveillance. Do we have any stakeholders?

Nonye Connor: Yes. So the first one I have on my list is Shannon. And Shannon, can you unmute yourself?

Shannon DiBartolo: Yes, I believe I just did.

Nonye Connor: Okay, perfect.

Shannon DiBartolo: Okay.

Nonye Connor: Just give me a quick second so that I can share my screen with the timer. Sorry.

Laura Beste: And Shannon, did you already share your conflict of interest form with us?

Shannon DiBartolo: I did. I submitted that via e-mail.

Laura Beste: [Cross-talk] Okay, thank you.

Nonye Connor: [Cross-talk] Yes. Okay, and the clock is coming up right now. Okay.

Shannon DiBartolo: Great, thank you.

Nonye Connor: Mm-hmm.

Shannon DiBartolo: Hello, my name is Shannon DiBartolo, and I am a Medical Value and Access Liaison with Amgen Medical Affairs. Thank you for the opportunity to provide testimony and respectfully request that Tezspire be added to the preferred drug list with coverage aligned to its label. So Tezspire is indicated as an add-on maintenance treatment in patients 12 years and older with severe asthma. And most recently, it is now indicated as an add-on maintenance treatment for adult and pediatric patients ages 12 and older with inadequately controlled chronic rhinosinusitis with nasal polyps. In clinical trials, Tezspire significantly reduced asthma exacerbations versus placebo in patients with severe asthma. In patients with CRS with NP, the efficacy of Tezspire was established by the Phase III WAYPOINT study. WAYPOINT was a multicenter parallel-group, double-blind, randomized, placebo-controlled 52-week trial in patients ages 18 and over, who were on standard-of-care treatment with severe uncontrolled CRS with NP. The study results demonstrated treatment with Tezspire significantly reduced nasal polyp size, congestion severity, the need for systemic steroids, and nasal polyp surgery, and resulted in an improved loss of smell versus placebo. Tezspire has an established safety profile. The most common ADVERSE REACTIONS in severe asthma are pharyngitis, arthralgia, and back pain. In CRS with NP, the most common ADVERSE REACTIONS include nasopharyngitis, upper respiratory tract infections, epistaxis, pharyngitis, back pain, influenza, injection site reaction, and arthralgia. Despite its efficacy and safety profile, Tezspire does not have preferred status on the Washington State formulary. I respectfully ask for the Committee to add Tezspire, with coverage aligned to its label for severe asthma and CRS with NP on the state PDL. Thank you very much.

Laura Beste: Thank you, Shannon. And just a question for the Board administration. So when we're discussing having these medications as preferred formulary, can we see that? I was thinking that actually with the last one too with the inhalers. Can we see what that is? And if somebody wanted this product over the preferred agent, they would just have to fill one or two based on what our motion is, correct?

Ryan Pistoiresi: So this is Ryan -- and I can try pulling up the Washington PDL in just a second. When a drug is recommended to be eligible to be preferred during your motions, it then goes to our cost analysis review, and that cost analysis is where the agencies get together, so Labor and Industries and Uniform

Medical Plan, and evaluate some of the different options of structuring the Washington PDL with different preferred and non-preferred drugs. And then from there, each of the programs adopts it within their PDL. So UMP has their own PDL, as Donna had mentioned, which has that subset of Washington PDL classes on it. Same thing for Labor and Industries.

Laura Beste: Okay.

Ryan Pistorresi: And I have a version up. This should be the version that was posted earlier this year. So if you'd like, I can share my screen and pull up this drug class.

Laura Beste: Yes, please.

Ryan Pistorresi: Okay. Okay, so this should be the Washington PDL, and we are going to pull up the asthma ones. And so this is the whole of the asthma class, in case you were curious, for the ones that we just reviewed. They would be these first nine that have asthma biologic in Column A. And then as you can see, Tezspire was not eligible because we had not done a full review of it as part of a DERP report.

Laura Beste: Okay, thank you. That's very helpful. Before we move on to any other questions, do we have any other questions from board members or any other stakeholders?

Nonye Connor: We have more stakeholders.

Laura Beste: Okay. Let's see. I know I have Rahul. I'm so sorry if I'm pronouncing your name incorrectly. I cannot find this person. Okay. Let's see, Carla. Okay.

Carla McSpadden: Hi, can you hear me okay?

Nonye Connor: Yes. I know you pre-registered, so let me go ahead and share my screen and share the --- so we can start the timer. Just give me a quick second. Okay, I'm ready whenever you are.

Carla McSpadden: Okay, great. Thanks. My name is Carla McSpadden. I'm a Pharmacist employed by Galderma, and we appreciate the opportunity to speak about Nemluvio, generic name nemolizumab. Nemluvio is indicated for two skin diseases. I know today's review was focused more on prurigo nodularis and some other INDICATIONS, but just to clarify that Nemluvio is indicated for

prurigo nodularis as well as moderate-to-severe atopic dermatitis, and that's in adults and pediatric patients 12 and older. Nemluvio is the first drug to target IL-31, which is a cytokine that is implicated in itch, chronic itch, inflammation, and skin barrier issues. In the atopic dermatitis trials, Nemluvio significantly improved skin lesions and disease severity at 16 weeks. In the prurigo nodularis trials, Nemluvio significantly improved itch and skin lesions. It has demonstrated fast itch relief and fast sleep improvement after just the loading dose as well as significant skin clearance also after the loading dose for both disease states. The only caveat being in prurigo nodularis, one trial was significant after the loading dose and the other was significant after two doses. But 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 dosed every 4 weeks for prurigo nodularis and starts at every 4 weeks for atopic dermatitis with the option to extend that out in atopic derm to every 8 weeks if a patient is responding. Nemluvio has been strongly recommended in the 2025 update of the American Academy of Dermatology guidelines to be used in combination with topical therapy. By the way, there are no specific treatment guidelines for prurigo nodularis. And lastly, we have a positive Phase II study in the 2 to 11-year-old atopic derm population that looked at PK efficacy and safety, with more info to come this year. So we are respectfully requesting that Nemluvio be considered safe and efficacious within this class and considered preferred after your financial analysis. And the rationale for that is to offer beneficiaries a different mechanism of action in IL-31 rather than just IL-13/4. The clinical benefit in itch, skin, and sleep that it offers as well as the potential value of responders in atopic derm extending that dosing interval to every 8 weeks, which would equal 6 pins per year for maintenance. Happy to answer any questions.

- Laura Beste: Thank you, Carla, for that review of Nemluvio. Does anybody have any questions? I think this is a really challenging class of medications as each one has its unique niche. And do we have further stakeholders? Nonye, I think you're talking, but we can't hear you.
- Nonye Connor: I'm sorry. Yeah, I said that we have a couple of more stakeholders hands that are raised, and I just unmuted. Is it Carman? I'm so sorry if I'm pronouncing your name incorrectly.
- Lisa Carman: Yes. Hi, Lisa Carman.

Nonye Connor: Okay. If you can just give me a quick second. I do not see that you have complete, that you pre-registered, but I do have the questionnaire if you just want to give me a quick second so I can share my screen. And then once you've answered the questions, you can go ahead and --

Lisa Carman: Sure.]

Nonye Connor: My apologies I need to --

Lisa Carman: And I have I have sent that form in previously, but I'm happy to answer the questions as well.

Nonye Connor: Okay I appreciate it. Thank you.

Lisa Carman: Sure. Lisa Carman, and I'm speaking on behalf of Genentech Roche. And I think that's all the questions, correct? Since I'm not a provider.

Nonye Connor: Okay, go [cross-talk] --

Lisa Carman: [Cross-talk] My conflict of interest is an employee.

Nonye Connor: Okay. Whenever you're ready, I will go ahead and start the timer.

Lisa Carman: Okay. I'm Lisa Carman, and I'm here from Medical Affairs, and I wanted to talk about Xolair or omalizumab today. And I specifically wanted to talk about one indication, which is chronic spontaneous urticaria, or CSU, in response to the DERP review, and just give it a quick update on safety and efficacy. So the indication I'm speaking about today is for CSU and Xolair in adults and adolescents 12 years of age and older who remain symptomatic despite H1-antihistamine treatment. And so I just wanted to hit a couple of the efficacy and safety highlights around Xolair for the treatment of CSU, which was really assessed in two pivotal placebo-controlled multidose clinical trials around 12 weeks' duration and 12 weeks' duration for the endpoints. And patients received three doses of Xolair. Really, the 150 mg and 300 mg was where the endpoints looking at 12 or 24 weeks. And disease severity was really around the activity urticaria scores, which is a composite of the weekly itch scores and weekly hive count scores. And in both of these trials, patients who received 150 mg and 300 mg had greater decreases from baseline in weekly itch severity scores and hive count scores compared to

placebo at week 12. The most common ADVERSE EVENTS in greater than 2% of patients included really around nausea, nasopharyngitis, sinusitis, upper respiratory tract infections, arthralgia, headache, and cough. And Xolair does have an anaphylaxis BLACK BOX WARNING on it. I additionally wanted to include for your information that there was a post hoc analysis around the ASTERIA-1 trial, and that the 300 mg had a 38% reduction in mean weekly itch scores at week one. The 150 mg dose had a 23% reduction at the week one symptoms and placebo was 14%. Additionally, these pivotal studies measured minimally important different reduction of symptoms, which is really a five-point weekly itch severity score reduction. And for reference, at that 300 mg across trials, you got that relief at one to 2 weeks. So I thought that was important to measure. And a few seconds I'll give back to the Committee if you have any questions.

Laura Beste: Great. Thank you, Lisa. Does the Board have any questions for Lisa? Okay. Thank you again. And next stakeholder.

Shirley Quach: Hi. Can your hear me okay?

Nonye Connor: Yes.

Shirley Quach: Great. So I'm Shirley Quach. I'm a Value Evidence Lead with Novartis. And I know the title of the review is Biologics, but I did notice there were other oral agents in the review. And so I wanted to share with the Board a recently approved agent for CSU, which is Rhapsido. Rhapsido is an oral treatment that was approved by the FDA in September of last year for the treatment of adult patients with chronic spontaneous urticaria who remain symptomatic despite H1-antihistamine therapy. It's a pill that's taken orally, twice daily and is the first and only Bruton's tyrosine kinase inhibitor, or BTK inhibitor, approved for this indication. It offers a novel mechanism of action, inhibiting the release of pro-inflammatory mediators by targeting BTK in the mast cells, which are the primary effector cells in CSU. Rhapsido demonstrated rapid and sustained efficacy in two pivotal Phase III trials, REMIX-1 and 2. Rhapsido demonstrated superiority in change from baseline versus placebo in the itch and hives and also the weekly urticaria activity score at week 12. Rapid onset with clinically meaningful symptom improvement was seen as early as week one, and significantly more patients treated with Rhapsido versus placebo achieved well-controlled disease as early as week 2, and at week 12, over half were able to achieve well-controlled disease. Responses were maintained through week 52 in the extension studies, and also

Rhapsido demonstrated broad efficacy with similar response in patients regardless of prior anti-IgE biologic use. And patients who were -- who are anti-IgE refractory has been a patient population with significant unmet need. Rhapsido has a favorable safety profile, no BOX WARNING, no anaphylaxis risk, and no lab monitoring requirements. PRECAUTIONS do include mucocutaneous bleeding risk. In the trials, the majority (92%) were mild and the rest were moderate. There were no severe. And also PRECAUTION for avoidance of live vaccines. Please refer to the PI for full description. And Novartis respectfully request that Rhapsido be added as preferred to the PDL and covered PA to label. Thank you for your time, and I'm happy to answer any questions you have. Thank you.

- Laura Beste: Thank you, Shirley. And Nonye, is that Rhapsido, is that on the -- or I guess I would ask Ryan that. Is that on the list? On the PDL?
- Ryan Pistorresi: Um, let me verify. I don't believe it is.
- Laura Beste: Shirley, what is the generic name?
- Shirley Quach: Remibrutinib.
- Laura Beste: Remibrutinib, okay.
- Shirley Quach: Yeah. It was just approved end of September last year. So [cross-talk] --
- Laura Beste: [Cross-talk] Okay. I think that would probably have to go through a different type of review to be added. Is that correct?
- Ryan Pistorresi: So this is Ryan. It likely would. But I think if it would fall within the scope of one of these DERP drug classes, we do add it to our Washington PDL as a drug that's not eligible because it hasn't been reviewed yet. But it may not have been captured within our scan because our scan looks at certain drug classes and certain mechanisms of action and other ways in which we group drugs together. So if this does fit within the scope of the DERP reviews, then it would fall within our Washington PDL drug class. And so this is something that I will need to look into further and see if it would fit within the scope of the Washington PDL or outside and then therefore be the responsibility for UMP and L&I individually. So I will be looking into that.

- Laura Beste: Okay. Thank you, Ryan. And thank you, Shirley. Any questions from the Board for Shirley?
- Kevin Flynn: Just wouldn't it not fall into this class review because this is specifically for biologics and that remibrutinib is [cross-talk] not a biologic? It's just for clarification because all the others are [cross-talk] --
- Shirley Quach: I'm not sure if that was meant for me, but correct. Remibrutinib is not a biologic, but the review did include another oral agent, so that's why I wasn't sure if it would be appropriate to testify.
- Kevin Flynn: Got it. Thank you.
- Laura Beste: Okay. Well, thank you for the information. Any other stakeholders?
- Nonye Connor: Yes, we have Jon.
- Jon MacKay: Hi, good morning. Can you hear me?
- Nonye Connor: Yes.
- Jon MacKay: My name is Jon MacKay, and I'm a Clinical Pharmacist with Providence. And I treat pediatric and adult patients in pulmonology for severe persistent asthma, and I'd like to address the clinical policy for asthma, if I could, please.
- Nonye Connor: Okay, I'm ready whenever you are.
- Jon MacKay: All right. Well, I have nothing to disclose. I would like to bring attention to the Committee the current clinical policy for asthma, especially for Tezspire, for our severe and moderate asthma patients that require a biological. They currently require trial and failure of, I believe, it's generic Xolair and dupilumab prior to approval of Tezspire. So for our type 2 low asthma patients with severe uncontrolled asthma, that creates a predicament where typically with dupilumab, you have to have an elevated IgE or eosinophil count above 150. And for Xolair, it's typically targeted towards an allergic phenotype. And so it really creates a predicament for this subset of patients for the type 2 low phenotype patient with severe uncontrolled asthma. So I wanted to bring that to the Committee's attention in terms of the requirement and trial and failure of those two agents prior to Tezspire. I would recommend that Tezspire those be removed for our type 2 low

patients with a low eosinophil count. Also, in addition to that, the clinical policy calls out functional status, but there is no, in terms of exacerbation risk that leads to, in terms of oral corticosteroid use, ED visits, or hospitalizations, in terms of whether they're well controlled or not and would require step-up therapy, I would recommend that those be added as well. And then also for renewal of these agents, I would recommend some objectives tests in terms of like asthma control tests for ongoing approval of these agents. I'm happy to answer any questions and yield my time back to the Committee.

Laura Beste: Thank you, Jon. Just to confirm, was that for this committee or for the Apple Health Policy for Asthma and COPD?

Jon MacKay: I think it's the Apple Health Policy. It's the current medical policy here that I'd like to address.

Laura Beste: So I think that is next on the agenda after we convene the DUR Board.

Jon MacKay: Okay.

Laura Beste: Is that correct, Nonye?

Ryan Pistorosi: This is Ryan -- yes. This is the Washington PDL portion for the P&T Committee. If you're talking about a clinical policy, that would be more appropriate for the DUR Board, which will convene after the P&T Committee concludes.

Jon MacKay: Great. I can address it then. Thank you.

Laura Beste: Okay, thank you. Any other stakeholders?

Nonye Connor: No other hands are raised.

Laura Beste: Okay. Any questions or comments from the Board for discussion?

Nonye Connor: Alex?

Alex Park: Thank you. Alex Park here. Jenny, this is a question for you, and I wanted to wait to let Laura get to the stakeholders because we usually have a lot of stakeholders for these classes. This is for my education and maybe also for those on the Committee. And I apologize if others on the Committee already

know the answer to this question. But I was confused by what you said on Slide 8 when you referred to biologics as human made. Is there -- I think they're made by any kind of cell, not just human cell. Or is there something that I'm not understanding about biologic drugs?

Jennifer Lyon: No. They can be from different laboratory sources. The idea is that they are not things that we necessarily find out in nature. They are things that are laboratory developed, I believe is the idea behind that. I mean, most of these are designed for human cells, for human systems, but by human-made, we mean we develop these.

Alex Park: Yeah. Okay. Okay. I think I understand. Thank you.

Laura Beste: Christy, you had a question as well or comment?

Christy Weiland: Yeah, I just wanted to clarify my understanding. Since this is a surveillance, even though nemolizumab was FDA approved recently, that's why it's not included. Is that is that my understanding correct?

Ryan Pistorosi: This is Ryan. Correct. Yeah, this is [cross-talk] only a surveillance document and not one of the full reports that we get from DERP. So any of the newly approved drugs would not be eligible to be preferred for the Washington PDL.

Christy Weiland: Thank you.

Laura Beste: And Kevin?

Kevin Flynn: Oh, I just wanted to -- so the -- just the answer to the question about biologics. So biologics are not like the small molecules where they're synthesized using classical chemistry like we think of. They're usually grown in cell lines. And so you could think of that you're almost brewing it like beer, and then they're purified from those cell lines. So that's why biosimilars are separate because you can never get it exactly the same like you can if you're synthesizing a chemical molecule. There's always going to be some like amino acid differences. So like -- but for the most part, they're exactly the same efficacy and safety of the original biologic.

Alex Park: Scary about biologics. It's really hard to make sure that each batch is exactly the same because you've got your little yeast cell doing its business and

churning out those little things versus chemically slapping together stuff for those small molecules. But in my mind, everything is human-made. But I think I understand where you're coming from, Jenny, so thank you for clarifying that.

Kevin Flynn: Yeah, normally, they're actually in CHO cells or Chinese hamster ovarian cells. Like, there's a specific cell line that usually they grow them all in, so it would just outside the scope of this. But to your point, very difficult to synthesize versus just a classical chemical molecule.

Alex Park: Yeah. Those hamster ovaries are really productive, huh?

Laura Beste: Okay, good discussion. Question on the motion, I guess, before we accept the surveillance. So they have medications reviewed on the left-hand column. I can't see the bottom of the screen. What is the yellow? Oh, there we go. Okay. So within the motion, I think we need to add, if everybody agrees, that tezepelumab is also safe and efficacious. I think that needs to be added to the motion.

Ryan Pistorosi: This is Ryan. And unfortunately, it cannot because it was not part of a review, it was only part of a surveillance. And so we haven't had the information presented by DERP around its safety and efficacy. That's why it is not in the draft motion as presented on the screen.

Laura Beste: Okay.

Zoe Taylor: So why hasn't that been done then?

Ryan Pistorosi: So the states haven't voted for a report to be commissioned by DERP with the full evidence review of the entire drug class. This is just a surveillance document that shows what amount of information has been published about these drugs in this drug class since then. And these documents are primarily used by the states to inform us of whether this should move forward for a topic nomination or not. And I believe we are planning to look at it at the May -- so the Spring DERP conference, but it is not eligible for being included as a preferred option on the PDL at this time.

Zoe Taylor: And are there doctors and pharmacists in that group, too?

- Ryan Pistoresi: This is Ryan. Yes. Pretty much everyone that is participating in that from other states are either pharmacy directors or are PDL directors or DUR representatives. So I would say most are pharmacists in that, and we do get some doctors from other states, especially for the states that have med participation as well.
- Zoe Taylor: And how does Washington advocate for something like Tezspire to be -- go through that review, if not by us?
- Ryan Pistoresi: So this is Ryan. So we do nominate two different drug classes that we anticipate the P&T Committee would be interested in and that we would also use internally for the development of clinical policies for our Apple Health and UMP programs. We do meet with the other states and advocate for our different topics. The different states are able to then decide whether this is a drug class that they would be interested in. And then we typically will vote at the end of the May conference. So in the spring, we will be convening and reviewing all of the different topic briefs that we had voted for to be developed, and those that do not move forward, we will present to the P&T Committee as a topic brief. Or in the instance of this because it was not moved at the prior -- probably the 2024 meeting -- then it moved forward as a surveillance document, and then that surveillance document was then moved here. So in the life cycle of the DERP clinical reviews, this is just trying to keep the eyes on this drug class to then say now is a good time for us to be able to review it, similar to what we saw with the previous DERP surveillance document where there really was no new clinical information published. And so then that is a sign for us that states that saying let's wait a bit on this. Let's wait for the triple therapies to have a little bit more, and then we can convene together and consider it given our limited budget.
- Laura Beste: Alex, you had a question as well.
- Alex Park: Yes. I'm curious what you, Laura, as Chair, and the Committee, feel about the motion that's before us because we've got two new drugs, one of which we couldn't include for TIP on the last, let's see, on the prior motion because we didn't have a full class review. Now we have the Nemludio as well. And then we have two SERIOUS HARM WARNINGS on dupilumab. It seems hard to go in and say these are all equally safe and efficacious as a class if you think about the new drug, new WARNING for dupilumab, and then you have these other two new drugs that we haven't really gotten a full review on. And I'm sure these are high ticket drug classes for the HCA. They are for the health

plan that I work for. So I would be interested to see if the Committee would want to recommend that we get an updated class review on the basis of this surveillance report.

Zoe Taylor: I agree. I guess, like, process-wise it sounds like perhaps Ryan is saying that if we approve this, it'll then push the other states to actually do the review that we need. If that's the case, we could do it just for that reason. But this is kind of -- I agree, this is kind of pointless to do this right now. We should be pushing for that further review.

Donna Sullivan: This is Donna. I just want to jump in. So just because it's not eligible to be on the Washington PDL doesn't mean it's not covered by Uniform Medical Plan or L&I, if they actually cover these drugs. I'm not sure. It just means that the therapeutic interchange doesn't apply, the DAW rules don't apply, those types of things. So it's still potentially a covered drug. It's just not going to be on the Washington PDL. It's not even in the class because it was not reviewed. So it's managed by however the UMP and their administrator with MODA determines how it'll be managed. This class is getting more and more complicated as the drugs have so many different INDICATIONS and which ones we lump them into, which like the dupilumab, I believe if you see that it's actually in a different -- it's not an atopic dermatitis -- or it's under the atopic dermatitis even though it has other INDICATIONS. But I just wanted to throw that out there as well. And Zoe, to your point, if you guys make this preferred or do something, it won't -- it can't force a review by the DERP program because the other states have just an equal vote as Washington does. It just means we would put it forward as a review. And then if it doesn't get selected, we would have to determine if there's funding for us to actually fund a report on our own. And at this point in time, it's -- that would be a challenge.

Zoe Taylor: So what is, in terms of what we have options to do right now, what is the strategy that would mean Washington was saying review this medication? Is it passing this? Or is this irrelevant to that, like --?

Donna Sullivan: If you were to make a motion asking for a review, then Washington would put it forward in the next -- when the next product topic selection comes about.

Zoe Taylor: Okay, [cross-talk] can't we add that here?

- Ryan Pistoiresi: Yeah, this is Ryan. So what we've done in the past is, at the end of the motion, then you would add in a separate line saying that the P&T Committee recommends Health Care Authority to nominate this for a full evidence review report to be commissioned by DERP. We've done that before in the past. I think the most recent one was with the hypnotics. So insomnia for children, where the report was deemed to be inadequate, and that motion was more of a direction for us to do an update, and then we did go through an update. But it did take a while because, again, we have to convince the other states to vote for our topic. And they have their topics that they're trying to get other states to vote for and there's, again, a limited budget, and so it is not always something that we can do immediately. But if you want to make that a part of your motion at the end, then Nonye can add it here to this page and then we'd go through the motion and the second and the discussion process.
- Nonye Connor: I was going to ask, Ryan, what did you say? I'm sorry.
- Ryan Pistoiresi: Um, I can offer some language or the P&T could, but --
- Zoe Taylor: [Cross-talk] I think we can [cross-talk] talk about it a little.
- Laura Beste: [Cross-talk]?
- Zoe Taylor: Oh, okay, sure.
- Laura Beste: Because we can put the language on there to see what it's going to look like and then decide if that's what we want to move forward with.
- Ryan Pistoiresi: Okay. So this is Ryan. So the language that I had said was that the P&T Committee recommends HCA nominate this drug class for a full updated report to be commissioned by DERP. And I think that should be clear for your direction. But again, this is part of your motion, so you can edit it as you see fit.
- Laura Beste: Thank you, Ryan. This is Laura. Going back to something Alex stated as well about the medications being safe and efficacious, I believe last Committee meeting we had discussed removing the word "safe" and just leaving it as "efficacious." Did anybody else have feedback on that?
- Nonye Connor: How does that look?

- Alex Park: Um, I'm just curious, HCA folks, is there boilerplate language that the Committee is required to use in adjudicating the medications based on our duty to the program? I mean, [cross-talk] are we [cross-talk]?
- Donna Sullivan: [Cross-talk] No. We have the Committee has removed the word safety in the past, or you've not said that they're equally safe. Sometimes you've just said that they're efficacious for their FDA approved indication. So there is no set boilerplate that you have to do or follow. But we -- this is just like the standard that we go with. But you're more than free to audit or edit it as you see fit and appropriate.
- Alex Park: Thank you, Donna, for that. Laura, are you thinking that we should change the language in the template going forward or just in this motion secondary to the various new WARNINGS that Jenny brought forward?
- Laura Beste: I feel like there are many of these medications that you -- in these classes, and I believe that's where it came up last time that you really can't say that they're equally safe and efficacious. Now, we can say they're efficacious based on their FDA INDICATIONS and the studies that are done behind that. But as far as safety, as was stated, there are more WARNINGS added to some of these medications over the others.
- Alex Park: Yeah, [cross-talk] that makes sense.
- Laura Beste: [Cross-talk] Hey, Chris, do you have a comment?
- Christy Weiland: Yeah, this is Christy Weiland. I guess part of this conversation I'm also thinking -- if one route would be to remove the therapeutic interchange, given the complexity of everything we've discussed, including the safety parameters. And I know it's for FDA-approved INDICATIONS, but we do have some new WARNINGS on some of the agents, and I guess it makes me a little uncomfortable thinking that there would be therapeutic interchange among the four listed. If that's one approach to it as well.
- Laura Beste: Donna, do you have any feedback on that?
- Donna Sullivan: Um, yeah. That's up to you. That's up to your discretion whether you want to remove therapeutic interchange or not. The -- and I also just want you to know as a caveat, I don't know how much therapeutic interchange actually

occurs because I know a lot of the chains don't let their pharmacists actually do it. But if you don't feel comfortable with the therapeutic interchange, I don't think there's much interchange going on in this class. And so removing it I don't think would create a big issue.

Zoe Taylor: I would not do the -- I guess, we removed like "safe and" already. I don't know if I agree with that for all of the meds. I think our only safety concern is dupilumab, right? So rather than removing "safe and" from the whole list, I think it would make sense to put that back and then maybe remove dupilumab from that list and then said -- add something about like dupilumab requires further review or something like that. I think the other option would be we could just refuse to do this until we have actual information. Like, I don't know if there's a point of doing this now, so that might be a simpler option than making all these changes.

Alex Park: Alex Park. I tend to agree with you, Zoe. And Donna, I'm just looking at the deck that you went over in our orientation to start the year. And the P&T Committee slide does say that we're determining which drugs are safe and efficacious for inclusion on the PDL. And I tend to agree with you, Zoe. I don't want to advocate that responsibility. At the same time, I don't feel like we've been presented data to really say one way or another anything about dupilumab. We know that there are new WARNINGS on it, what that came from, how many patients that might affect. Whether that's the same kind of WARNING that's on all the other drugs, I don't know. Maybe Jenny, that's something you can answer for us. But until we get that updated review, we may not be in a real strong position to make changes. I'm wondering if our best position is to take all these questions that we have and say the Committee does want to nominate this for a full drug review. Biologics are expensive. There are a ton of indications. There are safety issues. There's all the new studies that Jenny said that are coming up. We'd like to know about those and then look at that review down the line. And until then, maybe just reiterate the prior motion. That could be another approach.

Zoe Taylor: Or just say that one sentence at the end and not say -- and take away the rest of the motion. Or say something like we're -- abstain -- you know, please refer to the prior motion. We're abstaining from editing this -- you know, reaffirming this motion at this time.

Alex Park: Mm-hmm. You're saying don't reiterate the prior motion?

- Zoe Taylor: Well, I mean, the reiterating the prior motion is the -- like, that would mean we are saying we can say all of these are safe and efficacious right now.
- Alex Park: Oh, I see what you're saying.
- Zoe Taylor: So we could say, like, please refer to the power motion, but we are not, like, reaffirming that because we don't have the information to do that. I don't know what you would normally do. Or we could just say, like, let's just say that we recommend this be reviewed by DERP and not do anything else.
- Kevin Flynn: Can we just table the motion and then make the recommendations so that, like, effectively doing nothing, right?
- Zoe Taylor: [Cross-talk] I think that would be good.
- Laura Beste: [Cross-talk] And so would we still accept the surveillance and then just ask for further information before making a new motion?
- Zoe Taylor: I don't know. I think for the future, it'd be good not to be in this situation of, like, trying to reaffirm a motion that's only a year and a half old without any new information.
- Alex Park: [Cross-talk] I think [cross-talk] --
- Ryan Pistorosi: [Cross-talk] This is Ryan.
- Alex Park: Oh.
- Ryan Pistorosi: I just wanted to say -- so as we get these different documents like the surveillance documents are intended to be once a year, we do try to make sure that we review these. So even though this does have some new evidence and hasn't been nominated for a full topic yet, that's the reason we bring these surveillance documents, or in the past the scanned documents, was trying to make -- making sure that the P&T Committee was being updated, and that we could do updated cost reviews for these as these drugs continue to have cost changes and new indications and new rebates and things like that. So there are other things that happened after these reviews. So even though this one is a bit more challenging than some of the other P&T reviews that we do, just know that this then goes into that cost analysis phase later

and that we can then update this drug class to reflect kind of the current state of the class.

- Alex Park: So Alex Park. Ryan, I was gonna ask the -- if we don't reiterate the prior motion, then is it the case that what is practically happening on a day-to-day basis with prescribing in Washington State as far as this class goes is that we're just -- you're essentially already doing what the prior motion was. Is that correct?
- Ryan Pistoresi: This is Ryan. Yes. If you do not reiterate the prior motion and do not make a motion and do not have a decision, the existing motion would remain in effect.
- Alex Park: Okay.
- Laura Beste: If we do that, though, can we still recommend that the HCA nominate the drug class for a new report? Or is that part of our current reiteration?
- Ryan Pistoresi: This is Ryan. So if you were to want to only recommend that we pursue this as the -- as an updated drug class, the prior motion would still remain. I mean we'd have to still continue to cover these drugs, and so the prior evidence review as it is stated down there would remain. So unless you are going to make changes to what is considered safe and efficacious of the eligible drugs, then, yes, the old motion would remain in effect.
- Zoe Taylor: Okay, I feel neutral about whether we copy and paste the old motion or we don't put anything because I think either way it's the same. Whatever is easiest as long as we keep that last sentence also.
- Laura Beste: Okay. So I believe -- this is Laura Beste -- so to clarify what I think everyone is saying we are going to keep the motion as it was previously with no changes. So add the "safe" back in, and then we're going to accept the survey -- or vote on accepting the surveillance. And then the reiteration of the prior motion, we are going to say we would like to have the further review before we accept it. Yes? No?
- Alex Park: I'm processing, Laura. [laughter] It's a lot of -- I think, yes. Only, the only thing is we would -- we're reiterating -- I lost track of the last thing you said.

- Laura Beste: Yeah, we're reiterating it because we're adding the recommendation to nominate this drug class. So I think we still reiterate the prior motion and vote on that. And we're essentially voting on the fact that we want this drug class to have a full updated report.
- Alex Park: Yeah. Oh, that was my question. If we reiterate the prior motion, we're just saying we're rinsing and repeating, but we're adding this nomination piece to the motion. So is that a real reiteration? [cross-talk] Or are we making a new motion?
- Zoe Taylor: [Cross-talk] In the past, I don't remember like voting on two different things for the motion. I just remember voting on the motion.
- Laura Beste: Laura we accept -- we have to accept or deny the surveillance, and then we do have the motion.
- Zoe Taylor: But then why does the last one say N/A for both? If we're accepting a new motion, doesn't it cancel out both of those columns?
- Ryan Pistoresi: So this is Ryan. Potentially the reason that it was an N/A was that it was not a surveillance, that it was a report [cross-talk] and therefore, it was not a reiteration of the prior motion because we were able to add new drugs at that time. But I would need to see what report was reviewed in 2024.
- Zoe Taylor: Well, okay. I trust you then, Laura, on what we need to vote on because I don't know.
- Laura Beste: [Laugh] Ryan? Do you have any guidance for us on it is [cross-talk] --
- Ryan Pistoresi: So this is Ryan. Yeah, I think what you can say is that yes, it was adequate because it did reveal that there was a lot of new evidence that you are interested in, and that it is -- for the purposes of wanting us to then nominate it for a review. So you could say that, yes, it was accepted as adequate, and then for the reiteration of a prior motion, it would be no because you do have that extra line at the bottom that says that you are recommending it. And if that is the case, then I think it is ready for a motion in a second. And we would continue with the existing guidance that we got from the previous P&T Committee in 2024, and we would move forward with trying to nominate this for a full report the next time that we are able to.

- Laura Beste: [Cross-talk] Okay.
- Alex Park: [Cross-talk] This Alex Park. That makes sense to me.
- Laura Beste: Do we have any other feedback from the Committee or comments? Okay. If not, does everyone -- if all in favor of the surveillance as adequate, please say aye.
- Multiple Speakers: Aye. Aye. Aye. Aye. Aye.
- Laura Beste: So for the motion, we're going to deny the -- we're going to continue the previous -- the prior motion with the request that the P&T Committee recommends HCA nominate this drug class for full updated report to be commissioned by DERP. All in favor, say aye.
- Zoe Taylor: [Cross-talk] Well, meaning to [cross-talk].
- Multiple Speakers: [Cross-talk] Aye. Aye. Aye. Aye. Aye.
- Laura Beste: Is there any opposed or abstain? Okay, with that [cross-talk] --
- Nonye Connor: [Cross-talk] I think -- I think we need someone to [cross-talk] --
- Laura Beste: Read it?
- Nonye Connor: Yes, please.
- Laura Beste: Okay. I'll go ahead and read it. So our motion is biologics for non-asthma conditions. After considering the evidence of safety, efficacy, and special populations for the treatment of their FDA-approved indications, excluding asthma, I move that benralizumab, dupilumab, mepolizumab, and omalizumab are safe and efficacious for the treatment of their approved indications. Benralizumab, dupilumab, mepolizumab, and omalizumab can be subject to therapeutic interchange in the Washington Preferred Drug List for their FDA-approved indications, excluding asthma. The P&T Committee recommends HCA nominate this drug class for a full updated report to be commissioned by DERP. Do I have [cross-talk] a second?
- Alex Park: [Cross-talk] This is Alex Park, I'll second.

Laura Beste: Okay. All in favor, say aye.

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

Laura Beste: Any opposed or abstained? Okay, thank you very much for that. That was good commentary and discussion, and we will look forward to hopefully having an updated report in the future. With that, I believe we, the Pharmacy and Therapeutics Committee, is adjourned for the day. And we will have a 10-minute break before moving on to the Drug Utilization Review Board.

Nonye Connor: Okay. I'm going to go ahead. Yeah, we could take the 10-minute break. I'm going to put the sign up.

Laura Beste: Okay. Thank you.

Nonye Connor: Thank you. So we'll be back at 11:20. Oh, 11:29. Thank you.

[break]

Nonye Connor: Let me resume. Okay. Sorry about that.

Donna Sullivan: No, that's fine. I'm glad you caught it before [cross-talk].

Nonye Connor: Yeah.

Donna Sullivan: So if you recall, the Ingrezza policy, it required that it be prescribed in consultation with a psychiatrist or some other specialist, which did not include the nurse practitioners. So the testimony essentially was that nurse practitioners, especially the psychiatric nurse practitioners would be able to prescribe the antipsychotics that cause tardive dyskinesia, but they would not be able to prescribe without consulting with another prescriber or specialty the Ingrezza. So we took that into consideration, and we're going to add them as an allowable prescriber type. And then we also are working with some of our other policies to see if we have a similar situation where there might be a specialty or certification on a nurse practitioner that would -- which would make them appropriately prescribing different medications. So I don't think we have that public -- that policy republished yet, but we will be adding the nurse practitioners. So that was just my update.

Laura Beste: Did that -- this is Laura Beste -- did that address your concerns, Greg?

- Greg Hudson: Yeah, thank you. I was just bringing myself off mute. Yeah, this is Greg Hudson. I think that addressed the bulk of the concern there, just sort of an unnecessary barrier to the access of that medication. So I'd be curious. Like I said, Donna, -- I guess my one request would be that once that is published, Donna, if we could just have an update on that when it's live, so to speak. But thank you for speaking to that.
- Donna Sullivan: Great. Will do.
- Laura Beste: Okay. So with that, and since we're being recorded now, we will go back to Ryan Pistorosi with the Asthma and COPD Agents Monoclonal Antibodies Policy Review. Thank you.
- Ryan Pistorosi: Great. So this is Ryan. So, again, this was a clinical policy that was developed by Marissa, but I will be presenting it to you all today. So if there are some more technical or detailed questions about this clinical policy, I may not be able to answer them right away. I may need to do some research on that. So just giving you the heads up before we step into this. But here we have the draft Asthma/COPD : Monoclonal Antibodies policy. So similar to some of the DERP reports that you saw earlier today, you may recognize some of the same medications here in the medical necessity table. But essentially, this policy does cover the different drugs and their different indications as well as the clinical criteria for them. As you can see, this policy is 16 pages, so it is very long because it does cover so many different medications and so many indications. So I'll go ahead and begin. So at the top, we have it for asthma. And so this first part is for XOLAIR, and it may be approved with the following criteria. Given the size of this policy, I won't be able to read through everything. Otherwise, we'll be here -- but I will just go ahead and highlight where there are some of the clinical criteria, specifically at 5., 6., and then 7. And then the Tezspire criteria is going to be below this. So once we finish through the Xolair, then we come into the Tezspire.
- Laura Beste: Ryan, are you still there? We're not hearing any sound or I'm not.
- Ryan Pistorosi: Yes. No, I was letting the Committee, the DUR Board, sorry, [cross-talk] review this. But if there were no comments on this, sections 5, 6, and 7 are where we have the specific criteria regarding the disease state. So if they have moderate asthma, then the Criteria 4. apply. If they have severe asthma, that is number 6. And then the concurrent therapy there is at 7. And then as

you see down below is the start of the Tezspire clinical criteria, which would be the same as the Xolair criteria plus the additional criterion. And if you're ready, I can then scroll down further. Okay. And then the Tezspire criteria. So again, they have the different age indication. So where Xolair was 6 years, this one is 12. For the Criteria 10, that's 2 and 3, and then 6 for 8. So 2 and 3 were being prescribed by or in consultation with an allergist, pulmonologist, immunologist, or otolaryngologist, and to be not used in combination with any other monoclonal antibody. And then 6 through 8 were around the severe asthma indication, the concurrent therapy in 7, and then 8 as in the asthma controller. Okay, so if there are no questions or comments about this policy, I can go down to the Reauthorization Criteria. So once a patient meets the criteria and is approved for use, when they are submitting for reauthorization, it will be the same criteria for both Xolair and Tezspire, which is listed here. So these three criteria. So showing that they continue to not use another monoclonal antibody for the use of the same indication for asthma, that there is documentation showing some disease stability, showing that the medication is working and alleviating symptoms or morbidity, and that they are still continuing to use asthma controllers unless contraindicated. And then they would be approved for an additional 12 months. Okay. So moving on from the asthma indication, we have the chronic rhinosinusitis with nasal polyps indication. And so this has the same medications as above with Xolair and Tezspire, but this one now also includes Nucala. So, as you saw before, Xolair is the preferred on the Washington PDL, and so its criteria are listed here at the start, and then down below we will have the Nucala and Tezspire clinical criteria below. It is laid out similar to the others, so we will start with the age, the prescriber 2, the concurrent monoclonal antibodies in 3, and then some of the more diagnostic-specific criteria after that. So, hopefully, that makes these policies easier to navigate because we will be going through, I think, six more indications after this. Okay, does anyone need more time on the criteria on the screen?

Laura Beste: No, I think we're ready. However, I had one question in regards [cross-talk] --

Ryan Pistorosi: [Cross-talk] Yes.

Laura Beste: -- where it's saying that "it's been ineffective unless all are contraindicated or not tolerated," where you're saying that with the dupilumab and

omalizumab, so in some cases, the patients won't meet criteria for those agents either. So is some of this wording should be not, not indicated?

Ryan Pistoiresi: So for #8, correct?

Laura Beste: I'm going back here. It's where it says that to use like the Tezspire or the other agents, so depending on which one we're looking at. So in the first part for asthma, it would be #11, the treatment [cross-talk] --

Ryan Pistoiresi: Going back to asthma, one second. [cross-talk]

Laura Beste: Well, yeah, and it's going to be the same thing in the chronic rhinosinusitis as well. So the treatment with dupilumab and omalizumab have been ineffective unless all are contraindicated or not tolerated.

Ryan Pistoiresi: Correct, yes. And so since those are the preferred drugs, and this is a class that has trial and failure of two, that's why both the dupilumab and omalizumab are listed there. So if someone were to use dupilumab and it was ineffective, and omalizumab was contraindicated for some reason, then that would satisfy both those criteria and the Tezspire could then be approved after just the use of the one.

Laura Beste: Okay. And I think this is what they were talking about before, the IgE level. So if the patient doesn't have the IgE levels for treatment with the Xolair, would that be considered not indicated or ineffective or --?

Ryan Pistoiresi: So I believe the IgE was listed for Criteria 4, so it was not part of the Tezspire, correct. So in the case in which someone were to be requesting for Tezspire without the IGE and not having used the other, they would be able to submit for a PA for a clinician to review in accordance with this policy. So if that were the case and they did not have that elevated IGE but met the other criteria, that provider could submit the prior authorization request.

Laura Beste: Okay, thank you.

Ryan Pistoiresi: Mm-hmm. So let me scroll back down. And so just since I came back to these criteria again, I'm wanting to see if the Committee -- or sorry -- if the Board had any questions on this or if I should scroll down because there are more criteria on the Nucala and Tezspire than the page below. Hearing none. So for the Nucala and Tezspire, these are the Criteria 10 through 13, so for both

Nucala and Tezspire. And for the reauthorization criteria, similar to above, we have the three same criteria, where the Criteria 3 continues to be met, and that is the no concurrent use of another monoclonal antibody for the same indication, that the background medications are still continuing to be used, and that there is documentation that the medication is improving symptoms such as nasal congestion or reduction in nasal polyps. All right. So on to the third indication. Now we are going to the Chronic Spontaneous Urticaria. And for this one, we only have one drug, Xolair. And as you remember from the other ones, this is our preferred in this class. So Xolair just has these seven criteria, and in the reauthorization, we just have the two as shown here. Okay. So if there are no questions on this indication, I will scroll down to our fourth indication. So 4 of 8. This one is on COPD with Eosinophilic Phenotype. And the medication that is approved with this indication is Nucala. And so Nucala is our preferred for this disease state. And the criteria are listed on the screen and then also the reauthorization criteria. All right, let me continue on. So the next indication is for Eosinophilic Granulomatosis with Polyangiitis -- sorry. And so there are two drugs approved with this indication. So Fasenra is our preferred, and so that criteria is listed first. And then in this disease state, Nucala is non-preferred, and so its criteria will be listed in 8 and 9 below. Okay, I will continue to the reauthorization criteria. So like the others before, again, just making sure that there is no concurrent use of another monoclonal antibody and that there is some documentation of improvement from using the medication. Okay. The next indication in this policy is for Hypereosinophilic Syndrome. And the only medication with this approval is Nucala, so it is the preferred option again for this disease state. And on the screen now are the clinical criteria for this disease state. Great. I will continue to the next indication. So this is for IgE-Mediated Food Allergies. And so the only medication in this class with the approval for this indication is Xolair. And so the criteria are listed here on the screen. And the last indication in this policy is the Severe Asthma with Eosinophilic Phenotype. And so for these we have three medications. The preferred in this is Fasenra, and so its criteria are first, and then Nucala and Cinqair are listed beginning at criteria 8, further below. And that has just the 10 criteria. So 8 through 10 were the other medications. And I will scroll down to show you the reauthorization criteria, which mirrors the others above of, again, no concurrent monoclonal antibody and the disease improvement.

Zoe Taylor:

In #7, it says, "will be continued with the use of Xolair." Should it say that? Or should it be more -- be less specific?

- Ryan Pistoiresi: Um, let me make a note of that. I, again, so this is not my policy. I'll need to look at Marissa's work in this because this has gone through multiple reviews with us and with our managed care organizations, and so I do want to investigate and see if there was any other prior discussion about Xolair being specific here. or not. My thought is that this was a mistake because we talk about Fasenra up here rather than Xolair.
- Zoe Taylor: Yeah, I think it's just a typo.
- Ryan Pistoiresi: Yeah, I think so too. But again, I will need to -- I will need to investigate. But I appreciate you catching that, and it is now documented.
- Kevin Flynn: And then reslizumab is like an IV infusion still. This is supplied to like the medical benefits side, too?
- Ryan Pistoiresi: So this is Ryan. Yes, it can apply to certain drugs on the medical benefit. So if the medication is being dispensed through a specialty pharmacy to a provider's clinic or to an outpatient infusion or home health infusion, then this policy would apply. If this is being billed through kind of a non-pharmacy claim, like what I like to call on the medical benefit, then I don't believe this applies. Although, Donna, if you're on, I'm not sure how this is programmed within our P1 system.
- Donna Sullivan: I'm sorry, say that again.
- Ryan Pistoiresi: Do you know if this clinical policy applies to P1 as well as point of sale or if this is a point of sale only policy?
- Donna Sullivan: No, they would -- they should require a PA through medical or through pharmacy. The same [cross-talk] policy would apply.
- Ryan Pistoiresi: [Cross-talk] Okay. So the correction to what I was saying. So yes, this does apply to both a medical PA and through specialty pharmacy.
- Kevin Flynn: All right, thank you.
- Ryan Pistoiresi: Okay? And then so after the clinical criteria, we have the dosing and quantity limits. So this chart shows how much of a medication can be approved. So, depending on the indication, depending on the drug, and depending on the

age, we do have this chart here. So that shows when we would approve certain medications. And so if a provider were to request a dosage above one of these thresholds, it would also trigger for a prior authorization review and the documentation for why a dose above the FDA limit or the recommended limit is justified. And so that -- this table really focuses in on those types of things. So if it's being prescribed at or below these levels, that doesn't necessarily require any additional criteria than what was reviewed and likely approved above. But if a patient is being requested for a dosage above one of these here, then there is additional key criteria for going above these quantity level limits. And so this is the continuation. And then the Coding. So these are the different HCPCS codes that are appropriate for the different dosages. And then the remainder of the policy is general background information about the drugs and the disease states, and then the citations and the history of this clinical policy. So any general questions about the draft monoclonal antibody policy? I know it's very large given the number of drugs and the number of disease states but wanting to see if there were any other clinical questions and criteria before moving on to the pend form. Okay. Hearing none. So the other half of the policy is the monoclonal antibodies pinned form. So this is the draft form that we would submit when requesting additional information in order for us to do a prior authorization review. And so as you saw from the way that we structured the clinical policy, it was in a similar order. And that's because in this pend form, we tried to copy that order. So that way, depending on the drug and depending on the disease state, that that flow for the clinicians would be similar and hopefully improve efficiency in filling out these pend forms. What I do want to highlight is that at #5 are the different INDICATIONS. And so once a provider gets through the initial assessment, looking at their specialty and really the patient's weight, which does depend on some of the weight-based and age-based dosing, then they come down to the indication. And then there are a specific subset of questions that follow afterwards. And as you can see from these, they're all mutually exclusive sections. So the asthma and the severe asthma with eosinophilic phenotype do have different buckets of questions, so you're not having to answer one from one section and then move to another section, so they are built in their own components within this policy. And so if there are no questions on the first part, then you can see how they are. So starting here with 6 through 12, that is for asthma. And so if the patient has asthma, these are the questions as you had seen on the draft clinical policy prior to this. And then the severe asthma with eosinophilic phenotype is below, and you can see that some questions are similar. But again, it does not require the provider to kind of hunt through and answer different questions in different

sections. So hopefully, this was designed in a way to help the prescribers understand what questions we are asking and what types of clinical information we need in order for our pharmacists to do their review for medical necessity. And if you would like, I can direct your attention to any specific section that you may have questions about, but I can just kind of scroll through so you can see how the sections are drafted. Just know that these are the same questions that you saw on the prior slide. So if there are no other questions or comments from the Board, Nonye, I can hand it back to you. But I just wanted to reach the end. Yep, so I reached the end here. And so if there are no other questions, comments, from the Board, I will hand it back to Nonye.

Nonye Connor: And Laura, I do see one stakeholder hand raised.

Laura Beste: Okay. If we can have the stakeholder speak. [Cross-talk] Okay.

Nonye Connor: And it's Jon.

Laura Beste: Okay.

Jon MacKay: Hey. Good morning, again.

Laura Beste: Good morning.

Jon MacKay: All right. Good to see some familiar faces.

Laura Beste: Nice seeing you, too.

Jon MacKay: This is Jon MacKay, a Clinical Pharmacist with Providence. I just wanted to address the clinical policy for asthma, for biologicals, specifically for the requirement for Tezspire. If we could go to that, if we have a moment. But in terms of the requirements of trial and failure of dupilumab and omalizumab, there are a subset of patients with a phenotype with low IgE and low eosinophil count. And so the prevalence is not widely known, but probably 20% - 25% of those patients with severe uncontrolled asthma that would qualify for a biological, and so it's a large subset. And those patients likely would be ineffective treatment with Dupixent or Xolair. Dupixent typically requires an eosinophil count of 150 or greater. That's what the labeling requires. And Xolair typically requires an allergic phenotype. And so there is a subset of patients where requiring a trial and failure of those two agents

wouldn't be clinically appropriate. And requiring patients to step through both of those agents really increases the risk for harm and poor outcomes, and so I would really ask the Committee to consider making tests by our first line for those patients -- for that subset of patients. Also, I would recommend potentially adding lung function. It is important in terms of assessing the need of control, but also exacerbation risk isn't always necessarily tied to lung function. And so I think adding criteria that addresses oral corticosteroids, hospitalizations, and emergency room visits in terms of step-up therapy would probably be warranted to as well. So those would be some of my key clinical recommendations, and then also having objective monitors of clinical response, including like ACT tests to monitor ongoing response. I'm happy to take any questions you might have.

Laura Beste: Thank you, Jon. Does the Board -- oh, it looks like Zoe has a question.

Zoe Taylor: Yeah, is it possible for us to put up the policy for the section that he's talking about? I'm thinking that probably the part where it says 'unless contraindicated' will cover the issues that you're talking about, but I'd love to know from your actual clinical experience if there's a reason that it's still getting denied even though, you know, for those patients with low IgE, etc. Like that should be considered a CONTRAINDICATION to Dupixent. And I can't remember the other medication.

Jon MacKay: Yeah, that's a great question. So I think they're not technically contraindicated in terms of risk for harm but likely not clinically effective. So requiring two agents that are likely not effective but not technically contraindicated an off-label for that subset of patients with a low eosinophil count of 150 or less or a low IgE or a non-allergic phenotype. So yeah, so maybe not technically contraindicated but not likely clinically indicated as well.

Zoe Taylor: Can you scroll down a little bit?

Ryan Pistori: This is Ryan. Sure. How far?

Zoe Taylor: That's good.

Ryan Pistori: Okay.

- Zoe Taylor: Um, I don't know. I feel like that counts as contraindicated. I wonder if there's guidance we can give to the reviewers that wouldn't require changing the language, which should count as these two being contraindicated if they're not clinically indicated, then -- I mean, I agree that contraindicated isn't really the right word, but we could also add the language unless 'all are contraindicated' or 'not clinically indicated'.
- Laura Beste: This is Laura. I believe Donna has a comment.
- Donna Sullivan: Yeah. I would prefer that we actually go look at the evidence and see what the evidence says rather than listening to the testimony from a stakeholder, so before we make any changes to the policy.
- Zoe Taylor: Sure, yeah. I'm not advocating making any changes. I'm thinking that, you know, I imagine if somebody put in a prior auth and said the reason we didn't try these two are because these two are not indicated for this patient that would be effective, and so I don't know that there necessarily needs to be any change made.
- Donna Sullivan: Did we make that change? I thought based on somebody else's comment we might have inserted unless not indicated because [cross-talk] --
- Laura Beste: [Cross-talk] No. This is Laura. I had asked that question as well. But I think -- and then Ryan has stated that they would just have to submit prior authorization because the patient wasn't a candidate for the other two treatments, or one or two of the treatments.
- Ryan Pistoresi: And this is Ryan. Yeah, and I think that kind of fills the Criteria 11 here. So if the other medications are working on IgE and not -- yeah, I'm just looking at that -- contraindicated for not being effective, then that provider could submit that documentation for our clinical pharmacists to review for medical necessity.
- Laura Beste: This is Laura. I just want to confirm one point. When it says a minimum trial of 12 weeks, is that per agent?
- Ryan Pistoresi: So this is Ryan. And yes, it would be because I believe that the studies were showing efficacy at the 12-week mark. But again, this was not my policy, so I don't know all of the details and why 12 weeks was selected. But I believe

that was the duration from the clinical trials to show that minimum level of response.

- Laura Beste: Any other comments or questions from the Board? Oh, and as of note, Hope pointed out if we could possibly update the name of the policy to reflect the non-asthma and COPD INDICATIONS. I thought that was a good, -- it would be a good [cross-talk] --
- Ryan Pistoresi: [Cross-talk] So this is Ryan. I will make a note for Marissa. Since Marissa handles the Apple Health PDL and all of the drug category names and the drug class names and the policy names, I will defer to her because of how she manages and organizes all of these together. But I will make a note about the policy name.
- Laura Beste: Thank you.
- Ryan Pistoresi: Uh-huh.
- Laura Beste: So if we have no further comments or discussion, Nonye, do we vote on this? Or do we approve it?
- Nonye Connor: So Ryan will be sharing the motion soon.
- Laura Beste: Okay, thank you.
- Ryan Pistoresi: Yes. I just wanted to make sure that I -- even though it's more of the asthma COPD agents, just kind of making sure that that note was what you were looking for, Laura. I see Hope. Oh, sorry.
- Hope Barnes: Just a process question for my own understanding. So in our previous review board of the screening of the non-asthma related indications for these drugs, we decided not to move forward because we knew that there was more information coming. We asked formally for a review. And then we have a similar question in this with our pharmacist friend from Providence's. You know, is there further evidence that we need to review before updating and passing this motion to approve this policy? It sounds like there's more to tease out. And I'm curious if we pause this and wait for further evidence, would that be appropriate?

- Ryan Pistoresi: So this is Ryan. And that's a great question. So there is a separate process between what we reviewed earlier this morning and what we're reviewing right now. So earlier this morning was your role as the P&T Committee, and the P&T Committee is specific to the Washington PDL. So that impacts different programs than what this clinical policy does. So this clinical policy, as part of the DUR Board, is specific to Apple Health. And so even though you determined that you would like a full review, that will be for the P&T Committee to review. This, as the DUR Board does not operate under the same timeline, and so we are able to do our own individual research for our own clinical pharmacists for supporting decisions under the Apple Health program. And later on, when we're doing the drug class reviews towards the end of the meeting, those will be specific to the Apple Health PDL. So it may be confusing because there are multiple different programs and multiple PDLs and different clinical policies, and we're looking at the same drugs as before, it can be a little confusing. But just know that now and until the end of the meeting, we are now focused solely on the Apple Health program rather than Uniform Medical Plan, Labor and Industries, or any other entities that would participate under the Washington PDL.
- Hope Barnes: Thank you for that. So I'll have to take off my P&T hat and put on a different hat. And so what is the turnaround time for the evidence review for the Apple Health Plan with our own pharmacist?
- Ryan Pistoresi: This is Ryan. I'm not sure I understood your question. The [cross-talk] turnaround time.
- Ryan Pistoresi: [Cross-talk] Oh, yes. You were saying we could do our own separate evidence-based medicine review -- and sorry, this is Hope Barnes -- which is separate from the P&T Committee that we requested earlier. So what does that look like in timeframe-wise for this particular question that we have from our friend Jon at Providence?
- Ryan Pistoresi: So this is Ryan. Yes. So what we could do is we could hold off on finalizing this policy until we meet internally and can get the evidence that Donna had mentioned that we would need to review in order to make that consideration. So this policy would be held until the next meeting, I believe, April 15th, and then we would be able to re-review it then focusing just on any changes that were made from this meeting to that meeting.
- Hope Barnes: Thank you for explaining.

- Laura Beste: Any other questions or comments from the Board? And Ryan, I have one other question for you. So if, as Hope stated, if we decided to put this policy off, is there a current policy in place for these medications already and we're updating that, or is this a brand new policy?
- Ryan Pistoiresi: So this is Ryan. And fortunately, we do have the history located here at the tail end of the document. It looks like the last policy was the third version of this policy that was voted on in the February 2024 meeting and became effective August 1st. And so that policy would remain in effect until this updated policy is approved by the DUR Board. So one note is when we go to the motion screen on the next one, you could say everything else in this policy is approved pending the research that the Health Care Authority does regarding the non-IgE asthma indication.
- Laura Beste: Okay, thank you. Can we say the motion, please?
- Ryan Pistoiresi: Yes. Give me one moment to switch. And this looks like the right document. So the PowerPoint slide should be up. And the asthma, COPD agents, monoclonal antibodies, this is the draft motion that we have. So just confirming that everyone can see the PowerPoint.
- Zoe Taylor: I think that we can approve this motion because I think it's unlikely that the language needs to be changed in order for those cases to be considered. I think it's likely that more of like a process thing with making sure doctors know that those patients count as CONTRAINDICATIONs, and that they can write that and explain that in their prior auth request? How do other people feel?
- Kevin Flynn: I would agree with your statement.
- Christy Weiland: This is [cross-talk] Christy. I agree with you, Zoe. I think a statement of efficacy would like versus CONTRAINDICATION and stuff. I think most clinicians can kind of weed out themselves.
- Laura Beste: I also agree with that comment. This is Laura. Any other comments or discussion? And if not, would somebody like to make a motion?
- Kevin Flynn: This is Kevin Flynn. I can make the motion. I move that the Apple Health Medicaid program [cross-talk] --

Ryan Pistorosi: [Cross-talk] Oh, wait. We will need a second before.

Kevin Flynn: Okay [cross-talk] [indistinct].

Ryan Pistorosi: Oh no, sorry. Go ahead.

Kevin Flynn: Okay. I approve that the Apple Health Medicaid program implement the clinical criteria listed on policy 44.60.00-1 as recommended.

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

Laura Beste: Okay.

Ryan Pistorosi: Okay.

Laura Beste: Thank you for that. And all in favor, please say aye.

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

Laura Beste: Any opposed or abstained? Okay. And with that, that passes. So on to the next Apple Health Policy review of Oncology Agents: Antimetabolites - Oral by Ryan Taketomo.

Ryan Pistorosi: And Ryan, did you want me to share my screen? Or did you plan to share your screen?

Ryan Taketomo: If you could -- Hi. This is Ryan Taketomo. If you could please share your screen, Ryan, that would be great.

Ryan Pistorosi: Okay. I am pulling it up, so give me one second. Okay. And then I will let you tell me when to scroll through.

Ryan Taketomo: Great. All right, good afternoon. This is Ryan Taketomo, and I'll be going over the Oncology Agents : Antimetabolites - Oral clinical policy. There are two drugs that will be included, which include azacitidine and thioguanine. We can scroll down to the clinical criteria. I believe there's only one indication that's for acute myeloid leukemia. And I'll kind of walk through the criteria. So azacitidine or thioguanine may be approved when all the following criteria are met. Criteria 1 is patient meets one of the age criteria. So for 1(a),

for either azacitidine, it's 18 years of age or older; or for thioguanine, there's no age requirement. And Criteria 2 is it's prescribed by or in consultation with an oncologist or hematologist. And Criteria 3, there's a diagnosis of acute myeloid leukemia. And Criteria 4, the patient is being prescribed therapy for one of the following: So for azacitidine, they have to have one of the following: the first one is the patient is receiving continued treatment after achieving first complete remission, or Criteria 2, which the patient has achieved complete remission with incomplete blood count recovery following intensive induction chemotherapy and are unable to complete their intensive curative therapy. And then for thioguanine, the patient is receiving therapy for induction or consolidation therapy. And then once those criteria are met, the authorization will be approved initially for six months. And then for reauthorization, the criteria is there's documentation of a positive clinical response or stability. So the patient remains in remission, their stabilization of disease or lack of progression. And then once that's demonstrated, the reauthorization period will be six months at a time. We could scroll down, please. Okay. And then we just have our listed dosage and quantity limits and the background information. We can scroll down to the pend form.

Ryan Pistorosi: Give me one sec, I think the pend form is on a separate -- okay, the pend form should be up.

Ryan Taketomo: Yep. All right. We can just scroll down a little bit. That's good. Thank you. So this is a pend form. This helps to facilitate the prior authorization process with the provider. So I'll leave this up for the community to review and then open it up for any discussion, questions, or feedback.

Zoe Taylor: It doesn't really make sense to have hematologists and oncologists have separate boxes. A lot of times people are both, and a lot of the fellowships are combined.

Ryan Taketomo: Yeah, that makes sense. We can combine that into one box or just like hematologist/oncologists [cross-talk] --

Zoe Taylor: Yeah, I think that would make more sense.

Ryan Taketomo: Okay. And that was -- this is Ryan Taketomo, by the way.

Zoe Taylor: This is Zoe Taylor. Sorry, I always forget to see my name.

- Kevin Flynn: This is Kevin Flynn. Just working at an oncology center there are lots of random off-label uses for this. But they just have to do -- like, demonstrate medical need because I know there's -- I think for at least the one of these agents, there is, like, some off-label, like, studies for them.
- Ryan Taketomo: Yeah, hi. This is Ryan Taketomo. Great question. So typically, the INDICATIONS we include in these policies are -- either they are FDA-labeled approved INDICATIONS, or if they have met our compendia support requirements. I think when I reviewed the off-label request, they did not meet our compendia support, meaning it would be, like, it's recommended in some, but not most cases. So if we did receive a request that didn't meet the criteria, this would be reviewed -- these reviews -- I'm sorry, the determinations would be on a case-by-case basis. So we would have to look into like what the current guidelines is and have the other options been exhausted before considering an off-label use. But it wouldn't be an automatic denial.
- Kevin Flynn: Okay. So basically, if there was like a unique oncology patient, they could still theoretically get it. It wouldn't be just [cross-talk] --
- Ryan Taketomo: This is Ryan Taketomo. And that is correct.
- Kevin Flynn: Okay. Thank you.
- Laura Beste: Any other questions from the Board? This is Laura Beste.
- Nonye Connor: And Laura, there are no hands raised, so no stakeholders.
- Laura Beste: Okay, thank you. So if there are no further questions or stakeholders, do we want to see the motion?
- Ryan Pistorresi: Okay, give me one second. And share this document. Okay. The motion should be up on screen.
- Zoe Taylor: I can read the motion. This is Zoe Taylor. I move that the Apple Health Medicaid Program implement the clinical criteria listed on policy 21.30.00-1 as recommended.
- Hope Barnes: This is Hope Barnes. I second.

Laura Beste: Thank you. And all in favor, uh, all in favor, please say aye.

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

Laura Beste: Any nays or any opposition or any opposed or abstain? Okay. That motion is now approved. And we are going to move on to a review of oxazolidinones antibiotics by Nina Huynh.

Nina Huynh: Thank you. This is Nina, and I am sharing my screen. Okay. Hello, DUR Board. Again, this is Nina from Prime Therapeutics, and I'll be presenting today's drug class reviews. So for today's agenda topic, we will go over the disease states, any new updates from the past year, including guidelines, indication, dosage, and formulations. And as a reminder, the word in purple are the prime therapeutic market baskets and the word in blue are the AHPDL drug classes. So we'll be reviewing injectable oxazolidinones. So the first disease state we'll review is acute bacterial skin and skin structure infections or ABSSSI. This category includes cellulitis and erysipelas, wound infections, and major cutaneous abscesses with a lesion surface area of at least 75 square centimeters, measured by edema, induration, or redness. ABSSSI excludes certain conditions such as very mild or very severe infections, animal or human bites, burns, chronic wounds, diabetic foot infections, impetigo, necrotizing fasciitis, and myopic necrosis. Suboptimal treatment, whether due to misclassification of severity failure, to recognize risk factors, misdiagnosis, or incorrect antibiotic choice or duration, can lead to recurrence and treatment failure. Common pathogens are gram-positive bacteria, primarily *Staphylococcus aureus* and *Streptococcus* species. And treatment decision hinge on whether the infection is purulent or non-purulent, its severity, and patient-specific risk factors, such as MRSA history or comorbidities. So in April of 2025, the FDA expanded the indication for tedizolid, marketed as Sivextro. It is indicated for the treatment of acute bacterial skin and skin structure infections caused by designated susceptible gram-positive microorganisms. The new approval is indicated in adults and pediatric patients as young as 26 weeks gestational age and weighing at least 1 kg for the IV formulation. Previously, this indication was limited to patients 12 years and older. For pediatric patients, the IV dose is weight-based and administered for a six-day treatment course. And to note, it also comes in an oral tablet formulation, which should not be administered to pediatric patients weighing less than 35 kg. And this concludes the injectable oxazolidinones. I'm happy to take any questions.

- Ryan Pistoiresi: And then I can share the Apple Health PDL to show you the drugs' status. And so on your screen is a truncated version just showing this drug class. And it looks like all four products are preferred.
- Laura Beste: Any questions from the Board? If not, can we see the motion, please?
- Nonye Connor: And there are no stakeholders, and no one raised their hands.
- Ryan Pistoiresi: No stakeholders? Okay. Is the PowerPoint showing on your screen?
- Nonye Connor: Not yet, no.
- Ryan Pistoiresi: Not yet. Okay, let me just take a minute.
- Zoe Taylor: Sorry, I probably just missed this, but just to confirm, we're only reviewing the injectable ones.
- Ryan Pistoiresi: This is Ryan. So the four drugs that were shown as part of the Apple Health PDL, I believe, were all the injectables. So yes, that would be [cross-talk] --
- Zoe Taylor: [Cross-talk] Okay [cross-talk] --
- Ryan Pistoiresi: -- the drugs for this motion.
- Zoe Taylor: Okay, thanks.
- Laura Beste: This is Laura Beste, and I will go ahead and make the motion. I move that all products in the drug class listed on Slide 2 are considered safe and efficacious for the 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 non-preferred products require a trial of at least two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.
- Greg Hudson: And this is Greg Hudson. I second.
- Laura Beste: Thank you. All in favor, please say aye.

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

Laura Beste: Any opposed or abstained? Okay, motion is passed. So quick question. It is 12:30, so we're past our designated lunch. Do we want to keep moving on at least through the Antiviral and then take a lunch, and then do Antidiabetics when we get back?

Zoe Taylor: I think we can keep moving on.

Laura Beste: Or do you guys want to push through Antidiabetics, too?

Christy Weiland: We're on a roll, let's keep going.

Zoe Taylor: Yeah, I would prefer to keep going.

Laura Beste: Okay. So next class is Antivirals by Nina.

Ryan Pistoiresi: Okay. And so just since we're not sharing screens too much, I just thought I would go ahead and start by showing you. Here are the drug classes with the individual drugs that will be presented in Nina's slides. So you can at least see what we have preferred and non-preferred before going into Nina's update. And so with that, Nina.

Nina Huynh: All right, thank you. Okay. This is Nina. And next we have Hepatitis C agents. So Hepatitis C virus, or HCV, is a common bloodborne pathogen in the United States. It is transmitted primarily through blood-to-blood contact, and the most frequent route continues to be percutaneous exposure, especially from injection drug use and needle sharing. HCV is highly infectious and can survive on dry surface area for up to 6 weeks. Hepatitis C has two clinical phases. First, we have the acute HCV, which occurs within the first six months after exposure. The challenge here is that 75% to 85% of acute cases have no symptoms, meaning most patients don't realize they're infected. And because of that, a large proportion of infections progress to chronic HCV, which persists lifelong without treatment. Chronic infection carries significant long-term consequences. If untreated, 20% to 30% of patients will develop cirrhosis over roughly 25 to 30 years, and once cirrhosis develops, the risk of liver cancer and liver-related mortality increases substantially. The primary treatment goal is achieving a sustained virologic response, or SVR, defined as an undetectable HCV RNA for at least 12 weeks after completing therapy. SVR represents a functional cure, and that dramatically

reduced the liver-related complications and mortality. So here we have the 2023 AASLD/IDSA guidelines for hepatitis C, which recommends a simplified treatment approach for most treatment-naïve adults without cirrhosis or with compensated cirrhosis. So this approach includes pangenotypic direct-acting antiviral regimens, such as Mavyret or Epclusa delivered in short course treatment durations. So in June of 2025, the FDA expanded Mavyret's indication to include the treatment of acute hepatitis C in patients 3 years and older. Previously, it was approved for chronic HCV genotypes 1 through 6 in patients without cirrhosis or with compensated cirrhosis. With this update, Mavyret now covers both acute and chronic infections across all major patient populations. Dosing remains unchanged. Adults and pediatric patients 12 years and older or weighing 45 kg or more, receive three tablets taken together once daily with food. Children aged 3 to less than 12 years use weight-based oral pellets. Treatment duration ranges from 8 to 16 weeks, depending on genotype, cirrhosis status, and whether the patient is treatment naïve or treatment experienced. Okay, and then Zepatier was discontinued in December 2025. And that concludes the hepatitis C portion. I'm happy to take any questions.

Laura Beste: If no questions from the Board, then do we have any stakeholders?

Nonye Connor: Yes. So we had a pre-registered stakeholder, Erin. Just give me a quick second. Let me steal the screen so that I can have the timer up. All right, just give me a quick second. And Erin, you can -- I'm ready whenever you are.

Erin Nowak: Sounds good. Thank you. Hello, my name is Erin Nowak. I am a Medical Outcomes and Science Liaison with Medical Affairs at AbbVie. Thanks for the opportunity to speak on glecaprevir/pibrentasvir or Mavyret. And I acknowledge the Committee has already reviewed this in detail and that it's preferred on the PDL. But my purpose in speaking today is to briefly highlight a few key reminders about this therapy, provide an update on newly available packaging, and then be available if you have any questions. For a few reminders, Mavyret is a once daily pangenotypic ribavirin-free regimen. It treats all treatment-naïve patients with compensated cirrhosis and without cirrhosis in just 8 weeks. Approximately 95% of the HCV population eligible for treatment meet these criteria and would benefit from the 8-week treatment duration. This may help improve adherence to therapy. And I'd also like to thank the Committee for allowing the full treatment duration, or that two months to be filled at once, as this may further support patient adherence. For new information, I'd like to share that as of just last

week, on February 12th, Mavyret is now available in new packaging. The weekly packs are now smaller, the total packaging is lighter, the pills are contained in foil blister packs, and overall the monthly curtain is about half the size of the previous packaging, making it easier for patients to store and carry and offering a more discreet option. There are no changes to the medication itself. The dosing, efficacy, and the safety all remain the same. And then just to briefly touch on safety, Mavyret, like all DAA agents, carries the class-wide BOX WARNING regarding the risk of hepatitis B reactivation in patients that are co-infected with HCV and HBV. Mavyret is also contraindicated in patients with moderate-to-severe hepatic impairment, those with a history of prior hepatic decompensation, and those taking concomitant atazanavir or rifampin. Thanks for your attention, and I am available for any questions if you have any. Thanks.

- Laura Beste: Thank you, Erin. And are there any questions from the Board? Okay, if not, are there any other stakeholders, Nonye?
- Nonye Connor: Yes. I have one more that has -- oops, oops, oops, oops, oops, sorry. I thought I saw a hand raised. Okay, there we go. Okay. You can speak now. So if you have a chance, you want to go ahead and answer the question on the screen? And then I can start the timer.
- Stuart O'Brochta: Oh, Okay. I saw the timer still going.
- Nonye Connor: Sorry.
- Stuart O'Brochta: I was waiting for it to end.
- Nonye Connor: Sorry about that.
- Stuart O'Brochta: This is Stuart O'Brochta. I'm a Medical Evidence and Value Liaison with Gilead, and I'd like to speak on sofosbuvir/velpatasvir or Epclusa today. And I thank you for that opportunity to re-review the scientific and clinical evidence. And I realize, as Erin mentioned, this class has been reviewed multiple times in the past. While the treatment and cure for HCV has been available with high rates of success for over 10 years now, Washington has not succeeded in its goal of eradicating HCV with the current structure in place sofosbuvir/velpatasvir has the advantage of being the only one-pill, once-a-day, pangenotypic, panfibrotic, protease-free 12-week HC regimen. Additionally, sofosbuvir/velpatasvir has a low DDI potential and no food

restrictions or requirements, adding to its lack of complexity. It also has no decompensation restrictions, which does differ from other agents. Sofosbuvir/velpatasvir has consistently demonstrated high rates of SVR cure with favorable tolerability and low discontinuation rates. These have not only been seen in clinical trials. They've also been highlighted in multiple real-world studies, one being the MINMON study, where it's minimal monitoring is what that's an abbreviation for, where participants were treated with sofosbuvir/velpatasvir for 12 weeks without a genotype, without fibrosis testing, and only an SVR follow-up. At 12 weeks post-therapy, greater than 95% of the patients achieved a cure, with 0% of sofosbuvir/velpatasvir-related SAEs, and only 1% of sofosbuvir-related AEs leading to discontinuation. The patients were able to take the therapy, get success, and stay on the therapy without issue. These same real-world results have also been seen in the PWID (people who inject drugs) population, which you note is the significant population at most risk for HCV infection. And we successfully are able to treat those patients with very low discontinuation and SVR rates that are similar to the general population. Based on the breadth of this evidence and real-world experience with sofosbuvir/velpatasvir, I would respectfully request that Washington reconsider allowing open access to all DAAs that are broad spectrum, including sofosbuvir/velpatasvir, to the PDL and allow providers to have this choice when treating their patients. I'll be happy to answer any questions in the few seconds that are remaining. Thank you.

- Zoe Taylor: I was wondering if you had any -- this is Zoe Taylor -- any updates on trials during pregnancy or like any idea about timeline for when Epclusa might potentially, you know, be more officially used in pregnancy in the future.
- Stuart O'Brochta: Yes, we do have evidence in pregnancy, and I, uh -- it is slipping my mind of when -- what the timeline for that would be, but I'm happy to submit that to - - who would I submit that information to? Ryan or Donna, or who would you like that to go to? Because I'll follow up with you.
- Ryan Pistorresi: So this is Ryan. That would go to our Apple Health Pharmacy Policy mailbox.
- Stuart O'Brochta: Okay.
- Ryan Pistorresi: And then that way it can get triaged out to the appropriate parties here.
- Stuart O'Brochta: Happy to do that, Ryan. And thank you for the question.

- Laura Beste: Thank you, Stuart. Any other questions from the Board? Okay.
- Stuart O'Brochta: Thank you for your time.
- Laura Beste: And do we have any other stakeholders?
- Nonye Connor: No. No other hands raised.
- Laura Beste: Okay. Can we -- relook at the list of medications really quick again, and then we'll go on to the [cross-talk]
- Ryan Pistorosi: Oh. Yes. Let me switch to the other one. Okay. So the Apple Health PDL subclasses that we reviewed with Nina's slides should be present on your screen.
- Zoe Taylor: So effectively, Mavyret is the option that doesn't require a prior auth, and it is amazing that we have an option that doesn't require a prior auth. But I was wondering if we also have a policy or a form to look at for what the -- what is required for the others? Or is that not part of what we're doing today?
- Ryan Pistorosi: So this is Ryan. I can try to find what forms we might have for the others, but I had not prepared that. So let me do some digging.
- Zoe Taylor: Oh, no, that's okay. So we're not -- that makes sense. We're not editing the form today.
- Ryan Pistorosi: Yeah, correct. This is -- yeah. So we're not doing the -- any form or review or clinical policy updates. We're just doing a review of saying here is what the current evidence is and any updates. So similar to the P&T Committee where we do those reviews of what's going on with the evidence, this is the DUR side, so a much more comprehensive review since we do all of the Apple Health PDL drug classes through DUR.
- Laura Beste: Okay, this is Laura. Any other questions? If not, let's take a look at the motion, please.
- Zoe Taylor: I wanted to just -- sorry, this is Zoe. I don't have any questions, but I just wanted to alert everyone that the issue of treating hepatitis C in pregnancy is a really big issue and something where there has been and will be a lot of

forward movement in the next couple of years. Currently, there are no DAAs that are, like, approved in pregnancy, and it is only, like, rarely used, like, off-label with very intense, like, shared decision-making with the patient to use any in pregnancy. There have been some really promising initial data for Epclusa and Harvoni, not for Mavyret in pregnancy. And then there was just recently an expert review published, it's, like, this month in the American Journal of Gynecology for MFM about how important it is that we, like, start, like, using these medications in pregnancy. And so Harvoni and Epclusa are likely to be the first ones that are, you know, where more data comes out or are approved. And so I guess I just wanted -- I don't think there's enough to do anything about that right now, but I guess in terms of the timeline of thinking about the PDL, just wanted to keep it on everyone's radar that, like, it would be great if we can make sure to be really on top of, like, updating this, if needed, updating forms and things like that as this changes because a lot of updates will probably be needed based on that.

Laura Beste: Thank you, Zoe. That was very informative. Appreciate the information. And I believe we're ready for the motion.

Ryan Pistorosi: Okay. So the motion should be on the screen now.

Kevin Flynn: This is Kevin Flynn. I can make a motion. I move that all products in the drug classes listed on Slide 4 are considered safe and efficacious in 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 non-preferred products require a trial of at least two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Christy Weiland: This is Christy Weiland, I second.

Laura Beste: Thank you, Kevin and Christy. And all in favor, please say aye.

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

Laura Beste: Any opposed or abstained? No? Okay. Thank you. That motion is complete. And we will move on to anti-diabetics by Nina.

Ryan Pistoiresi: So just a quick issue. So my computer unfortunately wants to restart in, like, 10 minutes. So I'm not sure if we would be able to break and then have lunch here and then come back in 30 minutes and then do let my computer do its restart and install some updates. But I'm getting these messages and flashing issues.

Nonye Connor: Yeah, me too. So, Joey, are you getting the same restart Joey? Prompts?

Joey Zarate: I am not, but I'm in the HCA computer, so this might have already updated.

Nonye Connor: Okay, Okay. So I'm going to make you the host while it goes through the required restart. So if that's okay, we'll take the lunch now.

Laura Beste: Okay.

Joey Zarate: All right.

Ryan Pistoiresi: Okay. Yeah, sorry about that. I thought we might be able to get through all of them, but I'm thinking with this long of a drug class we probably won't, and I'm going to lose some of the documents that I've been editing, so I don't want to do that.

Laura Beste: Okay, with that, we are going to break for lunch for 30 minutes. See you back at, let's say, 1:20?

Nonye Connor: Okay, that works.

Laura Beste: Okay, thank you.

Nonye Connor: Thank you.

[lunch break]

Nonye Connor: Okay. I am back. I know Ryan said he is logging back in.

Ryan Pistoiresi: And I am back.

Nonye Connor: Okay, great. I am -- and let me just make sure we are -- a quorum. We need a couple more. Okay. Perfect. Laura, -- we are a quorum.

Laura Beste: Okay. Welcome back to Drug Utilization Review Board. And we will now go into Antidiabetic Agents by Nina.

Nina Huynh: Thank you. This is Nina from Prime Therapeutics, and I am sharing my screen. Okay. So diabetes remains a major public health challenge affecting about 38 million Americans, and the vast majority have type 2 diabetes. In the early stages of type 2 diabetes, patients often have normal or even elevated insulin levels, but glucose control is still inadequate. That's because the body becomes resistant to insulin and also loses its ability to secrete insulin appropriately in response to glucose. Importantly, early insulin resistance can be partially reversed through lifestyle change like weight loss and exercise as well as medications. Type 1 diabetes is different. These patients can't produce insulin at all, so insulin therapy is always the first-line treatment. And in type 2 diabetes, insulin is typically added only when the glycemic controls are not met with oral medications or non-insulin injectables. When used, exogenous insulin replaces the body's deficient insulin and supports normal metabolisms of carbohydrates, fats, and proteins. Because diabetes significantly increases both morbidity and mortality, achieving good glycemic control is essential. It helps prevent the microvascular complications we worry about, such as retinopathy, neuropathy, and nephropathy, as well as major macrovascular outcomes, including cardiovascular disease. The 2025 ADA Standards of Care emphasizes a patient-centered approach to managing type 2 diabetes in adults with treatment decisions individualized based on comorbidities, particularly cardiovascular disease, heart failure, and chronic kidney disease, as well as efficacy, hypoglycemic risk, weight impacts, side effects, cost, and patient preferences. Pharmacologic therapy should aim to achieve and maintain glycemic controls, typically starting with metformin, unless contraindicated, and progressing to combination therapy when targets are not met. For patients with established or high risk of atherosclerotic cardiovascular disease, a GLP-1 receptor agonist or a SGLT2 inhibitor with proven cardiovascular benefit is recommended. In heart failure, SGLT2 inhibitors are preferred across all ejection fractions, while GLP-1 receptor agonists may be considered in those with heart failure with preserved ejection fraction and obesity. For chronic kidney disease, particularly with an eGFR between 20 and 16, or albuminuria, either SGLT2 inhibitor or a GLP-1 receptor agonist with renal and cardiovascular benefit is appropriate regardless of A1C. And in more advanced CKD with the eGFR below 30, GLP-1 receptor agonists are preferred. The ADA advises against combining DPP-4 inhibitors and GLP-1 receptor agonists or dual (GIP)/GLP-1 receptor agonists

due to lack of added glycemic benefits. Insulin therapy should be initiated when A1C is greater than or equal to 10, blood glucose is greater than or equal to 300 mg/dL, or when symptoms of hyperglycemia are present, regardless of prior oral therapy. Okay. Listed on this slide is the NovoLog and its biosimilar. In February of 2025, the FDA approved Merilog as the first biosimilar rapid acting insulin referencing NovoLog. Merilog is indicated to improve glycemic control in adults and pediatric patients with diabetes consistent with the reference product. Like NovoLog, dosing is individualized and adjusted based on metabolic needs, blood glucose monitoring, and glycemic targets. Merilog is administered subcutaneously within 5 to 10 minutes before a meal and is typically used in combination with intermediate or long-acting insulins. Unlike NovoLog, which is approved for both subcutaneous and IV use, Merilog is currently only approved for subcutaneous administration. It will be available in a 100 Units/mL concentration as a 10 mL multidose vial, and a 3 mL SoloStar prefilled pen. In July of 2025, the FDA approved Kirsty, the first interchangeable biosimilar to NovoLog. It carries the same indication and administration as the reference product, and this biosimilar will be available in 100 Units/mL, as a 10 mL multidose vial, and a 3 mL single-patient use prefilled pen. Okay, over the past few -- past year, several insulin discontinuations occurred. Novo Nordisk discontinued unbranded insulin aspart, unbranded insulin degludec, insulin aspart protamine, and insulin aspart mixed 70/30 products. And then Eli Lilly discontinued the Tempo Pen presentations of Basaglar, Humalog, and Lyumjev, while KwikPen formulations for these insulins remain available. Okay, moving on to Incretin Mimetics and Enhancers? So in January of 2025, the FDA approved a new oral solution formulation of sitagliptin marketed under the brand name Brynovin. In it is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. It is not recommended for use in type 1 diabetes and have not been studied in patients with the history of pancreatitis. Brynovin is formulated as a 25 mg/mL oral solution with the recommended dose of 100 mg once daily. Dose adjustments are recommended for patients with an eGFR of less than 45. Okay. Also in January 2025, the FDA approved a new indication for Ozempic, the subcutaneous formulation of semaglutide. It is approved to reduce the risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death and adults with type 2 diabetes and chronic kidney disease. The recommended dose for this new indication starts at 0.25 mg subcutaneous weekly for 4 weeks, increases to 0.5 mg for another 4 weeks, and then to 1 mg weekly. Separately, in April of 2025, the FDA continued to issue WARNINGS about counterfeit Ozempic found in the US supply chain. Okay.

And then in October of 2025, the FDA approved an expanded indication for Rybelsus, the oral formulation of semaglutide, and it's indicated to reduce the risk of MACE, including cardiovascular death, nonfatal MI, and nonfatal stroke in adults with type 2 diabetes who are at high risk for these events. The R1 formulation recommended dose begins with 3 mg once daily for 30 days, followed by an increase to 7 mg once daily. If additional glycemic control is needed, the dose may be increased to 14 mg once daily after at least 30 days on the 7 mg. For the R2 formulation, the starting dose is 1.5 mg once daily for 30 days, then increased to 4 mg once daily, with a maximum dose of 9 mg once daily after at least 30 days on the 4 mg. Nova Nordisk announced plans to discontinue the R1 formulation as the R2 formulation with higher bioavailability replaces it. However, the trade name for Rybelsus R2 formulation is going to be updated to Ozempic tablet, and that's going to be launched later this year. And there were two discontinuations in the past year, Qtern tablets and SymlinPen. Okay, next is SGLT2 inhibitors. So in March of 2025, the FDA approved a new indication for Synjardy and Synjardy XR. Which is a combination of empagliflozin and metformin. It is now also indicated to risk -- reduce the risk of sustaining eGFR decline, end-stage kidney disease, CV death, and hospitalization for HF in patients with CKD at risk of progression in adults with type 2 diabetes. Dosing is consistent with all other indications. And this concludes the antidiabetic agents. I'm happy to take any questions.

Ryan Pistoiresi:

So this is Ryan. I'll go ahead and present the PDL classes. They should be up on your screen. And so this one, as you can see, is a lot larger than the others that we had reviewed earlier today, but they do show what is preferred and non-preferred within each subclass. Now let me scroll down so that way you can see all of the DPP-4s together with Jentadueto, linagliptin, saxagliptin, and Tradjenta as the preferred. For the GLP-1s, we have the liraglutide, exenatide, Byetta, and Bydureon. For the immediate-acting insulins, we have the Humulin and then Novolin FlexPen. Within the insulin long-acting, just the Lantis and the insulin glargine-yfgn biosimilar. Within the premix insulins, we have quite a few different ones that are preferred. So mainly the Humalog, Humulin, insulin aspart mix, and then the Novolog 70/30. And within the rapid-acting, we have the Humalog, the insulin aspart, the insulin lispro products, and then the Novolog products. For the short-acting, just the Humulin R products. And then the very end of the antidiabetics for what was reviewed with Nina slides, here are the SGLT2s.

Laura Beste:

I'm sorry. Could you go back to the long-acting insulins real quick for me?

Ryan Pistoresi: Sure thing. So here are the long-acting.

Laura Beste: Thank you.

Ryan Pistoresi: Yes, Hope.

Hope Barnes: Hi, this is Hope Barnes. I was wondering, is U-500 on this list? And then the other comment I have is, I thought I heard that Symlin or pramlintide was discontinued?

Ryan Pistoresi: This is Ryan. So it looks like the U-500 is here in the short-acting. And what was the second question?

Hope Barnes: I thought I saw at the top of this list SymlinPen --

Ryan Pistoresi: Yes.

Hope Barnes: -- as preferred, but I believe it was mentioned it was discontinued. Might want to [cross-talk] --

Ryan Pistoresi: [Cross-talk] Um, so -- was someone saying something? Okay. So yes, it may be discontinued, but while there may be product on stock and pharmacies, patients may be able to continue to use it. I would need to see when it was discontinued and when the product is expected to be exhausted on the market, but that is likely when it may be removed from the PDL.

Hope Barnes: Thank you.

Ryan Pistoresi: So Nina, did you have a date in which these SymlinPens were being discontinued?

Nina Huynh: Yes. It was announced in October of 2025. So usually we give it one year before we remove it from the AHPDL.

Ryan Pistoresi: Okay, great. So yeah, so in probably the October 2026 Update they would be removed. So until then they will be available so long as the pharmacy has that product in stock.

- Laura Beste: Any other questions or comments on this? If not, maybe we can see the motion to review. Oh, are there any stakeholders?
- Nonye Connor: Yeah. We had a Kat pre-registered, but I did not see your form. So if you can just answer the question on the screen, Kat, whenever you're ready. I'll be nice if I share my screen, right?
- Kat Khachatourian: Yeah, no problem. So my name is Kat Khachatourian. I am speaking on behalf of Novo Nordisk. I am not a -- I'm not seeing Washington Medicaid patients. I am a Washington resident. And the only conflicts of interest would relate to my employment and ownership of stock within Novo Nordisk.
- Nonye Connor: I'm ready whenever you are.
- Kat Khachatourian: Thank you. And so the team did a great review of the data. So I'm here today. So Kat Khachatourian, Scientific Director for Novo Nordisk, both a pharmacist and a Washington State resident. And I'm requesting that semaglutide, both the injectable and oral formulations, be -- moved to preferred status given the evidence and support to an A1C reduction, CV risk reduction, as well as the injectable Ozempic being the only GLP that also has a renal indication. And thank you for your time. I'm happy to defer the rest of my time back to the Committee and would be happy to answer any questions that you may have.
- Laura Beste: Thank you, Kat. And any questions from the Board for Kat? Okay. If not, any further comments or concerns from the Board? And can we see the motion, please?
- Ryan Pistorosi: Okay. So the motion should be up on screen right now. So again, these were all of the different classes and subclasses that were reviewed as part of the anti-diabetes update. And on this slide, we have the motion.
- Hope Barnes: This is Hope Barnes. I can make the motion. I move -- oh, excuse me -- 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 non-preferred 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.

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

Multiple Speakers: All in favor, say aye.

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

Laura Beste: Okay. Any opposed or abstaining?

Zoe Taylor: I was wondering, last year I think we added something to this one about long-acting. I don't know. Does anybody remember?

Laura Beste: I remember that, too, but I think that was a different type of review [cross-talk] --

Zoe Taylor: [Cross-talk] Okay, no worries. [cross-talk] --

Laura Beste: -- maybe a long-acting agent added as a preferred.

Zoe Taylor: Just because a couple meetings ago, it turned out that, like, our recommendations in the previous year hadn't been followed. I wanted to just see if we could also maybe add to this meeting like the last one we did and what -- like, whether that was -- whether the recommendation was followed. I totally understand if you can't find it right now.

Ryan Pistoiresi: Yeah, and this is -- this is Ryan. I don't recall. I don't always attend the DUR portion because most of my work is with the P&T, and sometimes I am not able to attend the full DUR portion, so I'm not certain. And with Marissa out and Donna not at the meeting right now, I would need to follow up with them to see if I can get that [cross-talk] information for you. [cross-talk]--

Zoe Taylor: No worries. I can also see if I can find it.

Ryan Pistoiresi: Okay.

Zoe Taylor: Okay. Thanks.

- Laura Beste: Zoe, I think that was part of the Washington P&T review versus the Apple Health.
- Zoe Taylor: Okay. I'll go back and look. [cross-talk]. We don't have to pause or anything. You're good. [cross-talk] --
- Laura Beste: [Cross-talk] I have the same thought, so good thought. Okay. Well, thank you for approving that. And next we are at Cardiovascular Agents by Nina.
- Nina Huynh: Okay. This is Nina, and I am sharing my screen. Okay, next is Apolipoprotein Inhibitors. So familial chylomicronemia syndrome (FCS) is a rare genetic disorder caused by loss of function mutation in the LPL gene, which prevents normal breakdown of triglycerides leading to severe hypertriglyceridemia. The most **SERIOUS COMPLICATION** is acute pancreatitis, which can occur as early as the first month of life. Nearly all patients with FCS experience at least one acute pancreatic episode, and many have recurrent attacks leading to significant morbidity and mortality. We should suspect FCS when triglyceride remains above 880 mg/dL on three consecutive tests, especially when levels are refractory to standard therapy and other secondary causes such as alcohol use, uncontrolled diabetes, hypothyroidism, and nephrotic syndrome, diet and medications have been ruled out. Diagnosis is supported by a history of acute pancreatitis or recurrent unexplained abdominal pain and ultimately confirmed by genetic testing. Standard triglyceride-lowering drugs are ineffective in FCS. Management relies on a strict low-fat diet along with complete avoidance of alcohol and high-sugar foods. Patients often require supplementation with fat-soluble vitamins and essential fatty acids, and medications that raise these triglycerides should be avoided. The significant advancement arrived in 2024, when the FDA approved Tryngolza, which is going to be reviewed on the next slide. So in December of 2024, the FDA approved olezarsen marketed as Tryngolza. It's in apolipoprotein C-III directed antisense oligonucleotide indicated as an adjunct to diet to reduce triglycerides in adults with FCS. **WARNINGS** include hypersensitivity reactions, including symptoms of bronchospasm, diffuse erythema, facial swelling, urticaria, chills, and myalgias. The recommended dose is 80 mg subcutaneous once monthly administered into the abdomen or front of the thigh. The back of the upper arm can also be an injection site if given by a healthcare provider or caregiver. Tryngolza is available as 80 mg/0.8 mL in single dose autoinjector. And this concludes that apolipoprotein inhibitors.

- Ryan Pistorresi: Okay. And this is a pretty easy drug class because there is only one drug, and it is preferred.
- Laura Beste: Okay. If we can see the motion, please.
- Nonye Connor: And there are no hands raised for [cross-talk] --
- Laura Beste: Thank you.
- Nonye Connor: Mm-hmm.
- Ryan Pistorresi: So let me go to the motion. Oops, that's the wrong one. Okay. So the motion should be here. So that's the drug class. And the motion is now here on the screen.
- Christy Weiland: Christy Weiland, I can make a motion. 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 the discretion of HCA. Products in these classes may require prior authorization to determine medical necessity. All non-preferred products require a trial of at least two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.
- Hope Barnes: [Cross-talk] This is Hope Barnes, I second.
- Greg Hudson: [Cross-talk] This is Greg Hudson, I second.
- Laura Beste: Thank you. All in favor, please say aye.
- Multiple Speakers: Aye. Aye. Aye. Aye.
- Laura Beste: Any opposed? Okay. Motion is passed, and we will move on to the anticoagulants.
- Nina Huynh: Okay. This is Nina again. Okay. Next is Oral Factor XA and Thrombin Inhibitors. So venous thromboembolism, also referred to as VTE, manifests as deep vein thrombosis or DVT and pulmonary embolism. VTE is a major consequence of various surgical procedures and medical conditions. DVT happens when a blood clot forms in the deep veins of the extremities, usually

the legs. The blood clot breaks free and travel to the lungs. It can cause a pulmonary embolism by blocking blood flow in the pulmonary artery or one of its branches. The exact number of patients impacted by DVT and PE is unknown. However, it is estimated that these conditions affect up to 900,000 people in the US every year. An estimated 10% to 30% of patients with DVT or PE are estimated to die within one month of diagnosis. And generally, the risk of VTE increases with the number of risk factors present, major traumas, and age. Due to the risk of morbidity and fetal PE associated with DVT, prophylaxis has become the standard of care for patients at high risk for thrombosis. Okay. The 2024 ASH/ISTH guidelines recommend direct oral anticoagulants, referred to as DOACs, primarily rivaroxaban or dabigatran over traditional therapies such as low-molecular weight heparin, unfractionated heparin, vitamin K antagonists, or fondaparinux for most pediatric BTLE cases, when available and appropriate. Apixaban and edoxaban were excluded from the 2024 pediatric VTE guideline recommendations because Phase 3 trial data for these agents in children remain pending at the time of publication. However, apixaban is FDA approved for pediatric VTE, while edoxaban is not FDA approved for this population. In 2025, the FDA approved generic versions of Xarelto 2.5 mg tablets and 1 mg/mL oral suspension. And as mentioned earlier, apixaban is now indicated for the treatment of VTE and reduction in the risk of recurrent VTE in pediatric patients from birth and older following at least 5 days of initial anticoagulant therapy. Pediatric dosing is weight based and is not recommended for patients weighing less than 2.6 kg. The duration of Therapy should be individualized based on treatment benefit and bleeding risk. To support pediatric administration, the FDA also approved a new formulation, 0.5 mg tablets for oral suspension and 0.15 mg powder for oral suspensions and capsules, and that is known as Eliquis Sprinkles. And this concludes anticoagulants. I'm happy to take any questions.

- Ryan Pistorosi: Okay. And then for the Apple Health PDL, this is the Anticoagulant class. And you can see that we have quite a few different preferred options between the dabigatran, apixaban, rivaroxaban. Yep. And those are just rivaroxaban strength, so the rivaroxaban.
- Laura Beste: Okay. Any questions from the Board? Any stakeholders?
- Nonye Connor: Yes, I do see a hand raised.
- Mandeep: Hi. Can you all hear me?

- Nonye Connor: Yes. Hold on. Let me go ahead and share my screen and a timer. Okay. After answering the question, please let me know when you're ready, and I'll start the timer.
- Mandeep: Um, yeah. I'm ready.
- Nonye Connor: Okay. Um, do you want to answer the question first and then...?
- Mandeep Sohal: Yeah. My name is Mandeep Sohal, and I'm speaking on behalf of BMS. And I filled out a conflict of interest form already. I'm employed by BMS.
- Nonye Connor: Okay.
- Mandeep Sohal: All righty, thank you.
- Nonye Connor: Mm-hmm.
- Mandeep Sohal: As I stated previously, my name is Mandeep, and I am on the Field HEOR Team at BMS. I understand that you're already aware of the new pediatric Eliquis dosage forms. From a utilization perspective, the pediatric population requiring treatment with Eliquis is very small. I just wanted to offer the opportunity, if you have any questions about the Eliquis pediatric indication. And I will cede the rest of my time back. Thank you.
- Laura Beste: Thank you, Mandeep. Does anyone have any questions for him? Okay. On that note, I guess, can we see the motion please?
- Ryan Pistorosi: Okay. So these are the drug classes that are part of this motion. And then the motion is present on the slide.
- Laura Beste: This is Laura Beste. 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 non-preferred products require trial of at least two preferred products with the same medication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

- Greg Hudson: This is Greg Hudson, I second.
- Laura Beste: Thank you. All in favor, say aye.
- Multiple Speakers: Aye. Aye. Aye. Aye. Aye.
- Laura Beste: Any opposed? Okay. Motion for the anticoagulants is passed. And next we will be moving on to Endocrine and Metabolic Agents.
- Nina Huynh: Okay. And this is Nina. Next, we have Mineralocorticoid Receptor Antagonist or MRAs. So heart failure is a common clinical syndrome in which symptoms arise from structural or functional cardiac disorders that impair the ventricle ability to fill with or eject blood. It can arise from a wide range of conditions affecting -- anything that affects the myocardium, pericardium, endocardium, the heart valves, the blood vessels, or even certain metabolic disorders can ultimately lead to heart failure. Clinically, heart failure is categorized by ejection fraction. Heart failure with reduced ejection fraction is defined as an LVEF of 40% or less and is often referred to as systolic heart failure. The mid-range category includes patients with an LVEF between 41% and 49%, and heart failure with preserved ejection fraction is defined as an LVEF of 50% or higher and is typically associated with diastolic dysfunction. The American Heart Association, American College of Cardiology, and Heart Failure Society of America published updated heart failure management guidelines in 2022. MRAs may be considered inpatients with heart failure with mid-range ejection fraction to reduce heart failure and CV mortality, particularly when LVEF is in the lower end of the range. They may also be considered in heart failure with preserved ejection fraction to reduce hospitalization, especially when LVEF is closer to 50%. In July of 2025, the FDA approved a new indication for Kerendia to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adults with heart failure and a left ventricular ejection fraction of 40% or more. The starting doses range from 10 mg to 20 mg once daily based on eGFR and serum potassium threshold. The target dose for this indication is 40 mg once daily for patients with an eGFR of at least 60, and 20 mg once daily for those with an eGFR between 25 and less than 60. And this concludes the MRA section. I'm happy to take any questions.
- Laura Beste: Thank you, Nina. And do we have any stakeholders?
- Ryan Pistorosi: And just to confirm, yeah, this is the only one in this specific drug class.

Nonye Connor: And there are no hands raised.

Laura Beste: Okay. If we can see the motion, please.

Ryan Pistorresi: Great. So the motion is here.

Greg Hudson: [Cross-talk] And this is Greg. [cross-talk] --

Kevin Flynn: [Cross-talk] This is Kevin. Oh. [cross-talk]

Greg Hudson: [Cross-talk] I can motion that I move 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 the HCA. All products in this class require prior authorization to determine medical necessity. All non-preferred products require a trial of at least two preferred products in the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Kevin Flynn: This is Kevin Flynn, I second.

Laura Beste: Thank you. All in favor, say aye.

Multiple Speakers: Aye. Aye. Aye. Aye.

Laura Beste: Any opposed? Okay. The motion for Endocrine and Metabolic Agents is approved, and we will move on to Pulmonary Hypertension Agents.

Nina Huynh: Okay. Pulmonary hypertension is defined as a mean pulmonary arterial pressure greater than 20 mmHg at rest. The Who World Health Organization classifies pulmonary hypertension into five groups based on underlying cause. Group I is pulmonary arterial hypertension, or PAH, a rare condition characterized by narrowing, thickening, and stiffening of pulmonary arteries, which can be idiopathic, hereditary, drug induced, or associated with connective tissue or congenital heart disease. Group II includes PH due to left heart disease. Group III encompasses PH related to lung disease and/or hypoxia commonly seen in chronic lung conditions like COPD, interstitial lung disease, or sleep disorder breathing. Group IV is PH due to chronic thromboembolic pulmonary hypertension. And finally, Group V includes PH

due to blood and other rare diseases. For our review, we'll focus on Group I and Group III. For PAH and health prostaglandin analogs such as treprostinil are recommended for patients who remain at intermediate risk despite oral therapy or as part of initial triple therapy in advanced disease. For Group III pulmonary hypertension, PAH specific therapy is generally not recommended except in selected cases. So in May of 2025, the FDA approved Yutrepia, a new dry powder inhalation formulation of treprostinil for the treatment of pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease to improve exercise ability. For treprostinil-naive patients, therapy begins at 26.5 mcg and held three to five times daily, using two breaths per capsule with weekly titration by 26.5 mcg per dose as tolerated. The target maintenance dose ranges from 79.5 mcg to 106 mcg four times daily, and doses above 848 mcg per day have not been studied in PAH. Patients switching from Tyvaso should start Yutrepia at an equivalent dose based on prior Tyvaso breaths. And Yutrepia is available in four strengths 26.5 mcg, 53 mcg, 79.5, and 106 mcg. And then Tracleer was discontinued in June 2025. The generic remains available. And this concludes pulmonary hypertension. And I'll pass it back to the Committee.

Laura Beste: Thank you, Nina. Does anyone have any questions for Nina? Do we have any stakeholders?

Nonye Connor: Yes. Richard, whenever -- I'm sorry, Ryan. Go ahead.

Laura Beste: Okay.

Ryan Pistorosi: Oh, yep. Nope. Here is the Apple Health PDL with the preferred and non-preferred for these. So I'll let you take a look at these just before we move over to the stakeholder. But any questions? Okay. So if not, then, yes, now we can go over to the stakeholder.

Nonye Connor: Okay, Richard? You can unmute yourself whenever you're ready.

Richard Oliver: Thank you very much. How's everybody doing? I hope well.

Nonye Connor: Yeah. Give me -- give me a quick second so that I can pull up that timer for you. Sorry.

Richard Oliver: Thank you.

Nonye Connor: Okay. I'm ready whenever you are.

Richard Oliver: All right. So hello, everybody. My name is Richard William Oliver. I am a Medical Science Liaison with Liquidia. Obviously, I'm employed by them, so I speak on behalf of this organization. So Liquidia is a biotech company that's dedicated to the investigational development of best in class therapies that would potentially improve, obviously, standard of care for patients with pulmonary hypertension. So we're expanding our, you know, our presence within the PH mark -- PH market with treprostinil inhalation dry powder, in this case, Yutrepia, which is the first and only dry powder formulation of treprostinil that it's enabled, which makes it makes it unique is this proprietary manufacturing process known as PRINT. PRINT is an advanced technique that creates drug particles with precise size and shape and chemical composition. This allows for uniformity and homogeneity on each molecule. And what it's intended to do is to achieve enhanced deep lung delivery use of [indistinct] with a low-effort device for these patients who have, you know, inspiratory issue and requires minimal inspiratory effort. It's not position dependent and does not require refrigeration. This obviously would allow a specialist to titrate their patients to higher therapeutical doses and potentially mitigate side effects. This obviously is indicated as the other person showed for PAH and PHL, the WHO Group I and III, respectively. In the INSPIRE trial, which was a PAH trial, patients that took Yutrepia were either transitioning from nebulized type ASO or inhaled treprostinil, or those who are naive to prostacyclin therapy in a dry powder inhalation therapy. Overall, it was the largest study to date with PH patients, and what we found out is that the most common ADVERSE EVENTS reported were cough, headache, and throat irritations. But we actually broke apart the severity of it by classifying it by mild, moderate, or severe. Most of them were mild-to-moderate. After the one year [indistinct] time point, no patients in the transition group, and only two patients in the naive group discontinued Yutrepia because of cough -- which this is a huge thing because cough is the main issue why patients continue the medication. So potentially, Yutrepia can allow for more compliance in this patient population that, one, requires tolerance of the medication, and second, requires patients to continue with a titration and up the dose. We know that the literature shows that 9 to 11, 9 to 12 breaths is where you want to keep these patients. And finally, Yutrepia allows this in our studies. The patients remained with it reached this level and remain with this medication with minimal to moderate side effects, in this case, cough. So given the safety and intolerability of Yutrepia along with the potential to titrate doses, we respectfully ask for consideration to assign

Yutrepia on your preferred drug list in a pairing position to other prostacyclin products. Thank you very much.

Laura Beste: Thank you, Richard. Does the Board have any questions for him? Any other stakeholders?

Nonye Connor: There are no other hands raised.

Laura Beste: Okay. With that, can we see the motion, please?

Ryan Pistorosi: All right. Is it showing? Do you see the PowerPoint?

Laura Beste: Yes. I see the pulmonary hypertension agents, the first slide.

Ryan Pistorosi: Great. Okay.

Bradley Pope: Yeah, this is Brad Pope. 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 the HCA. Products in these classes may require prior authorization to determine medical necessity. All non-preferred products require a trial of at least two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated, not medically appropriate, or only one product is preferred.

Alex Park: This is Alex Park seconding the motion.

Laura Beste: Thank you. All in favor, say aye.

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

Laura Beste: Any opposed? Okay. Pulmonary Hypertension Agents is approved, and we are moving on to Migraine Agents.

Nina Huynh: Okay. This is Nina. Migraine is a complex neurological disorder that causes episodic, often debilitating headaches along with a range of sensory changes. It accounts for about 10% to 20% of all headaches and affects over 37 million people in the United States, with women more commonly affected than men. We classify migraines as either episodic or chronic. Episodic means fewer than 15 headache days per month, while chronic means 15 or more

headaches per month for over 3 months with at least eight of those days showing migraine features. Migraine attacks typically last between 4 to 72 hours and are marked by two key features, which includes unilateral pain, a throbbing quality, moderate-to-severe intensity, or worsening with routine physical activity. In addition to these, patient often experiences nausea or vomiting or sensitivity to light and sound. Migraines can occur with or without aura. Aura refers to reversible neurologic symptoms such as visual or sensory changes that typically precedes the headache. However, migraines without aura are more common. Okay. The American College of Physicians release updated 2025 guidelines for preventing and treating episodic migraine in the outpatient setting. For prevention, recommended first-line monotherapy options include beta blockers such as metoprolol or propranolol, valproate, venlafaxine, and amitriptyline. If these are not tolerated or ineffective, then next step is a CGRP antagonists or a CGRP monoclonal antibody as monotherapy. And then if all of these fail, then topiramate is suggested. The guidelines for acute treatment of episodic migraine highlights the use of combination therapy for moderate-to-severe attacks. The first-line approach is to add a -triptan to a NSAID in non-pregnant adults who do not achieve adequate relief with NSAID alone or to those who do not respond to acetaminophen alone. If -triptan combinations are not tolerated or effective, alternatives include CGRP antagonists or ergot alkaloids. Okay. The FDA has approved Symbravo, a fixed-dose combination of 20 mg meloxicam and 10 mg rizatriptan for the acute treatment of migraine with or without aura in adults. It should only be used where a clear diagnosis of migraine has been established, and it's not indicated for the prevention of migraine or for the treatment of cluster headaches. Recommended dose is 1 tablet by mouth as needed not to exceed 1 tablet per day. And then in August of 2025, the FDA approved a new indication for Ajovy, making it the first CGRP antagonist indicated for the prevention of episodic migraine in pediatric patients aged 6 to 17 years old, who weigh at least 45 kg. The recommended dose for these patients is 225 mg administered subcutaneously once a month. And then the authorized generic of Imitrex 5 mg and 20 mg nasal spray will be discontinued. Distribution will cease in the next coming weeks, and the generic will remain available. And this concludes Antimigraine Agents. I'm happy to take any questions.

Laura Beste: Thank you, Nina. Do we have any questions from the Board? Okay. Do we have any stakeholders available?

Nonye Connor: Yes. Or, Ryan, [cross-talk] did you want to go over?

Ryan Pistorosi: Yeah. Yeah. [cross-talk] --

Laura Beste: [Cross-talk] Oh, sorry [cross-talk] --

Ryan Pistorosi: So here are [cross-talk] -- that's all right -- So this is Ryan. Here are the current statuses for the drugs in these drug classes on the Apple Health PDL. So at the top are the CGRPs, and then below are the -triptans. Okay. And just rolling back up to the CGRP's before we go into the stakeholders.

Laura Beste: Did we want to hear from the stakeholder now, please?

Nonye Connor: Yeah. First one I have -- and I'm -- I apologize if I mispronounce your name, is Sheta.

Sheta Ara: Yeah, you got it right.

Nonye Connor: Oh nice.

Sheta Ara: Yay.

Nonye Connor: Let me go ahead and put a timer on for you. Sorry. Let me know when you're ready.

Sheta Ara: Yeah, I'm ready. Thank you so much. Hi, everybody. My name is Sheta Ara. I'm a Licensed Pharmacist with Pfizer Medical Affairs. I did send over a conflict of interest form. You should have it. And Pfizer respectfully requests that the Board consider enhancing access for Nurtec ODT to preferred status to label. Nurtec ODT or rimegepant is a calcitonin gene-related peptide or CGRP inhibitor. It's approved for acute treatment of migraine and also for preventative treatment of episodic migraine in adults. It's recommended to be dosed 75 mg orally as needed for acute treatment or every other day for preventative treatment of episodic migraine. The max dose in a 24-hour period is 75 mg, and the safety of using more than 18 doses in a 30-day period has not been established. In the prevention clinical study, the most common ADVERSE REACTIONS were nausea, followed by abdominal pain or dyspepsia. Nurtec ODT is contraindicated in patients with a history of hypersensitivity to rimegepant or Nurtec ODT or any of its components. I would like to provide a couple of updates today. The first one is specific to the package labeling, and it applies to all CGRP's. And following post

marketing analysis of case study submitted to the FDA, FDA has concluded that CGRP pathway antagonists including Nurtec ODT have the potential for SERIOUS RISK associated with hypertension and Raynaud's phenomenon. As such, in March of 2025, the WARNINGS, PRECAUTIONS, ADVERSE REACTIONS and PATIENT COUNSELING sections to the PI was updated. The second update that I want to provide is around the American Headache Society Migraine Prevention Position Statement published in 2024. I saw Nina had a great slide up there for the ACP recommendations. I wanted to sort of complete the picture with the AHS 2024 recommendations, and it's specific to CGRP targeting therapies for prevention of migraine based upon the results of review of the available evidence for the efficacy and safety of CGRP therapy. And basically, they say that there is substantial cumulative evidence supporting the efficacy, tolerability and safety profiles of CGRP-targeting therapies as an option for preventative therapy. Pfizer respectfully requests that the Board consider enhancing access to Nurtec ODT and that it be added to the PDL. And thanks for your time. I can take any questions.

Laura Beste: Thank you, Sheta. Any questions from the Board? Okay, thank you. And do we have any other stakeholders? Nonye, I think you're turned off.

Nonye Connor: Thank you. I will say, Erin, whenever you're ready.

Erin Nowak: Great. Thank you. Hello. My name is Erin Nowak, Medical Outcomes and Science Liaison with AbbVie. Thank you for the opportunity to speak today. I'll be touching on atogepant or brand name Qulipta, also an oral calcitonin gene-related peptide receptor antagonist. This is indicated for the prevention of migraine. And although not a new therapy, I would like to provide some unique characteristics of Qulipta as well as some newer information with the purpose of supporting a request to add Qulipta as preferred to the PDL. So first, there are three unique characteristics of Qulipta that I'd like to share. 1.) This is an oral therapy offering a mode of delivery that is often preferred by patients and offers a solution to patients with needle phobia. It also does not need to be refrigerated and is uniquely the only oral CGRP that covers the full spectrum of migraine prevention, so both the episodic and chronic migraine. 2.) Compared to monoclonal antibodies, there was a shorter half-life. This offers suitability for daily dosing as well as fast clearance of the drug in approximately 3 days shall a patient need to withdraw therapy for any reason, such as if the patient becomes pregnant. 3.) For episodic migraine, there are 10 mg, 30 mg, and 60 mg tablets that are available. This is suitable for dosing flexibility, caters to patient's efficacy, tolerability, and/or dose

modification due to organ dysfunction or drug interactions. Next, what I'll do is share three pieces of data made recently available. First, in a cost per responder analysis, atogepant had the lowest number needed to treat when compared to all approved CGRP therapies as well as higher relative clinical effectiveness when looking at 50% response rates. Secondly, real-world evidence suggests that Qulipta switch rates are lower than that of CGRP monoclonal antibody. And 3, in July of 2025, data from the temple study were released. This was a Phase 3 randomized blinded trial directly comparing Qulipta to topiramate. Here Qulipta had fewer patients discontinuing therapy due to ADVERSE EVENTS and had a higher percentage of patients achieving a 50% reduction in their monthly migraine days. Same WARNINGS and PRECAUTIONS here for hypertension and Raynaud's phenomenon, as the last speaker mentioned, and more information on safety can be found at [rxabbvie.com](https://www.rxabbvie.com). So with the information covered, I respectfully request the Committee to add Qulipta as preferred to the PDL. I thank you for your time. And I'm also available for questions that you have. Thank you.

- Laura Beste: Thank you, Erin. Any questions for Erin? Okay. Do we have any other stakeholders?
- Nonye Connor: No. I do not see any other hands raised.
- Laura Beste: Okay. Can we see the motion please?
- Ryan Pistorosi: All right. So here, we have the Migraine Agents and now the motion.
- Laura Beste: Actually -- this is Laura Beste. I have one question beforehand. So two preferred products with the same indication includes what classes. Is it any prophylactic product, or is it specific ones?
- Zoe Taylor: Can we look at the preferred list again for the CGRPs? I think that would be helpful to see what [cross-talk] kind.
- Ryan Pistorosi: Yes. [Cross-talk] Let me pull that up.
- Zoe Taylor: Because I think last time we did this one was in July, and we requested that there be, like, specific preferences for this class too for, like, oral versus not oral and for as needed versus controller.

Ryan Pistorresi: Yes. And I see here that the preferred products are the Aimovig and Ajoyv and Emgality. I believe that those are for the controller, whereas the kind of more immediate relief is the Ubrelvy.

Zoe Taylor: There is one oral preferred.

Ryan Pistorresi: Correct.

Zoe Taylor: Okay.

Laura Beste: Well, and the oral preferred. Ubrelvy is only for acute attacks, I believe.

Zoe Taylor: Let's see, yeah. Yeah, I believe so. So then [cross-talk] --

Laura Beste: There's no preventative oral agent, which would be the [cross-talk] --

Zoe Taylor: [Cross-talk] Preferred.

Laura Beste: -- Qulipta or the Nurtec.

Zoe Taylor: Preferred.

Ryan Pistorresi: Correct, yes. All of the preventative, I believe, are the injectables.

Zoe Taylor: So it would be helpful to know what we said last time and whether that was followed or not, and we can decide whether we want to try to specify that again. I guess we could do it either way regardless of what happened last time, but ...

Ryan Pistorresi: Yeah. Again, I would need to do research [cross-talk] to see what was.

Zoe Taylor: Yeah.

Laura Beste: This is Laura Beste. Ryan, is there a policy on being able to get approved for any of the injectables? [Cross-talk] Yeah.

Ryan Pistorresi: [Cross-talk] Um, it looks like they all have a prior authorization. So column H with a Y means that there would be PA criteria. And our PA policies are these with that O2O there.

- Laura Beste: Okay.
- Ryan Pistorresi: Whereas these ones -- so Nurtec has 010. Same for Ubrelvy and Zavzpret.
- Laura Beste: Okay.
- Zoe Taylor: Yeah. For all the CGRPs, you have to step through several other medications. But I think the thing that -- the other thing that's important to think about is whether there's an oral preventative, even that's preferred.
- Laura Beste: Which there's not currently.
- Zoe Taylor: Which there's not right now.
- Ryan Pistorresi: Right. So if there's a situation in which you know a patient is not able to use one of the preferred injectables, the provider could submit a PA and provide justification for medical necessity for why an injectable CGRP for preventive is inappropriate.
- Laura Beste: This is Laura. Would they have to use two injectables prior to moving on to an oral?
- Ryan Pistorresi: [Cross-talk] Correct.
- Kevin Flynn: But if they had some type of reason, like, where they couldn't use the injectable, wouldn't -- like if the provider indicated there was a contraindication, like, someone that had, like, really bad peripheral neuropathy and couldn't manipulate the needle on their own. I'm thinking, like, there's [cross-talk] --
- Zoe Taylor: Yeah, we need to look at the form or the policy, I think.
- Ryan Pistorresi [Cross-talk] Um, let me see if I can pull up the policy [cross-talk] --
- Zoe Taylor: [Cross-talk] It's really hard to find these forms such as another [indistinct] part of the problem [indistinct] [laughing] in general, but -- and coverage criteria. Okay. Let's see. Mi--graine, migraine agents, CGRP.
- Ryan Pistorresi: [Cross-talk] Okay. I think I have the current policy that is applicable. So I am going to share my screen. So this is pulled from our website, and this says

that it's effective date is October 1st. So this is -- it should be the current policy that we have for the CGRPs. Is there a particular section that you are interested in?

Zoe Taylor: Yeah. In the first section of Migraine Prophylaxis, if you Scroll down past #7 to the section that starts with atogepant, I think is probably -- yeah. So basically, to get Nurtec ODT, which is the oral preventative, you have to do all the above and then two preferred CGRPs -- so basically, you have to do Aimovig and Ajovy unless [cross-talk] --

Ryan Pistoresi: [Cross-talk] Or Emgality.

Zoe Taylor: -- contraindicated or not tolerated.

Ryan Pistoresi: Yeah. So, there are the three, so Aimovig, Ajovy, and Emgality.

Zoe Taylor: Right.

Ryan Pistoresi: So two of those three.

Zoe Taylor: I think it's excessive. [Cross-talk] I think you should have to try one.

Laura Beste: This is Laura. Yeah, my comment on that, too, is like with the injectables, is that there are some patients that, as Kevin pointed out, may have issues doing injections. There are some people that just can't do injections because of the fear of needles, and they would end up being denied the oral product. So is there any way to change our motion then, so they only have to trial one?

Ryan Pistoresi: So the criteria there for the two preferred says they don't have to use them if they're ineffective, contraindicated, or not tolerated. So I believe in the case in which a patient has the inability to administer the medication, if they have a peripheral neuropathy or other disability that prevents them, the provider could put that on the PA form and use that to justify why the Emgality, Aimovig, and Ajovy products are not -- reasonable for that patient. [Cross-talk] So that would be acceptable. [cross-talk] --

Zoe Taylor: [Cross-talk] But I think we can still modify the recommendation, right?

Ryan Pistoresi: Yeah. So I can go back to the modification for that, but without looking at the clinical evidence between the Nurtec and the other three -- yeah. . Yeah,

again, this isn't my policy, so I don't have the background in why we have the recommended for two preferred. But again, we would need to look at the evidence and see are there subpopulations or general superiority or non-inferiority between these different products.

Zoe Taylor: We reviewed it in July, so it's been less than a year and most of us are the same people.

Kevin Flynn: I mean, they're all the -- they all target the same receptor, like the [indistinct] works. I mean, I'm sure it's certain it's probably just a cost thing, which is okay. It's just there are some patients who can't do injectables.

Ryan Pistorosi: [Cross-talk] Yeah, yeah. And so the criteria here would allow that. So if they are not able to do injectables -- and we do see that for some of the other drug classes. So we do see that for the targeted immune modulators. Oh, sorry, Donna. You were speaking.

Donna Sullivan: Yeah. I was going to say, there is a significant cost difference. I was trying to look that up real quick while we were deliberating. The oral products are significantly more expensive than the injectables. That's probably why with the preventives we don't have the orals on the PDL as preferred. But again, they all require prior authorization, so it's not like they're going to get to it faster if they have to try and fail one if they have many of the indications or many of the things that you talked about. If that's documented in the chart a note of why they couldn't use that or submitted with the PA request, they would get approved for the oral. But they're still going to require prior authorization.

Laura Beste: Just a thought about Ubrelvy is an oral that is on there for acute migraines. Is there any possibility to change Ubrelvy to Nurtec as the preferred, or to consider doing that due to it can be used as preventative and acute?

Donna Sullivan: We can take a look at it. They're not significantly different. But yeah, we can take a look.

Laura Beste: Okay.

Donna Sullivan: We don't get a supplemental rebate from Nurtec. That's part of the problem. They haven't offered supplemental rebate.

- Laura Beste: Okay. Okay, can we go back to the motion, please?
- Ryan Pistorresi: Yes, give me one second. Okay. So this should be the motion for the Migraine Agents.
- Laura Beste: Okay. Any further discussion? Or would somebody like to make a motion?
- Kevin Flynn: I can make the motion. I think -- I know I brought up the oral, but I mean if they have to get a anyway, it doesn't seem -- reasonable to modify this unless [cross-talk] --
- Zoe Taylor: I mean, the difference is basically like if you have a patient who's tried Aimovig and wasn't able to do it or it didn't work, whether you have to then try Ajovy or Emgality, or you can try Nurtec next. So it does make a difference for patients like that additional trial that they have to do. I guess if what you're saying is the doctor can -- you know, the doctor would have to put in a PA for the Emgality anyway, and so they can put in the PA for Nurtec and just write, you know, they can't do the needles. If that works, that's fine, but if that still gets rejected, then you know that's the issue.
- Ryan Pistorresi: And This is Ryan. And, yeah, we do see those PAs from time to time, and we do consider them on a case-by-case basis. So if there is that justification, we do approve them.
- Zoe Taylor: I'm always for us being more radical because I think it doesn't make a difference anyway, but at least we can sleep at night. So I would be happy to change it to say something about this. But I'm also fine if we decide not to. I think we can vote on it.
- Laura Beste: Okay. Well, based on that, I'll go ahead and make the motion and with the recommendation that hopefully they can look at maybe changing the oral one that's approved to the oral one that has dual actions of both acute and prophylactic. So I'll make the motion. I move that all products in the drug classes listed on Slide 16 are considered safe and efficacious for their medically approved 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 non-preferred products require trial of at least two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

- Kevin Flynn: This is Kevin Flynn, I second.
- Laura Beste: Thank you. All in favor, please say aye.
- Multiple Speakers: Aye. Aye. Aye. Aye. Aye.
- Laura Beste: Any opposed? Okay. Migraine Agents is approved. And our next is Antiemetics and Antivertigo Agents.
- Nina Huynh: Okay, and this is Nina. Next, we're going to go over Chemotherapy-Induced Nausea and Vomiting or NCINV, which is one of the most distressing complications of cancer treatment severely impacting quality of life and adherence to therapy. Beyond discomfort, CINV can lead to **SERIOUS COMPLICATIONS** such as depletion of nutrients, metabolic imbalances, impaired self-care, anorexia, mental decline, wound healing issues, esophageal tears, and even treatment discontinuation. Its prevalence is striking up to 80% of patients receiving chemotherapy experience nausea and vomiting, and 29% reports anticipatory nausea and 11% anticipatory vomiting. For high emetogenic chemotherapy, the risk is even greater. Without prophylaxis, 90% of patients experience acute emesis, though premedication and antiemetics can reduce vomiting episode to about 30%. According to the 2024 Children's Oncology Group guidelines, serotonin receptor antagonists such as ondansetron, granisetron, and palonosetron are recommended as the cornerstone for prevention of acute CINV in pediatric patients. These agents should be administered prior to chemotherapy and are typically combined with dexamethasone for moderate to highly emetogenic regimens. For highly emetogenic chemotherapy, the guideline also recommends adding a NK1 receptor antagonist, such as aprepitant or fosaprepitant to the regimen. Palonosetron is often preferred for multi-day or highly emetogenic protocols due to its longer half life and efficacy in both acute and delayed phases. So in April of 2025, the FDA approved a new pediatric indication for Posfrea for the prevention of acute nausea and vomiting associated with initial and repeated course of emetogenic cancer chemotherapy, including highly emetogenic chemotherapy in patients age one month to less than 17 years. Previously, Posfrea was only indicated for adults in selected use. The recommended pediatric dose is 20 mcg/kg up to a maximum of 1.5 mg administered as a single IV dose infused over 15 minutes by a healthcare professional approximately 30 minutes before chemotherapy. And then in June of 2025, the FDA issued a **DRUG SAFETY**

COMMUNICATION for SERIOUS RISKS of heat-related complications with Transderm Scōp. The patch can increase body temperature, leading to heat-related complications, resulting in hospitalization or even death. Most cases were reported in patients under 18 or over 60 years of age, with SERIOUS HARM occurring within 72 hours of application in the younger population. As a result, the FDA required an additional WARNING on the product labeling to address these complications. And this concludes the Antiemetic and Antivertigo Agents. I'm happy to take any questions.

Laura Beste: Thank you, Nina. Any questions from the Board? Okay. If we can see the PDL. There it is.

Ryan Pistoiresi: All right. And so this one has, I think, four subgroups, so we can go through them bit by bit. So this first part will be the serotonin, so the ondansetron are the preferred. In the other, we have quite a few different products preferred. It looks like most of the meclizine products are preferred. Metoclopramide tablet is preferred. Akynzeo, which is an injectable, is preferred. There are the promethazines. Scopolamine patch is preferred. That's it for that class. For the Substance P Neurokinin-1 receptor antagonists. We just have this aprepitant capsule as preferred. And then for this Substance P Neurokinin-1 receptor antagonist combinations, this Akynzeo tablet is non-preferred. So let me just scroll up real quick. So the vial is preferred, and the capsule is non-preferred. Okay.

Kevin Flynn: Was that on purpose? I can't imagine anyone's giving themselves the vial.

Ryan Pistoiresi: This is Ryan. And yes, I believe so. But with Marissa out, I don't know when that decision was made or kind of what was part of the review for looking at which of these products would be preferred or non-preferred in these classes. But I do imagine that because they do have the different preferred status between them that there was some decision made.

Donna Sullivan: Which one are you saying is preferred that is a vial, Ryan?

Ryan Pistoiresi: This one that's the capsule is the non-preferred. But in the other category, this combo vial is preferred with PA.

Donna Sullivan: It was probably [cross-talk]. Yeah, it it's probably -- it's not really a preference status. It's on PA for professional. Like, why do you need -- why are you getting this through pharmacy rationale? [laugh] So I -- it doesn't

require try and fail of anything. I don't think anybody would be using it that often.

Kevin Flynn: Yeah. I was gonna say that. I mean, you'd probably be giving that to, like, an Oncology center [cross-talk] --

Donna Sullivan: [Cross-talk] Right.

Kevin Flynn: [Indistinct] throughout each pharmacy anyway.

Laura Beste: This is Laura. That always brought my question, too. So for, like oncology centers, this wouldn't apply. Because like the aprepitant, I noticed it was capsule, but the injectable was non-preferred. So that's because this is for like dispensing in a pharmacy, correct?

Donna Sullivan: Correct.

Laura Beste: Okay. Any other questions from the Board? And then we'll move on to stakeholders. Okay. Nonye, do we have any stakeholders?

Nonye Connor: There were none. There were no pre-registered stakeholders, and I do not see anyone's hands raised right now.

Laura Beste: Okay. Can we see the motion please?

Ryan Pistorosi: All right. So we are here on the Antiemetics and Antivertigo agents. So the motion is now ready.

Kevin Flynn: This is Kevin Flynn. I can make 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 eligible for preferred status and grandfathering at the discretion of HCA. Products in these classes may require prior authorization to determine medical necessity. All non-preferred products require a trial of at least two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Greg Hudson: This is Greg Hudson, I second.

Ryan Taketomo: Laura, you're on mute.

- Laura Beste: Thank you. Thank you for that. And all in favor, say aye.
- Multiple Speakers: Aye. Aye. Aye. Aye. Aye.
- Laura Beste: Any opposed? Okay. Motion is passed. So next, we have Gastrointestinal agents.
- Nina Huynh: Okay. And this is Nina. Next is Antispasmodics. So peptic ulcer disease effects about 1% of the US population and leads to roughly 54,000 hospital admissions each year for bleeding ulcers. The most common cause are H. pylori infection and NSAID use. Additional risk factors include smoking, alcohol, stress, and genetic predisposition. Many patients are asymptomatic, but when symptoms do occur, they often include burning or gnawing pain in the upper abdomen, along with bloating, burping, heartburn, nausea, and loss of appetite. SERIOUS COMPLICATIONS can occur, including vomiting blood, black tarry stools, iron deficiency anemia, sudden severe abdominal pain, and signs of gastric outlet obstruction. The prognosis is generally favorable because most ulcers heal when treated. Eradicating H. pylori with antibiotics and a proton pump inhibitor reduces recurrence from 50% to 60% to under 2%. A proton pump inhibitor alone can heal most ulcers within 4 to 8 weeks. And discontinuing NSAIDS heal about 95% of ulcers. Though if NSAIDs must continue adding a PPI and considering a COX-2 inhibitor is recommended. Since July of 2025, the FDA added a new limitation of use to glycopyrrolate, stating that the product is not indicated as monotherapy for the treatment of peptic ulcer disease because effectiveness in ulcer healing has not been established. This update reinforced that glycopyrrolate should only be considered as adjunctive therapy for symptom control and not as a stand alone treatment for ulcer resolution. And this concludes the Antispasmodic agents. I'm happy to take any questions.
- Laura Beste: Thank you, Nina. Do we have any questions from the Board? Okay. If not, maybe we can see the PDL.
- Ryan Pistorosi: All right. And so this is a larger drug class, so it doesn't fit all on your screen right now, but I will be able to scroll down. But pretty much in this class it's going to be the generics that are preferred.
- Laura Beste: Okay, thank you. Any questions? If not, do we have any stakeholders?

- Nonye Connor: Hello. There are no pre-registered stakeholders, and no hands are raised right now.
- Laura Beste: Okay. Can we move to the motion, please?
- Ryan Pistorosi: All right. Motion for the Antispasmodic - Other should be on your screen.
- Bradley Pope: Yeah, this is Brad Pope. 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 non-preferred products require a trial of at least two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.
- Zoe Taylor: This is Zoe Taylor. I can second.
- Laura Beste: Thank you, Brad and Zoe. And all in favor, please say aye.
- Multiple Speakers: Aye. Aye. Aye. Aye. Aye.
- Laura Beste: Any opposed? Okay. Gastrointestinal agents is passed, and we're moving on to the Corticosteroids.
- Nina Huynh: Okay. Okay, next is Corticosteroids for Muscular Dystrophy. 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 results of genetic mutation that leads 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 duplication accounts for 10% to 15%. The disease effects approximately 1 in 3600-6000 male births and has a prevalence of approximately 1 in every 7250 males age 5 to 24 years. Boys typically present with symptoms such as -- abnormal gait and proximal weakness between the ages of three and five years old. Without treatment, ambulation is usually lost by 12 years old. And here we have the AAM guideline published in 2016 and reaffirmed in 2022, which recommends

prednisone and deflazacort as the standard of care treatment for DMD. King Jaythari is the FDA-approved generic equivalent of Emflaza, the original deflazacort brand widely used for Duchenne muscular dystrophy in patients five years and older. Both products share the same indication and dosing regimen with a weight-based dosing at approximately 0.9 mg/kg once daily. Jaythari is available in tablet strengths of 6 mg, 18 mg, 30 mg, and 39 -- sorry -- 36 mg. Pyquvi is an FDA-approved generic equivalent of Emflaza oral suspension, both containing deflazacort for the treatment of Duchenne muscular dystrophy in patients 5 years and older. Pyquvi provides the same concentration of 22.75 mg/mL and follows the same weight-based dosing of approximately 0.9 mg/kg once daily. And this concludes the DMD treatment. I'm happy to take any questions.

- Laura Beste: Thank you, Nina. Any questions from the Board? And if not, if Ryan can bring up the PDL.
- Ryan Pistorosi: All right. so this subclass of the corticosteroids should be on your screen.
- Laura Beste: Okay. So no preferred agents [cross-talk] --
- Ryan Pistorosi: Correct. Everything in this class is on prior authorization.
- Laura Beste: Okay.
- Ryan Pistorosi: So they would all get reviewed regardless of which one is being requested.
- Laura Beste: Okay. And do we have any stakeholders?
- Nonye Connor: We do have a pre-registered stakeholder. I apologize again if I mispronounce your name, Darnell. If you just give me a quick second, I'm gonna share my screen with the timer.
- Donielle Martin: Sure. You pronounced it perfectly. Can you hear me?
- Nonye Connor: Yes, I can hear you.
- Donielle Martin: Oh, great. Thank you.
- Nonye Connor: Thank you. Okay. Let me know when you're ready.

Donielle Martin: Ready to go. Hello. My name is Donielle Rome-Martin, and I'm with PTC Therapeutics Medical Affairs and a Licensed Occupational Therapist. Thank you for your time today. I would like to provide testimony regarding Emflaza or deflazacort, a treatment for Duchenne muscular dystrophy. Duchenne or DMD is a progressive and severely debilitating neuromuscular disorder affecting approximately 1 in every 3600 males. Without treatment, the mean life expectancy is around 19 years of age. It is caused by an X-linked recessive mutation, resulting in the lack of structural protein called dystrophin, leading to muscle fiber damage and eventual loss of ambulation in most boys before their teens and eventual bone, pulmonary, and cardiovascular complications. There is currently no cure. Corticosteroids are considered the standard of care and have shown to slow the decline in muscle strength and loss of function in DMD. It allows patients to remain ambulatory and retain upper limb function longer as well as reducing the risk of scoliosis. Deflazacort was the first FDA-approved steroid for the treatment of Duchenne. It has been shown to preserve muscle strength and improve motor function while delaying disease progression and extending survival over 5 to 15 years of treatment as supported in the 2016 AAN Guidelines. The Cooperative International Neuromuscular Research Group, or CINRG, published the largest prospective natural history study in DMD in Lancet in 2017. The data compared age at loss of key functional milestones for deflazacort versus prednisone, which tended to be more delayed in the deflazacort treated patients. Significant values were reported with the deflazacort extending these milestones for age at loss of ability to stand from supine by 2.3 years, age at loss of ambulation by 2.8 years, and age at loss of hand-to-mouth function by 2.3 years. The most common side effects in all steroid-treated patients were weight gain, cushingoid features, behavior changes, growth delay, fractures, cataracts, and skin changes. In 2019, ICER released an evidence report on the efficacy of deflazacort for DMD. The institute concluded with the majority of the ICER Committee voted deflazacort was superior to prednisone. Currently, Washington's Medicaid requires a step-through prednisone, a product that is not FDA-approved for treatment of DMD, shows less long-term effectiveness than deflazacort and often has significant ADVERSE EVENTS. We ask to remove the requirement to fail prednisone before granting access to deflazacort. Our recommendation would maintain coverage of prednisone but allow physicians and patients to use deflazacort as the first-line therapy if they deem it most appropriate. The numerous data continued to demonstrate the superiority of deflazacort and treating patients with DMD and how it significantly improved muscle strength, pulmonary function, and was more effective in extending motor

function and survival as compared to prednisone. DMD patients lose muscle every day, and it cannot be regained once it's lost. However, the loss can be slowed with the use of deflazacort. Thank you for your time and consideration today.

Laura Beste: Thank you, Donielle. That was very informative. Any questions from the Board? Any other stakeholders?

Nonye Connor: No other pre-registered stakeholders and no hands are raised.

Laura Beste: Okay. Can we go to the motion, please?

Ryan Pistorosi: All right. So here we go for the Corticosteroid.

Kevin Flynn: This is Kevin Flynn. I can read the motion. I move that all products in the drug classes listed on Slide 22 are considered safe and efficacious for their medically accepted indications and they 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 non-preferred products require a trial of at least two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Bradley Pope: It's Brad Pope, I'll second it.

Laura Beste: Thank you, Kevin and Brad. So all in favor, please say aye.

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

Laura Beste: Any opposed? Okay. That has passed. Next topic. So we're due for a [audio cuts out] section and then break for 10 minutes so Nina can have a drink of water.

Nonye Connor: Okay.

Laura Beste: Sound good? Okay.

Nonye Connor: So are you saying take a 10-minute break?

Laura Beste: We can, or we can do one more section and then take a 10-minute break.

- Nonye Connor: Oh, what is the preference?
- Laura Beste: Let's do one more section.
- Nina Huynh: Okay. This is Nina. Okay, next is Dystrophic Epidermolysis Bullosa and gene therapy. So epidermolysis bullosa, or EB, is a rare genetic disorder characterized by extreme skin fragility, painful blistering, and chronic wounds affecting both skin and mucosal surfaces. In severe cases, blisters and sores can extend to the mouth, esophagus, GI tract, upper airway, bladder, and genitals. EB is most often identified in young children, as symptoms typically appear at birth or shortly thereafter. The condition is classified into four main types: epidermolysis bullosa simplex, or EBS, which is usually dominant inherited and linked to mutations in Keratins 5 & 14, or plectin. Junctional EB or JEB is recessively inherited and associated with defects in Laminin 332, plectin, and integrins. Dystrophic EB, or DEB, can be dominant or recessive and involves type VII collagen abnormalities. Kindler syndrome, a very rare form affecting all skin layers with extreme fragility. There is currently no cure for EB, and management focuses on support of care to reduce complications and improve quality of life. In April of 2025, the FDA approved Zevaskyn as the first autologous cell sheet-based gene therapy for treating wounds in adults and pediatric patients with recessive DEB. Key WARNINGS include hypersensitivity reactions to vancomycin, amikacin, or excipients. Potential retroviral vector-mediated insertional oncogenesis and risk of transmitting infectious agents due to human and bovine reagents used in manufacturing. Each sheet contains the patients own viable gene-modified cells engineered to express functional Collagen VII protein via insertion of the COL7A1 gene. One sheet covers 41.25 square centimeters, and up to 12 sheets may be manufactured from patient biopsy for use in a single surgical session. So the skin is shipped directly to qualified treatment centers and applied at room temperature. In September of 2025, the FDA's expanded the indication for Vyjuvek, a topical gene therapy for wounds and patients with DEB caused by COL7A1 mutations, previously limited to patients 6 months and older, and clinic-only application. Vyjuvek can now be used in all pediatric patients starting at birth and applied at home by a caregiver or patient. The gel is prepared by the pharmacy and applied once weekly directly to the wounds with dose based on age. So it's up to 2×10^9 PFU for children under three years and 4×10^9 PFU for those 3 years and older. Treatment continues until wounds close. And if previously treated wounds reopen, they should be prioritized. Wound dressing are now removed at the

next scheduled change rather than waiting 24 hours. And this concludes the DEB and gene therapy section. I'm happy to take any questions.

Laura Beste: Thank you, Nina. Does anyone have any questions? Okay. I think Ryan can show us the PDL now.

Ryan Pistoiresi: So for the PDL, we just have three drugs across these two drug classes. As you may notice, for the Zevaskyn, there is that X. And that X is there because this is an inpatient-administered medication, so it is not available through the Apple Health PDL, but rather, it has to go through an inpatient claim. And so it is handled differently than the other drugs on the Apple Health PDL, but nonetheless, it is still presented here as part of the DUR Board because it is -- it falls within kind of our drug benefit.

Laura Beste: Hey, thank you. And do we have any stakeholders?

Nonye Connor: Yes, we do have a pre-registered stakeholder. Keith, you can unmute yourself whenever you're ready. And just give me a quick second to share my screen [cross-talk] for the timer.

Keith Dilly: [Cross-talk] Hello? Hello? Can you hear me well?

Nonye Connor: Yes, we can hear you.

Keith Dilly: Hi, thank you for the opportunity to speak with you today. I'm Keith Dilly, Scientific Director Abeona Therapeutics. I'd just like to ask to -- for you to respectfully reconsider the non-preferred status of Zevaskyn for its ability to treat a larger body surface area in a single application than any other FDA-approved product for epidermolysis bullosa. I'll read a short testimony and then take any questions. Let's begin with the unmet need in recessive dystrophic epidermolysis bullosa or RDEB. This is a severe ultra rare genetic disorder caused by mutations in the COL7A1 gene, resulting in a deficiency or absence of type VII collagen. This leads to a lack of anchoring fibrils that normally connect the epidermis to the dermis, causing extreme skin fragility and blistering. Clinically, patients present with chronic painful wounds that are slow to heal, highly susceptible to infection, and associated with squamous cell carcinoma, and significant morbidity. Current management is primarily supportive, relying on time consuming and costly bandaging routines, along with symptomatic relief for pain and itch. While a topical non-cell-based gene therapy is available, it requires ongoing reapplication, and an

unmet need remains for many patients, particularly those with extensive or chronic wounds to achieve durable wound closure and sustained healing. Zevaskyn is an autologous gene-modified cellular sheet indicated for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa. These sheets are engineered to express type VII collagen at the dermis/epidermal junction and are designed for a one-time surgical application where applied. The COL7A1 [indistinct] gene integrates into the host genome at the site of application and is maintained through cell division, supporting sustained expression of type VII collagen. In the pivotal vital study, patients treated with Zevaskyn demonstrated clinically meaningful wound healing with 81% of wounds achieving greater than 50% healing at 6 months compared to 16% of control wounds, which underwent the standard of care of bandaging. Among those 65% achieved 75% or greater healing compared to 7% for control, and 16% of wounds reached complete closure compared to 0% for control. In addition to wound healing, patients reported significant reduction in pain benefits that are unique to Zevaskyn. Zevaskyn has an established safety profile in clinical trials. The most common side effects were pruritus and procedural pain. SERIOUS ALLERGIC REACTIONS including anaphylaxis may occur with Zevaskyn, and lifelong monitoring for the development of cancer is advised. No cases of squamous cell carcinoma have been reported in Zevaskyn-treated wounds, but SCC was observed in non-Zevaskyn-treated sites in four patients. Zevaskyn is designed to promote durable wound healing and reduce pain with a single surgical application where it's applied. As an autologous therapy, it's gene-modified cellular sheets provide a personalized approach to managing wounds associated with RDEB, including large or chronic areas. And I'll take any questions. Thank you.

- Laura Beste: Thank you, Keith. And a fascinating treatment. I did not know it existed. Any questions from the Board? No? Okay. And I think -- is there another stakeholder?
- Nonye Connor: Yes. I see your hand raised. Susan, you can unmute yourself whenever you're ready.
- Susan Bolton: Hi, my name is Susan Bolton. I'm with Abeona Therapeutics as a Senior Director. I just wanted to point out one thing that I had noticed on the PDL, I noticed that the federal rebate status was marked NO, and I just wanted to inform the Committee -- and I don't know if this is the -- appropriate time to do so, but there is a national drug rebate agreement that has been signed

with the CMS in October of '25 -- or it became effective October of '25. So that is available in case there was any interest in carving out Zevaskyn from the DRG in patient bundle. And that is it. Thank you.

Susan Bolton: Thank you. Any questions? Okay. Then can we move to the motion please?

Ryan Pistorosi: All right. So the -- where there were the two drug classes with the three drugs across. And so that's what this Dermatologics motion will cover.

Laura Beste: Okay. This is Laura Beste, and I will make a motion that I move the all products from the drug classes listed on Slide 24 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 non-preferred products require trial of at least two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

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

Laura Beste: Okay, thank you. And all in favor, please say aye.

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

Laura Beste: Any opposed? Okay. Dermatologics is approved. And let's pause for a 10-minute break. So Nina, without her speaking, can get some water. And see you back at 3:15.

Nonye Connor: Perfect. Thank you.

[break]

Nonye Connor: And I'm just going to check and make sure we are at quorum. Committee members, please turn your cameras on. Two. Yes. We're a quorum, Laura.

Laura Beste: Okay. We are starting the DUR Board Review of Genitourinary Agents by Nina. Thank you.

Nina Huynh:

All right, thank you. I really needed that sip of water. So next is Hyperoxaluria Agents. Primary hyperoxaluria type 1, referred to as PH1, is a rare autosomal recessive genetic disorder caused by mutations in the AGXT gene, leading to extreme high oxalate levels in the urine. This drives recurrent kidney stones, progressive kidney damage, and systemic complications. Management requires a multilayer approach. First, aggressive hydration, typically at least 3 liters a day for adults to keep oxalate diluted. Second, a trial of vitamin B6 for 3 months, since about 30% of patients will see meaningful reductions. We now have RNA interference therapies such as lumasiran and nedosiran, which target hepatic oxalate production. Additional strategies include citrate or bicarbonate salts to reduce urine acidity, avoiding high-dose vitamin C, and pairing high oxalate foods with calcium to limit absorption. In advanced disease, dialysis is required with specialized settings for PH1, and definitive treatment often involves combining liver and kidney transplantation or stage approaches depending on residual enzyme activity. So the FDA expanded the age indication for nedosiran marketed as Rivfloza to include patients as young as 2 years old with PH1 and relatively preserved kidney function defined as an eGFR of at least 30. Previously, Rivfloza was approved only for patients 9 years and older. Dosing is weight based for patients aged 2 to under 12 years. Those weighing less than 39 kg received 3.3 mg/kg subcutaneously once monthly. Those between 39 kg and under 50 kg received 128 mg monthly, and those 50 kg or more received 160 mg monthly. All doses are based on actual body weight, and administration for patients under 12 years old should be administered by a healthcare professional or caregiver. Okay. And then next, is IgA Nephropathy Agents. So IgA Nephropathy, also known as IgAN or Berger's Disease, is a chronic kidney disorder, where IgA antibodies deposits in the glomeruli, causing inflammation and progressive damage. Patients often present with proteinuria, hematuria, changes in urine color, swelling, hypertension, fatigue, and reduced urine output. There is no cure, so treatment focuses on slowing chronic kidney disease progression and managing symptoms. ACE inhibitors or ARBs remain first-line therapy to reduce proteinuria and control blood pressure. And SGLT2 inhibitors are increasingly used for additional renal protection and cardiovascular benefit. Newer options include endothelin receptor antagonists such as sparsentan and atrasentan, which relax renal blood vessels and reduces proteinuria. Short-term corticosteroids may be used for immune modulation. And most recently, complement factor B inhibitors like iptacopan has emerged as targeted therapy to reduce inflammation and slow disease progression. Since April of 2025, the FDA granted accelerated approval to atrasentan, marketed as

Vanrafia, for adults with primary IgAN, who are at risk for rapid progression, generally defined as a urine protein-to-creatinine ratio of 1.5 g/g or higher. When this approval is a base -- this approval is based on proteinuria reduction. It's important to note that it has not yet been established whether atrasentan slows kidney function decline. The product carries a BOX WARNING for major birth defects and is contraindicated in pregnancy and hypersensitivity. Other notable risks includes hepatotoxicity, fluid retention, decreased sperm count, peripheral edema, and anemia. The recommended dose is 0.75 mg orally once daily with or without food using a 0.75 mg tablet. And that concludes this portion of the presentation. I'm happy to take any questions.

Laura Beste: Thank you, Nina. Any questions from the Board? Okay. Can we see the PDL, please?

Ryan Pistorresi: All right. And so for the two drug classes that were just reviewed by Nina, here are their statuses on the Apple Health PDL.

Laura Beste: Okay. And do we have any stakeholders?

Nonye Connor: Yes. We do have a pre-registered stakeholder. And, Shirley, you can unmute yourself whenever you're ready. And just give me a quick second and I'll share the timer.

Shirley Quach: All right. And can you hear me okay?

Nonye Connor: Yes.

Shirley Quach: All right.

Nonye Connor: Just give me a quick second. I'm sorry. You do not need to answer the questions. Can you see my screen? Wait, let me -- I'm sorry about that. Did that again. Okay, I'm ready whenever you are.

Shirley Quach: Great. Well, hi, again. My name is Shirley Quach, and I'm a Value Evidence Lead with Novartis. Thank you for the thoughtful review of the IgA nephropathy agents and Vanrafia. The only things that I would like to add is to highlight about Vanrafia is that the key differentiator for Vanrafia compared to other ERA agents for IgAN is that Vanrafia is a once daily oral treatment that can be added on top of supportive care, a RAS inhibitor with

or without SGLT2 without requiring dose adjustments or discontinuation of the patient's supportive care and does not require a REMS program. Other than that, the other information that was presented just now is -- I don't want to repeat those. So just wanted to thank you for the thoughtful review, and we're aligned with the preferred status on the PDL and with PA to label. Thank you.

Shirley Quach: Thank you, Shirley. Any questions from the Board? No? Okay. So if we can see the motion, please.

Nonye Connor: We did have another registered [cross-talk] --

Laura Beste: [Cross-talk] Oh, I'm sorry.

Nonye Connor: -- but I cannot find Matt. I don't know if Matt is here. If you are, raise your hand because I just can't find you on the attendance list. I don't see any other hands raised, so back to you, Laura.

Laura Beste: Okay. So let's take a look at the motion, and if anybody would like to take -- make a motion.

Kevin Flynn: Kevin Flynn. I move that all products in the drug classes listed on Slide 26 are considered safe and efficacious for their medically accepted indications and eligible for preferred status and grandfathering at the discretion of HCA. Products in these classes may require prior authorization to determine medical necessity. All non-preferred products require a trial of at least two preferred products with the same indication before a non-preferred 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. All in favor, please say aye.

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

Laura Beste: Any opposed? Okay. It is approved. Moving on to Analgesics. I don't know, maybe not. Antihemophilic Agents.

Nina Huynh: Okay, hello. This is Nina. So we're going over the minor update, so I'm going to go through these pretty quickly. First is Hemophilia treatment, which has one discontinuation. So Beqvez was discontinued in February of 2025. Next,

is Contraceptives, which have one name change. And FDA approved proprietary name change of Phexxi to Phexx. Okay. There was one FDA communication for Androgenic Agents. So in March of 2025, the FDA issued a class-wide labeling change for testosterone products based on the finding from the TRAVERSE clinical trial and postmarketing ambulatory blood pressure monitoring study. The TRAVERSE study was designed to evaluate whether testosterone replacement therapy increases the risk of MACE. Participants were randomized to receive daily transdermal testosterone gel or placebo with the mean follow up of 33 months. The primary endpoint MACE occurred in 5% of patients in the testosterone group, and 77.3% in the placebo group, with a hazard ratio of 0.96, meaning the criteria for non-inferiority. However, secondary endpoints revealed a higher incidence of atrial fibrillation, arrhythmias requiring intervention, acute kidney injury, and pulmonary embolism in the testosterone group. So based off of the TRAVERSE trial, the FDA has recommended to include the TRAVERSE trial results in the Prescribing Information for all testosterone products. The BOX WARNING should be revised. The previous language suggesting an increased risk of adverse cardiovascular outcome should be removed, reflecting the updated evidence from the TRAVERSE. For ABPM, for products with completed ABPM studies, the labeling should include product-specific data showing increase in blood pressure. And for those without such data, a new general WARNING about increased blood pressure should be added to the labeling. Okay. And the last class, we have one new generic in the Parenteral Iron. So FDA approved the first generic for Venofer single-dose vial in August of 2025. And that concludes my portion of the meeting. I'm happy to take any final questions.

Laura Beste: Okay. Thank you, Nina. A lot of reviews there. So do we look at these drug classes too, and then just make a motion on all of them together?

Ryan Pistoresi: Correct. So there are separate motions for each of these subclasses [cross-talk] --

Laura Beste: [Cross-talk] Okay.

Ryan Pistoresi: -- so I will be able to go through them. But for the purposes of reviewing the status on the PDL, I do have them broken out by those different subsections. So you'll see how they are listed. So for the first one, for the Hemophilia Gene Therapies, they're listed up here in these first four. They're all preferred with PA. For the next Contraceptive one, the two products are preferred. For the

testosterones, you can see that we have just a few select testosterone products as preferred. The rest are non-preferred with a PA status. And then for the last one, the iron sucrose that was just mentioned, all of those iron products are preferred with PA.

Laura Beste: Okay, thank you. Any questions from the Board? Okay. Then can we see the motions, please?

Nonye Connor: I do have a pre-registered [cross-talk] stakeholder. No problem. [cross-talk] Let me see. [laugh]. Chad. You can meet yourself whenever you're ready, Chad, and I'm going to share the timer.

Chad Duncan: All right. Can you hear me?

Nonye Connor: Yes, I can hear you.

Chad Duncan: Thank you. Thank you for this opportunity to provide information regarding Alyftrek, oral CFTR modulator indicated for the treatment of cystic fibrosis in patients 6 years and older who have at least one F508del mutation or another responsive mutation in the cystic fibrosis membrane -- transmembrane conductance regulator gene. Alyftrek does carry a BOXED WARNING related to drug-induced liver injury and liver failure in the FULL BOXED WARNING. And FDA approved indication can be found in the US Prescribing Information. CF has long -- cystic fibrosis has long been perceived as primarily a respiratory disease. And while FEV1 has been a standard endpoint in cystic fibrosis improvements, an FEV1 do not capture all of the systemic impacts of cystic fibrosis and may not be possible to demonstrate in clinical trials due to the irreversible lung damage or relatively preserved lung function. CF is a multisystem disease caused by CFTR dysfunction, which can be readily measured by sweat chloride. Sweat chloride tests are long established diagnostic tool for cystic fibrosis, and there is an inverse relationship between CFTR function and the sweat chloride levels in the literature. Alyftrek is the first and only CFTR modulator with once-daily dosing and is a treatment option for 31 additional eligible mutations not eligible for any other CFTR modulator therapy, which equates to about 150 additional patients here in the US. Alyftrek is a fixed dose combination tablet that contains vanzacaftor/tezacaftor/deutivacaftor, which either increased the amount of CFTR protein to the cell surface or potentiate the channel open probability or gating of the CFTR protein at the cell surface. The combined effect of Alyftrek is increased in CFTR function

that can be measured by sweat chloride. As I mentioned, Alyftrek is the first and only triple combination CFTR modulator therapy that expands the eligibility to CFTR modulator treatments to more patients while also providing an option for those patients who may have discontinued another CFTR modulator. Vertex is asking that all CF potentiators have the same formulary criteria. Specifically, Vertex is asking that Alyftrek be added to the Apple Health PDL. And I'll be more than happy to answer any questions.

Laura Beste: Thank you, Chad. I don't think we have reviewed the cystic fibrosis agents yet, but we will take it into consideration when we do.

Chad Duncan: Okay, sorry.

Laura Beste: That's okay. Do we have any other stakeholders? Okay. So on to the motions.

Ryan Pistorosi: Nonye, I think you were muted.

Nonye Connor: I'm so sorry. No hand raised. Sorry about that.

Ryan Pistorosi: Okay. So the different products are going to be reviewed by their classes, so we'll start with the Hemophilia Gene Therapies.

Greg Hudson: This is Greg Hudson. I can do the motion here. I move that all products in the drug classes listed on Slide 28 are considered safe and efficacious for their medically accepted indication 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 non-preferred products require a trial of at least two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

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

Laura Beste: Thank you. And all in favor, say aye.

Multiple Speakers: Aye. Aye. Aye. Aye. Aye. [cross-talk]

Laura Beste: Any opposed? Okay. Next, we have the Contraceptive section.

- Ryan Pistoiresi: Great. So for the Contraceptives, there is just the one drug class that is part of this motion.
- Laura Beste: Would anybody like to make the motion?
- Hope Barnes: This is Hope Barnes. I can make the motion. I move that all products in this drug class listed on Slide 30 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 non-preferred products require a trial of at least two preferred products within the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.
- Zoe Taylor: This is Zoe Taylor. I can second.
- Ryan Pistoiresi: All right.
- Laura Beste: Thank you. All in favor say aye.
- Multiple Speakers: Aye. Aye. Aye. Aye. Aye.
- Laura Beste: Any opposed? Okay. Contraceptives is approved. And next motion, please, for [cross-talk] --
- Ryan Pistoiresi: [Cross-talk] So we are now on to the testosterone products. So for just the testosterone products.
- Christy Weiland: [Cross-talk] This is Christy [cross-talk]. I can move forward with the motion. I move that all products in the drug classes listed on Slide 32 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 non-preferred products require trial of at least two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.
- Greg Hudson: And this is Greg Hudson, [cross-talk] --

Zoe Taylor: [Cross-talk] I second.

Greg Hudson: -- I second. Aw.

Laura Beste: All in favor, say aye.

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

Laura Beste: Any opposed? Okay, approved. Next motion.

Ryan Pistorosi: Okay. So this is for the Iron and Iron Combinations - Injectables.

Greg Hudson: I'm Greg Hudson, and I move that all products in the drug classes listed on Slide 34 are concerned 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 non-preferred products require a trial of at least two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Kevin Flynn: This Kevin Flynn [cross-talk] --

Hope Barnes: [Cross-talk] This is Hope Barnes, I second.

Laura Beste: Okay. Thank you. All in favor, say aye.

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

Laura Beste: Any opposed? Okay, approved. And next.

Ryan Pistorosi: So at the end of the meeting are all of the other Apple Health drug classes. These are -- ooh. Sorry. These are all the drug classes in which there was no evidence review or any other update, and so I will go ahead and do a review of these individual classes from the Apple Health PDL. You'll recognize that a lot of these are other subclasses from drug classes that were reviewed by Nina and by you earlier today. However, these are the ones that do not have any updates. So to just have that comprehensive review for that drug class or that disease state, I will go ahead and pull them up in just a second. Okay. So at the top -- actually, so on this review, we have Opioid Agonists - Long-

Acting, several Antibiotic classes, one Anti-Diabetes subclass, a few Antihypertensives, COVID-19 Antivirals, Bone Density Regulators, Cardiovascular Agents, the Other Contraceptives, Corticosteroids, and Cough and Cold Inhalants. So for this, these are the current preferred status for those selected drug classes. And when we go back to the motion, these are all the drug classes that will be on Slide 36. Nope. I did not mark these all that well. So here is the start of the Inhaled Aminoglycosides. As you can see, for most of these drugs in these drug classes, the generics are preferred. Okay. So let's scroll back to the top. The next slide will have these drug classes. So the Dermatologics and Endocrine subclasses. So there's just really two drug classes on this grouping with the Dermatologics up here for these two, and then everything else will be an Endocrine and Metabolic drug in the rest of this grouping. All right? And then the final grouping of drugs are going to be the ones on Slide 38 of the motions, and this one has the remaining drug classes that were part of the review today. So going back to GI Agents, Gout Agents, Hematological, Immunosuppressive, Mouth, Musculoskeletal, Ophthalmologic, Respiratory, and then the final one are going to be the Sleep Disorder Agents. That may help with some of the differentiation because some of these, like this one, are only one drug in that drug class. Okay. So those are the different statuses for the drugs in each of those drug classes.

Laura Beste: Any questions from the Board? That was a lot of information.

Ryan Pistorosi: Yes. Yeah, I know. These are all of the other drug classes, so that way we continue with our annual review. And so, as you know, a lot of these drugs are older drug classes in which there are a lot of generics available, so there's not a lot of studies or research or other work being done that we have presented for the meeting. So again, these were all the drugs from that first grouping on Slide 36. These are the ones that were on slide -- or this is Slide 37, so these were the Dermatologic and Endocrine ones. And then, lastly, from the GI Agents to the Sleep Disorder Agents. And so, fortunately, you don't have to go through all of them. We do have just this one slide that encompasses them all just because there has been no evidence or no updates. This is just kind of you reiterating that the current way that we've been managing these classes can continue.

Alex Park: Thanks for not making us sit through individual [laugh] -- nothing to say about each group.

Ryan Pistorosi: Oh, for sure.

- Alex Park: I can make the motion here for the AHPDL classes, moving that all products in the drug classes listed on Slides 36 through 38 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 non-preferred products require a trial of at least two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.
- Zoe Taylor: This is Zoe Taylor. I can second.
- Laura Beste: Thank you. All in favor, say aye.
- Multiple Speakers: Aye. Aye. Aye. Aye. Aye.
- Laura Beste: Any opposed? Okay. And I believe that was the last item on our agenda, which we've made through the whole thing at 3:45. Nice work. So at this point in time, unless Nonye has any other topics of discussion --
- Nonye Connor: I think you can adjourn the DUR Board.
- Laura Beste: The DUR Board will now adjourn. Thank you.
- Nonye Connor: Thank you.
- Laura Beste: Then we'll see everyone, April [cross-talk] --
- Nonye Connor: Yeah. Thank you, everyone. Let me double check the dates we'll be meeting again. So we're going to be meeting again April 15th. I just want to give everyone a heads' up, we are phasing out Zoom, so we're going to be getting - - you'll be getting a meeting invite through Teams. So just wanted to let everyone know of that change in platform for our virtual meeting. But other than that, congratulations again, Kevin. Congratulations again, Christy. And I appreciate everyone of you. Thank you all.
- Laura Beste: Thank you. Bye-bye,
- Greg Hudson: Thank you all.

Nina Huynh: Thank you. Bye.

Ryan Pistoresi: Thank you.

[end of audio]