Washington State Pharmacy and Therapeutics Committee
Drug Utilization Review Board
Meeting Transcription
October 16, 2024

Nonye Connor: Okay, Kavita, whenever you are ready.

Kavita Chawla: Great. Good morning, everybody, and happy fall. We will now convene the P&T Committee Meeting. I am Kavita Chawla, the Chair of the P&T Committee. I will read off the names of the participating attendees, so please say "here" when I call your name, starting with our P&T Committee Members. Peter Barkett. I don't see him here yet. Laura Beste.

Laura Beste: Good morning, here.

Kavita Chawla: Morning. Michael Corsilles?

Michael Corsilles: Morning, here.

Kavita Chawla: Morning. Kevin, I don't think is here. Um, Greg Hudson?

Greg Hudson: Hello, here.

Kavita Chawla here: Hey, Greg. Jon MacKay?

Jon MacKay: Good morning, here.

Kavita Chawla: Good morning. Good to see you. Zoe Taylor?

Zoe Taylor: Here.

Kavita Chawla: Morning. And Christy Weiland.

Christy Weiland: Hi, here.

Kavita Chawla: Hi. All right. Our Health Care Authority Members. Nonye Connor.

Nonye Connor: Good morning.

Kavita Chawla: Amy Irwin.

Amy Irwin: She's not here right now.

Kavita Chawla: Okay. Elizabeth Punsalan?

Elizabeth Punsalan: Good morning.

Kavita Chawla: Good morning. Donna Sullivan.

Donna Sullivan: Marissa Tabile?

Marissa Tabile: Good morning.

Kavita Chawla: Ryan Taketomo?

Ryan Taketomo: Morning, I'm here.

Kavita Chawla: Hey, Ryan. Joey Zarate.

Joey Zarate: Good morning.

Kavita Chawla: Good morning. And then from our Magellan Medicaid Administrative Presenter, we have Nina Huynh.

Nina Huynh: Good morning.

Kavita Chawla: There she is. Good morning. And then our Managed Care Organization Representatives, we have Greg Simas from Molina, Heidi Goodrich from Molina, Petra Eichelsdoerfer from United Healthcare, Omar Daoud from Community Health Plan of Washington, and Jeffrey Natividad from Community Health Plan of Washington. Now, Nonye will go over the meeting logistics.

Nonye Connor: Yes. Hello, again. The Committee and presenters can mute and unmute themselves at any time, but please mute yourselves when not speaking so as to limit background noise. Presenters, please share your webcams while presenting. Committee, please share your webcams while discussing and motion considerations. For stakeholder participation, to share, we will read the list of stakeholder names who pre-registered to speak. We will unmute

you. After the share, we'll ask if there are any other stakeholders. If there are, please raise your hand, and we will call upon you and unmute you. You can also use the Q&A box. We will address your questions during the stakeholder time and concerns. The chat for this meeting is muted, so the Q&A box would be the best way to communicate with us if you have any questions. If you did not fill out the stakeholder conflict of interest form, that's okay. Please answer the questions we'll post on the screen. Your 3 minutes will start after you have answered the questions. Thank you.

Kavita Chawla: Thank you, Nonye. Okay. So with that, let's get started. I see Marissa. You're up first to go through our Apple Health Policy for Bone Density Regulators.

Marissa Tabile: Good morning. This is Marissa. Yes, I will go ahead and start to present. Let me just get my bearings with trying to show my screen. All right. Hopefully, you all can see that. I do have Bone Density Regulators : Parathyroid Hormone Analogs showing. If not, just feel free to stop me if you can't see anything or if it's not moving as it's intended to. So good morning, DUR Board. I will be going through the Bone Density Regulator Clinical Policies. So just to give you all some background on these policies. So these policies I should say are a refresh of our current policy that we have listed online. That policy is number 30.04.00, and the last time that that policy was updated was in 2019, so it is in need of a refresh. It's been quite some time since we have gone through it and refreshed that policy. So currently, the way that the policy is, all of the drugs and indications that I'm going to go through here, there is one additional policy that we'll be presenting in December that is a part of this breakout. We just did not have time to include it in this review, but, currently, all of those live in that one policy that we have posted online. So it's very similar to the strategy that we did for the Cytokinin and CAMs, where we're breaking them out by mechanism of action. So that is really currently the method of how we're doing it for these policies as well as we have broken them out by their mechanism of action. So we have a Parathyroid Hormone Analog-specific policy. I think it's a RANK ligand policy. And I think there is -- I have to remember the other one -- but you'll see all three of them. They're all broken out. Currently, our policy that we have posted online that we currently use really only addresses the Osteoporosis indications, and that Osteoporosis indication houses everything in one. It's not specific to really, I guess, the different types of osteoporosis that these drugs and these policies can address. So we have split them out by Postmenopausal Osteoporosis, Male Osteoporosis, Glucocorticoid-induced Osteoporosis just to be a little bit more specific. We were finding that it was a

little hard to, with the way that the policy is currently live. Getting into those nuances of those different osteoporosis indications was getting a little difficult to read between the lines, so we did make them very specific in these policies. And we did also try to keep all the criteria the same across the indications, so if there was overlap in some of with some of the drugs, like, I'm just going to say Postmenopausal Osteoporosis, for example, we did try to keep those criteria largely the same across all of the different policies if it was applicable. So some of these I might go through rather quickly just because you will have seen that criteria in a previous policy that I might have presented moments earlier. The criteria should be largely the same. And we did also include the indications where there are some related to cancer and bone metastasis for those specific drugs. So those are now included in these policies if it's appropriate for that drug. And you will also see two in at least in this first policy that I'll be presenting, we do have new language that we have included or will start including in our policies about non-preferred brand name drugs. And we do have policies called our non-clinical policies which we are currently in development for some of -- currently in development for some of the other ones, but we do have one right now that is live on our website that we do use called NC-001, and that addresses our brand with Generic Equivalence Policy. So if you have a brand and generic product on the market, and we prefer the generic product over the brand or we want patients to use the generic over the brand, and there is a clinical policy we will include that language in our policies moving forward, and that's only if those products do have those generics available on the market. So you will see some of that in some of these newer policies than the policies here today as well. I don't think we have gone over that in previous policies this year, so I just wanted to make a note of that. So I'll just go ahead and jump right into the first policy. So this one is the Parathyroid Hormone Analog Policy, and this policy really encompasses two drugs, which is abaloparatide and teriparatide, or Tymlos and Forteo are the brand names. The medical necessity language is really the same as what you have seen before. That hasn't changed with the exception of the non-clinic -- referencing the non-clinical policies here at the top. So this is really just pointing out if there is a generic on the market that we want a patient to use, they must still use that generic product first before they could be eligible for the brand product. I don't have that non-clinical policy pulled up, but there are specific kinds of criteria that we have for that. They have had to -- I think it's along the lines of they have to try like X amount of manufacturers or the generics, if there are multiple manufacturers of the product, before they can be eligible for the brand. So that's just referencing that here because I believe

there are some generics on the market for some of these products. So getting into the criteria, specifically, I'm going to start first with the Postmenopausal Osteoporosis indication. This really applies to Tymlos and Forteo. And for this one we have an age indication, so 18 years of age or older, a diagnosis of osteoporosis, 3.) the patient is a postmenopausal female, and 4.) at least one of the following fracture risk categories is met: so it would be a presence of fragility fractures of the hip or spine regardless of bone mineral density, or a T-score less than -2.5 in the lumbar spine, femoral neck, or total hip, or T-score between -1 [audio cuts out] and -0.5, with a history of recent fragility fracture of proximal humerus, pelvis, or distal forearm, or T-score between -1 and -2.5, with a FRAX 10-year probability for major fracture greater than 20% or hip fracture greater than 3%. So they just need to meet any one of these A, B, C, or D. And 5.) the treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone during their lifetime, or 6.) -- and this is really just addressing if patients need to use teriparatide longer than 24 months. So the patient has received treatment with the parathyroid hormone for more than 24 months during their lifetime, and the patient essentially still remains at a very -- having high or very high fracture risk, which is defined as the following, and these are just some examples: They have had a fracture in the past 12 months. They have had a fracture while they have been on osteoporosis therapy, a history of multiple fractures, T-score less than -3, high risk for falls, and a FRAX 10-year probability for major [audio cuts out] fracture of greater than 30% or hip fracture greater than 4.5%. So they would need to meet either 5 or 6, and 6 really only applies really for teriparatide. And 7.) the medication will not be used in combination with other bone density regulators, so bisphosphonates, Raloxifene, and RANKL inhibitors, and 8.) a history of at least one of the following: So this is where we're getting into the trial and failure [audio cuts out] products that we would expect. So it's really just one of these, so A, B, or C, that the patient would need to meet. So one preferred AHPDL oral or intravenous bisphosphonate medication that's been ineffective or it’s contraindicated or not tolerated for a minimum trial of 12 months or at least one preferred Selective Estrogen Receptor Modulator (SERM) has been ineffective, and that minimum trial is 24 months, or they have been treated with denosumab and that's been ineffective or contraindicated or not tolerated for a minimum trial of 12 months. And if they meet all the criteria, we would approve the request for up to 12 months unless the total combined duration of parathyroid hormone analog would exceed two years, then we would just go up to whatever that time frame is if they meet if it gets up to 24 years. And then for re-authorization for this one, Criteria 7 just continues to be met so

they're not using it in combination with another bone density regulator, and documentation is submitted demonstrating disease stability or positive clinical response with examples that are listed there. For the abaloparatide, if they meet the re-up criteria above, we would approve it for up to 12 months unless the total combined duration of parathyroid hormone analog would exceed two years. So if they have gotten approved before for 12 months and then they need it for an additional 12 months, then we would just approve the 12 months if, for example, they were up to -- I'm just making it up, 20 months or -- well, we wouldn't do that, but as long as it doesn't exceed two years, that's kind of how that would work, or we would go up to the two years. For teriparatide, all of the criteria are met, approved for up to 12 months, and that's -- we did not have that same language for abaloparatide because for teriparatide you can use it beyond 24 months if they're at very high risk, so that's why the language between the two differs. Getting into Male Osteoporosis. The criteria is similar but a little bit different for the postmenopausal and male osteoporosis, so I'll kind of just note the differences between them. The age is still the same, diagnosis of osteoporosis, 3.) is different where the patient is a biological male, 4.) the risk categories are still the same for both men and women, 5.) and 6.) are still the same across both. And then where it gets a little different is 7.) is still the same. 8.) is different because treatment with at least one preferred AHPDL oral or IV bisphosphonate medication indicated for male osteoporosis has been ineffective unless all are contraindicated or not tolerated. So this one, we would just expect them to try and fail an oral bisphosphonate, whereas, in the female in postmenopausal osteoporosis, they have a little bit more options, including SERMs, which you may or may not expect to see in those patients. So just the trial and failure are a little bit different. And then here, the re-up criteria are still the same for that. Same for abaloparatide and teriparatide. For Glucocorticoid-Induced Osteoporosis, this indication only applies for teriparatide or Forteo. For this one still age indication, osteoporosis diagnosis. 3.) This is where it's a little bit different. So the patient has a history of, or is currently taking sustained systemic glucocorticoid therapy, and the daily dosage equivalent is greater than 5 mg of prednisone, and that would be a minimum use of three months. The risk fracture categories are still the same as what you have seen in the previous. Criteria of 5, 6, and 7 are still the same as what you have seen in the last ones. And then for this one, 8.) it would just be trial and failure of an oral or IV bisphosphonate. And if all the criteria are met, we would approve it up to 12 months but not more than two years depend -- yeah, not more than two years. And then for this one, same with the re-auth criteria, it's the same as

above. So if they need all of it, we approve it up to 12 months. For this one, these are the dosage and the quantity limits for the different products, HCPC coding and background. And then I'll just go through the policies quickly, and then we can answer -- we can ask questions for all three at the end if we want. So then the next policy is for RANK Ligand (RANKL) Inhibitors, which is really just denosumab, and those brand names are Prolia and Xgeva. For this one, the Postmenopausal Osteoporosis, these criteria should be -- is the same as what you just saw in the parathyroid hormone, same age, diagnosis, risk categories. Where it is a little different is you don't see C here, which is the treatment with denosumab because this is a denosumab-specific policy. So they would just need to meet A or B, so oral or IV bisphosphonate or a serum medication. Same thing -- authorized up to 12 months. Re-auth criteria is pretty much the same as the last policy, and then re-auth duration is 12 months. For Glucocorticoid-Induced Osteoporosis, these criteria are still the same as well. The only thing that you'll notice that is different between this policy and the parathyroid hormone policy is that the daily dosage equivalent of prednisone is a little bit different than what you saw in the last policy. So in the last policy, it was 5 mg, whereas in this policy it's greater than 7.5 mg of prednisone. And that was really based off of the clinical trial that Prolia was approved for. In the Prolia-specific clinical trial, their inclusion criteria had patients on a daily dosage equivalent of greater than 7.5 mg of prednisone, whereas, in the teriparatide it was 5 mg. So that's why you'll see the differences between the two is just really based off of how these drugs were approved and what those daily equivalents of prednisone were. But everything else is still the same. Still treatment with trial and failure of an oral or IV bisphosphonate, and the re-auth criteria is still the same, same durations. For this one, for Prolia specifically, this one is for the treatment of bone loss in Men with Prostate Cancer. For this one, age indication 18 or older, the patient has a diagnosis of bone loss or osteoporosis indicated by one or more of the following: So they can have either A, B, C, or D, or they can have multiple presence. I believe this is still the same as what we would use -- what we used for the risk above in the other criteria, so that is still the same. For 3.) the patient is currently receiving androgen deprivation therapy, so leuprolide, degarelix, relugolix for nonmetastatic prostate cancer, and 4.) the medication will not be in use in combination with denosumab, which is specifically Xgeva. I believe those two have different indications. That's why we listed it there just to make sure they're not using that Xgeva product while they're taking Prolia. Authorized for 12 months. Same re-auth criteria is that they continue to meet 3 and 4 above, so just making sure that they're still taking ADT therapy, and then it

won't be used in combination with the other denosumab product. And they have documentation that they're stable. And re-authorization duration for 12 months. For the treatment of Bone Loss in Women With Breast Cancer, this applies to Prolia. For this one, it's pretty much the same as above for the treatment of [audio cuts out] prostate -- Bone Loss in Men With Prostate Cancer. The only thing that's different here is that for these patients, we would expect that they're receiving adjuvant aromatase inhibitor therapy, so anastrozole, letrozole for breast cancer, and same as long as they're not using it in combination with Xgeva. The request will be approved for 12 months. Same re-auth criteria that you have seen above. For this particular indication, Multiple Myeloma and Bone Metastasis From Solid Tumors. This applies to Xgeva. For Xgeva, the criteria are that the patient is 18 years of age or older. The patient has one of the following: so a diagnosis of multiple myeloma with skeletal-related events. So examples of those are radiation to the bone, pathologic fracture, surgery to the bone, and spinal cord compression, or they have bone metastasis from solid tumors, so metastatic breast cancer, metastatic castration-resistant prostate cancer, and metastatic lung cancer, and 3.) history of failure, contraindication, or intolerance to zoledronic acid, so just that one product, and then 4.) medication will not be used in combination with Prolia. These criteria we kept pretty broad just because of the indication, so not very much there. Authorized for 12 months. They still continue to meet 4, above, just not used in combination with Prolia. And then documentation showing disease stability or positive clinical response, 12 month re-auth. This indication is Giant Cell Tumor of Bone. This applies to Xgeva. For this one, the patient is 12 years of age or older and skeletally mature, and 2.) they have a diagnosis of giant cell tumor of the bone, and so they could either meet A or B, disease is resectable, or surgical resection is likely to result in severe morbidity, or the disease is recurrent or metastatic, and 3.) the medication will not be used in combination with denosumab. A 12-month authorization. And then same re-auth that you have seen before. For Hypercalcemia of Malignancy, this applies to Xgeva. For this one, patient is 18 years of age or older, diagnosis of hypercalcemia of malignancy, and they have a baseline corrected serum calcium greater than 12.5 mg/dL, 3.) treatment with at least one preferred oral or IV bisphosphonate medication indicated for glucocorticoid-induced osteoporosis has been ineffective unless all are contraindicated or not tolerated, and 4.) medication will not be used in combination with Prolia. Same duration, 12 months, and same re-auth criteria. Here are the dosage and quantity limits for those products. And then I'll go ahead and get into the last policy, which this one is the Bone Density Regulator Sclerostin Inhibitors. And there is only one product that this

applies to, which is Evenity or romosozumab. For this one, there is really only one indication as well, which is Postmenopausal Osteoporosis. For this one, the criteria are the same as what you have seen before. Where it's a little bit different is here we have for the treatment. This one is not for #6, they would have to be treated with all of these products and not just one of them. It can't be like A , B, C, or D. It's A, B, and C, so they have to meet all three of these. For this one, one preferred oral or IV bisphosphonate, one preferred selective estrogen receptor modulator, and Prolia. And for this one, it will be authorized up to a total of 12 months of treatment per lifetime, and for this product it can't be renewed. There is only -- it will only be authorized for up to a total of 12 months of treatment per lifetime. And here are the dosage and quantity limits. And then here are the forms. I'll actually just put one up, but I can open it up now to any questions, any criteria that you want to see. Again, I know I went through that pretty quickly, but I'll go ahead and pause here for the Board.

Kavita Chawla: Thank you, Marissa. Let's see. We can start with this one, and then our Committee, if you can come back on camera as well. So I had a few questions. One was if you scroll down where it talks about the trial period for 12 months, I think it says.

Marissa Tabile: Yes, for the bisphosphonate? [Cross-talk] --

Kavita Chawla: [Cross-talk] Yeah. [Cross-talk] --

Marissa Tabile: [Cross-talk] It is #5 here. And we're looking at the pen form. If you want me to go back to the criteria, let me know.

Kavita Chawla: Okay. I guess that's fine because it's also -- yeah, it reflects what's in the policy. Did you want to go through this form before I ask my questions?

Marissa Tabile: If anyone -- I can go back to the criteria if no one has any questions on these.

Laura Beste: So this is Laura. The only question I had was under the treatment in breast cancer and also prostate cancer. There is no option, so they have to be receiving, like in the males, androgen deprivation therapy, and there is no option if they don't tolerate it. That's not stated. So what if same thing with the women if they don't tolerate adjuvant aromatase inhibitor therapy? They wouldn't qualify for it even if they were intolerant because it doesn't state that.

Marissa Tabile: Excuse me. This is Marissa. I think we just need to add that language in here. Let me see. I think it's up here.

Laura Beste: It was the prostate and the breast cancer.

Marissa Tabile: Yeah, right here. We have the language that we use, I think, unless contraindicated -- this one -- ineffective unless all are contraindicated or not tolerated. Is that [cross-talk]. Are you recommending that we add that in there?

Laura Beste: That would be my suggestion because there are some patients that won't tolerate it.

Marissa Tabile: Yeah. So I think I can add that. That's a good -- that was an oversight on our end, but a good call out for sure. Let me try this. There we go.

Kavita Chawla: Kavita here. So what we're seeing here is if they're not tolerating the treatment or they are at the end of their treatment. Right? Like, so for example, for the adjuvant hormone therapy with breast cancer, the usual timeline is about five years, maybe sometimes 10 years. So may -- they might have ended that treatment. But at the same time, denosumab can be stopped. Right? Like, there is no end point to denosumab because if you stopped denosumab and don't convert over to either a bisphosphonate or some other, like raloxifene, you will lose all of the bone density, and you will be at risk for -- high risk for fragility fractures. So how do we accommodate for that in the criteria here? Does that question make sense? That they will at some point in their hormone therapy, but they cannot stop denosumab for life unless converting.

Marissa Tabile: This is Marissa. I think I understand what you're saying. Um, I'm trying to think of a way how we can add that type of language in here. That might be something that I need to think about. I'm not good at thinking about it on the fly [cross-talk] --

Kavita Chawla: [Cross-talk] I'm sorry. I know. [cross-talk] --

Marissa Tabile: [Cross-talk] on the fly [cross-talk] --

Kavita Chawla: [Cross-talk] No, that's totally fine. [cross-talk] --

Zoe Taylor: [Cross-talk] -- or renewals? Like sometime -- it seems like some drugs like there is never a problem with just continuing it, and some drugs it's really hard to get approved even if you're continuing it. I wonder if there is a way to make it some sort of process where if you're continuing it, we don't have to deal with any of this.

Marissa Tabile: [Cross-talk] This is Marissa. [cross-talk] --

Kavita Chawla: [Cross-talk] I wonder if it could be -- because I do realize the price point for denosumab is crazy, so I do understand why there is a pre-auth on it, but at the same time I wonder if there is some language in here that can be said, you know if, um, to do, if basically if no -- if bisphosphonates cannot be tolerated or are contraindicated, then that is one of the criteria for re-authorizing it. Does that make sense? Because like, again, there is nothing else for them to transition to from denosumab if they are on hormone therapy. I don't think they can go on to Raloxifene long-term. Someone better than me in Oncology might be able to answer that. But my understanding is after that, you don't have any other options left if you can't tolerate bisphosphonates.

Christy Weiland: This is Christy Weiland. What if under re-authorization criteria? Because it says you must meet Criteria 3 and 4 [cross-talk] that language changed to, you know, Criteria 3 or history, right? And then plus 4 because that would allow for them to either be on current therapy, right, or history of.

Kavita Chawla: I like that, yeah.

Marissa Tabile: This is Marissa. Uh, let me see. Criteria 3 [cross-talk] --

Kavita Chawla: So I think -- Kavita here -- I think Christy is saying in the bullet point 3, right, Christy?

Christy Weiland: I was actually saying re-authorization because if they're in that first year, I would suspect they would be in current therapy. So if it's being re-authorized, that's where we would know that they had the history of, and they might be done with therapy.

Kavita Chawla: Hmm.

Christy Weiland: And so rather than having to meet Criteria 3, specifically, we could say they have met Criteria 3, and they still need to meet Criteria 4.

Marissa Tabile: This is Marissa. I think maybe in that case, we can just consider removing Criteria 3 from here, and then it would just be that Criteria 4 continues to be met, and then they would just need the documentation that they are stable. So we could do that. Let me do this the simple way so it looks cleaner. There you go.

Laura Beste: This is Laura. Do we have to state that they can't tolerate bisphosphonates, too, with that, though? Because usually you would switch to a bisphosphonate to maintain bone density after discontinuation.

Marissa Tabile: Okay. This is Marissa. Can you repeat that question one more time, Laura? Sorry. So, once again, I'm not Oncology, but once you discontinue denosumab, then you would -- if the patient can tolerate bisphosphonates, it looks like the recommended therapy is to continue with bisphosphonates to maintain the bone density, so we have to state in there somewhere for re-authorization that they cannot tolerate bisphosphonates.

Kavita Chawla: Kavita here. I get what you're saying, Laura. And I almost wonder if that actually needs to be in the authorization part to begin with to even allow patients to get on denosumab. We say that the patient cannot tolerate or is contraindicated, even for the initial authorization.

Marissa Tabile: This is Marissa. That's what I was thinking too, Kavita, was that might be more appropriate up in the initial.

Kavita Chawla: Yeah, I do think that that's an important call out up front because once you get on that train, you can't get off.

Marissa Tabile: So I can add that.

Kavita Chawla: Yeah. And that probably would be true for authorization for pretty much, yeah, all of them.

Marissa Tabile: Would you -- is the DUR Board recommending also that I add that for the prostate cancer indication as well? I would think [cross-talk] -

Kavita Chawla: [Cross-talk] Yeah.

Marissa Tabile: -- yes. [laugh] [cross-talk] I don’t want to assume.

Kavita Chawla: Yes. No, I [cross-talk] --

Marissa Tabile: [Cross-talk] Okay, okay. And I'm going to add it here.

Christy Weiland: This is Christy Weiland. Just to clarify, is this going to mean that a patient has to be continuing a bisphosphonate and cannot switch over to denosumab even if they don't have clinical stability with the bisphosphonate? [cross-talk] --

Kavita Chawla: Mm.

Christy Weiland: Like if they continue to worsen, I fear that the language we are putting in is going to continue them to use a bisphosphonate and not allow that to transition over with disease progression.

Kavita Chawla: Kavita here. I, yeah, see what you're saying. I guess my -- what I wonder about that is, it is from all of the studies -- I don't -- I'm not aware of any study that shows that denosumab does better than bisphosphonates in any scenario, so if we are -- would have ever seen if a patient has ever been transitioned to denosumab, it is because either chronic kidney disease or they can't tolerate the side effects of the bisphosphonate, but it would never be for lower clinical efficacy. But I might [cross-talk], if someone knows.

Zoe Taylor: Yeah. I have one patient on denosumab, and it was because I did a consult with a rheumatologist who specialized in osteoporosis and because her T-score was like -3.5 or something. She said that because it was so severe, it would be better to use it. And maybe that's just expert opinion, but I don't think that the insurance rules should get in the way of that. So like we don't -- what we want to avoid is the primary care doctor having to fill out a million papers and jump through a million hoops when it's indicated. So just be careful about being too specific about, you know, there are all sorts of different clinical scenarios.

Kavita Chawla: Yeah, Kavita here. Totally agree. I guess -- and yes, we probably don't want to have like a clinical debate here, but I would say that when T-score is that severe, all the more reason that you would first go with an anabolic and then a bisphosphonate rather than going to denosumab because there are just so

many issues, and you can see that in all of the recent guidelines in the past three years that have been published that have called out problems with denosumab. And so while it was the savior when it initially came out, we're now seeing 10 years later so many problems with it [cross-talk] the biggest one being when they can't make it to that six-month shot, and then they are suffering from these fragility fractures. So this is one of those rare scenarios where I would like if with like the -- where insurance puts in some barriers to easily accessing a medication that not all clinicians may be up to speed with and like continue to just prescribe it, thereby, not protecting patients, if that makes sense. But I don't know if that [cross-talk]. So yeah.

Zoe Taylor: I mean, but you also wouldn't want the insurance to be the reason the patient misses the shot, right?

Kavita Chawla: Yeah.

Jon MacKay: This is Jon MacKay here, Kavita. I kind of echo your opinion, too, in terms of like anabolic therapy and severe osteoporosis. I was hoping that we could maybe revisit the criteria for like the anabolic agents [cross-talk] Forteo, Tymlos, and Evenity. Sometimes, you know, if there is a fragility fracture with moderate osteoporosis or a severe osteoporosis [audio cuts out] with a T-score of [audio cuts out] -3 and be clinically appropriate to go right to anabolic agent, I don't think it would be appropriate to stay on like an antiresorptive like Prolia or a bisphosphonate. So I think in terms of requiring somebody, especially like a SERM, not very clinically efficacious, but I would probably jump right to an anabolic agent like Tymlos or Forteo or Evenity if there is a history of multiple vertebral fractures regardless of their T-score or if they have a less than -3 T-score. So I don't know if the Committee has any opinions on that.

Kavita Chawla: Yeah, Kavita here. I definitely second that and, in fact, there are studies that have shown that start for bisphosphonate-naive patients if you put them on an anabolic treatment first and then do bisphosphonates, they have way higher bone density buildup than starting with bisphosphonates and then trying to add an anabolic, so yeah, I completely echo what you're saying, Jon. So I know we are jumping back and forth, Marissa, between the two policies. I don't know if you want to resolve one and then go to the other or how you want to do it. Sorry.

Marissa Tabile: Oh no, that's fine. I guess we will go back to the cancer, and then we can go back to the anabolic.

Kavita Chawla: Okay.

Marissa Tabile: These particular indications don't really have crossover in the others, but if we do decide to change anything in the Parathyroid, then I can just apply it across all of the policies if we do decide to make any changes. So I believe where we left off was requiring -- I think, Kavita, you were recommending adding the step through the oral or bisphosphonate before they could be eligible for Prolia unless, of course, it's contraindicated or not tolerated.

Kavita Chawla: Yeah. And I would -- this is just a typing thing. I do see the glucocorticoid-induced osteoporosis as being carried over.

Marissa Tabile: Yeah.

Kavita Chawla: Yeah, in all of the paragraphs. I think I saw that in the hypercalcemia of malignancy as well.

Zoe Taylor: I would also maybe just move this minimum trial of 12 months parenthetical to after the word has been effective because the way it reads right now, it seems like you would have to try it for 12 months even if it were not tolerated, which I don't think is the intention. Like if it's to determine it's ineffective, there is a minimum of 12 months but not to determine that it's not tolerated.

Marissa Tabile: Um, I see what you're saying. Let me think about how we do that because that's just our standard for how we have done that in the past, but I can consider moving that.

Zoe Taylor: Okay.

Marissa Tabile: Um, yeah, for the other ones. But I see what you're saying for sure.

Laura Beste: This is Laura. Could you word it at the beginning of the sentence, minimum,, minimum trial of treatment with at least one preferred has been ineffective unless contraindicated or not tolerated.

Marissa Tabile: This is Marissa. Sorry. Can you repeat that one more time? I was trying to type and listen at the same time. Minimum trial -- is that what you were saying? Hopefully did not put [indistinct].

Kavita Chawla: What do you think, Zoe?

Zoe Taylor: Yeah.

Kavita Chawla: Pretty simple?

Zoe Taylor: Yeah.

Kavita Chawla: I agree. And then when we say -- sorry, Kavita Chawla here -- when we say ineffective, are we saying -- or actually one of the requirements is for re-authorization that they are demonstrating stability. Is that to say that they need a bone density scan every year or just the lack of a fracture? Or what is it that we want the clinician to document to demonstrate stability?

Marissa Tabile: This is Marissa. So that we have kind of put like examples. So we have here that they haven't suffered. So if the doctor notes that they haven't had a fragility fracture or if their bone mineral density continues to improve or remain stable, those are just some examples that we came up [audio cuts out] with, but [audio cuts out] there are other clinical examples. Those are just the ones I could think of that you can think of that I can definitely add those in. [Cross-talk] But those are kind of what you were alluding to or what the examples that you listed were what we would be looking for.

Zoe Taylor: I just don't think that that should be required because I think it's too hard to prove and honestly, not realistic.

Marissa Tabile: This is Marissa. Zoe, sorry, I did not hear you. Can you repeat that?

Zoe Taylor: Like after 12 months, you just wouldn't necessarily have any proof of that, and I wouldn't go out of my way in a note to specifically write that they did not have a fragility fracture, so I just worry that this is just the way that it would get denied when it shouldn't be.

Marissa Tabile: Well, we include language like that just so that then in the chart notes we can see. Because how would we be able to see that a patient is either not progressing on therapy or having a clinical [cross-talk] --

Zoe Taylor: But if somebody had a fragility fracture after being on 12 months of denosumab, would we want the patient to stop it?

Kavita Chawla: I think the idea -- Kavita here -- I think the idea there would be that fragility fracture indicates that they would probably need to transition to an anabolic treatment at least.

Zoe Taylor: Which is something that the provider can decide, right? It's not something that the insurance company needs to force on the provider, right? [Cross-talk] And why would it be denied just because it hasn't been -- I don't know. It doesn't really make sense to me.

Jon MacKay: And I had a quick comment. This is Jon MacKay here. A ton of criteria. I mean, it's kind of the standard of care for the bone mineral density every two years. I mean, sometimes more often. But if we're looking at this annually, are you going to have a clinical review every year?

Zoe Taylor: No, you won't.

Marissa Tabile: And these -- this is Marissa. These examples that we provided like if there are other examples or other kind of notes that the provider puts in the notes saying that they are stable or that they are responding to therapy, then we would definitely take that into consideration. These are not like parts that they have to have a bone mineral density scan every year, it's just kind of examples of what we would accept. So I just want to caveat that by saying as long as there is some type of note in the chart notes if they -- as long as there is some kind of documentation in the chart notes saying that they are responding well to therapy, that they are stable on the medication, then however that's worded -- however, providers -- word it differently. When we are looking at the chart notes, then we would take that into consideration and accept it if we think it clinically meets what we are looking for.

Peter Barkett: This is Peter. I think kind of what's going on here is if the medication isn't having its intended effect, you're not getting the benefit of the medication. However, you may still get the risks of the side effects, and patients don't always show up saying, like, "hey, I had a fragility fracture." I've seen this in my practice where until something happens with the insurance company, like, I don't realize that they had a fracture last month and have been seeing Orthopedics. But if I get some kind of flag, whether it's a denial of medication

or some kind of outreach about HCC coding or something like that, that can be actually triggered to make sure the patient is on appropriate care. Personally, I think it's reasonable to have it in the way that this is written, and I think that's the way a lot of health plans actually write their criteria. I'm okay with it. I definitely understand Jon's point. Like most of the time, you're not going to have a DEXA scan within a couple of years, but definitely, if somebody had a fragility fracture, then it would indicate probably that this isn't the best treatment and that the fact that prolongation or continuation of a medicine that doesn't seem to be working would get denied actually would be a good trigger for both the patient and the prescribed clinician to reevaluate treatment. I'm okay with it.

Laura Beste: [Indistinct] This is Laura. It does say “example” so it's not requiring it.

Zoe Taylor: It is it standard that you have to submit chart notes for continuation of the medication like always?

Marissa Tabile: [Cross-talk] This is Marissa. [cross-talk] --

Zoe Taylor: [Cross-talk] this is like a burden, you know?

Marissa Tabile: This is Marissa. Usually, yes, for re-authorizations, we typically do require chart notes. I believe in the pen forms we do have -- let me double-check -- yeah, we do have at the bottom that the chart notes are required with the request, so usually standard for most of the requests we do require chart notes. There are some where maybe we won't, whether or not we have that program, you know, specifically in our system to do like electronic PAs or whatnot, that's not really working right now, but in most cases, yes.

Zoe Taylor: Okay. Yeah, it's probably fine. I'm just trying to be the voice of, you know, reducing clinician burden every meeting.

Marissa Tabile: This is [audio cuts out]. And we totally understand. You know that it is a burden for providers to submit that documentation. We just want on our end as the Health Care Authority kind of going through these requests, just making sure we're doing our due diligence to make sure that it is being prescribed for the right things that we, any monitoring that we need to do that we do see that, so that's why we usually require the chart notes, just to make sure.

Kavita Chawla: Yeah. Kavita here. I agree, and I mean for that I even have a history of fragility fracture. It is like part of my osteoporosis follow up template for my patients, so I agree with the way it's written as well. Is there any other discussion from, I guess, the Committee for this one before we jump over to the Anabolic Treatments?

Marissa Tabile: And this is Marissa. I just wanted to point out to the Board that I am adding the trial and failure of an oral or IV bisphosphonate for the prostate cancer and for the breast cancer for Prolia, so I have added that here in #5, and this we will consider striking out. I added it here, but we may go back as HCA and maybe talk about how we could better word that as well, where it like shows the ineffective trial is the 12 months. So just wanted to point that out, but I definitely noted that here.

Kavita Chawla: Thank you. And Kavita here. Marissa, as we're going through this, are there any requirements for coverage of Raloxifene for osteoporosis?

Marissa Tabile: This is Marissa. No. To my knowledge, Raloxifene is preferred without PA on our AHPDL.

Kavita Chawla: Okay. All right, thank you.

Marissa Tabile: Yeah. And I believe the bisphosphonates are as well. We have some preferred without PA.

Kavita Chawla: Thank you. Okay. So then we can look at the anabolics, both the PDH analogs, and then the romosozumab.

Marissa Tabile: And This is Marissa. This is the Postmenopausal Osteoporosis criteria that I'm showing here, so if you wanted me to change -- if you wanted to look at another one, just let me know.

Laura Beste: This is Laura. I think, once again, if we want to change the verbiage on the 12 months trial to the beginning from the end.

Kavita Chawla: Kavita here. I think this is the part, Jon, that you were speaking to that we should not require a history of SERM or bisphosphonates if the patient is starting out with severe osteoporosis or multiple fragility fractures.

Jon MacKay: Yeah, correct. Jon here. So I think it's just important to recognize that it would be clinically appropriate to jump to an antiresorptive in certain cases. So in terms of like moderate osteoporosis with a fragility fracture or multiple vertebral fractures regardless of, or fragility fractures regardless of T-score or severe osteoporosis. So I think that we should just recognize that.

Kavita Chawla: Kavita here. So in terms of wording it, it seems like history of at least one of the following. So maybe that we could add a D on there that the patient has had severe osteoporosis with a T-score of -3 or multiple fragility fractures, or, I don't know, just fragility [audio cuts out]. Yeah. Two [audio cuts out] fragility fractures or something like that, Jon?

Jon MacKay: I think that would be great. Or maybe in addition like a moderate osteoporosis less than -2.5 with a fragility fracture as well [cross-talk] --

Zoe Taylor: [Cross-talk] of [indistinct] because it sounds pretty similar.

Kavita Chawla: Sorry, Zoe, your voice is distant. Yeah.

Zoe Taylor: Let me try --

Kavita Chawla: Yeah, that's better.

Marissa Tabile: There you go. You sound better.

Kavita Chawla: Yeah, that’s better.

Zoe Taylor: Can you hear me now?

Kavita Chawla: Yeah.

Zoe Taylor: Because 6 says something similar to that, so I just wanted us to reconcile those. Like we could copy the same criteria that it says in 6 instead of having it be slightly different where it says less than three and multiple fractures, or we could make it different, either way.

Kavita Chawla: Yeah, Kavita here. I think that might be tricky only because it says, if the patient has very high fracture risk, so if we just said that. And then I think those are just examples of documentation that might encompass too many patients for seeing [cross-talk] anabolics as first-line.

Zoe Taylor: Okay.

Marissa Tabile: This is Marissa. So sorry, I think I might have missed [cross-talk] what Kavita and Jon were saying.

Kavita Chawla: So I think, yes, so in D., it can say so T-score less than or equal to -2.5 with fragility factors. Jon, I'll let you take over.

Jon MacKay: Yep. So I think T-score of less than -2.5 with a fragility fracture, history of multiple fragility fractures regardless of T-score, or T-score of less than -3.

Marissa Tabile: All right. So T-score less than -2.5 with a fragility fracture, history of multiple fragility fractures -- I'm sorry, I'm trying to type [laugh] [cross-talk] --

Jon MacKay: Or a T-score of less than -3. I'm not remembering my guidelines very well. [laughter].

Kavita Chawla: I think you're spot on.

Jon MacKay: Okay.

Marissa Tabile: This is Marissa. Hopefully, I captured that correctly.

Kavita Chawla: I guess just for all of those, I would say less than equal to sign.

Marissa Tabile: No. I don't know the shortcut to insert that, so if anyone has any tips on how to do that, let me know because I always have to go to the symbol.

Laura Beste: And this is Laura. For standards it shouldn't have a trailing zero, so just make it -3 and get rid of your point zero (.0). There you go.

Marissa Tabile: This is Marissa. I'm just going to see if the risk appears. We have 2.5 with fragility fracture or multiple fractures and T-score of -3. Okay, I see. The intent of D is, just so that I'm understanding correctly, is that the abaloparatide or teriparatide would be used first line. Correct?

Kavita Chawla: Correct.

Marissa Tabile: Okay, I'm trying to think of some language that we might want to put in addition to this, like in this sentence so that then for the clinical reviewer, they know that that's the intent. So let me [cross-talk] --

Kavita Chawla: Kavita here. Would it be something like this, this, and this, indicating severe osteoporosis which would warrant first-line anabolic treatment, something like that?

Marissa Tabile: Yeah, I was thinking something saying like that it would be used first line.

Jon MacKay: All right. This is Jon here. Regardless of previous therapy.

Marissa Tabile: I think that might address the need. Hopefully, what I added doesn't make that more confusing. I'm just trying to differentiate between that [indistinct]. These should be, it would be defined as a T-score less than -2.5 or history of multiple fragility fractures or a T-score of -3. Right. Okay. Hmm. Sorry, this gets kind of just so then -- and I might have to take this back. I don't want you all -- watching me wordsmith can get kind of -- okay, this is Marissa. I did a little bit of -- got a little bit more specific. Let me know if you all like that, if you don't like that, if it meets the need. I can change it.

Laura Beste: This is Laura. The only comment I would have is it says, will be used first-line. I think I would change that to maybe or can be considered to be first line. I don't know. However you want to word it.

Kavita Chawla: Can be used first line.

Laura Beste: Yeah.

Peter Barkett: You might even consider reversing the order of the phrase there to say something like, um, teriparatide and blah, blah, blah may be considered medically necessary for first-line therapy in patients with severe osteoporosis, as defined by one of the following: and then 1, 2, and 3.

Laura Beste: I like that.

Marissa Tabile: Can you repeat that one more time, Peter? I'm sorry.

Peter Barkett: Yeah. I think it was like, uh, maybe considered medically necessary for first-line therapy of severe osteoporosis as defined by one of the following:

Marissa Tabile: Okay. I think we may have [audio cuts out] [indistinct] [laugh]. Okay. [laugh].

Kavita Chawla: Yay! Great job, team!

Marissa Tabile: The abaloparatide or teriparatide may be considered medically necessary for first-line therapy for severe osteoporosis defined as -- there we go. This is Marissa. So this was in the Postmenopausal Osteoporosis section. You, the DUR Board recommending that I add it to all the indications that are listed here in this policy as well [cross-talk] Criteria D, specifically.

Kavita Chawla: So I see osteoporosis. Which were the other indications? I would agree with them. [Cross-talk] --

Marissa Tabile: [Cross-talk] So we have male osteoporosis -- apologize for the scrolling -- glucocorticoid-induced osteoporosis. And that's it. Just those three.

Kavita Chawla: I would agree with male osteoporosis, I guess. I mean it makes sense also for the glucocorticoid being used, but I don't know if anybody else --

Zoe Taylor: I think so just because I have patients where it's like both, you know, and I might have coded it glucocorticoid if I feel like that's the main reason, but they're also postmenopausal, so I feel like it probably makes sense to put it on all of them.

Marissa Tabile: This is Marissa. That's what I was thinking. So I can put it --

Zoe Taylor: This has been super helpful for me, though, because I guess when I did that consult a couple of years ago, I think the main reason that she did not recommend this was because of insurance not covering it. So I guess it's good to know that if we can make a difference to make it easier to get teriparatide, and it's better than Prolia, then maybe that will actually push -- convince people that it's not actually so hard to get that it's not worth trying, if that makes sense. I mean, I think the adherence issue is also still an issue, right? Like, it's way easier to get something every six months than do it every day. But yeah.

Marissa Tabile: This is Marissa. So I believe I added it to all of them, so I think we should be good.

Kavita Chawla: This is Kavita. I just looked up the guidelines super quick, and it is recommended the same, PDH analogs should be used as first-line if they have severe osteoporosis, even before initiating glucocorticoids by the way.

Jon MacKay: Hi, this is Jon here. I was just wondering, too, if we should look at romosozumab as well for the criteria. I understand the expense is probably prohibitive compared to the PTH analogs, but there might be a place in therapy for them as well.

Marissa Tabile: This is Marissa. Yeah. Are we -- let me just double-check for this policy. Is there any other comment or anything that we wanted to add? Okay. I'm going to save this real quick all of our beautiful work, and then let me go ahead -- and I believe I made a change to the other one. Let me just make sure I'm saving all of these, and then I will move to the one that Jon just mentioned, which is the romosozumab. All right, and this is just the one criterion here.

Kavita Chawla: Kavita here. I guess the only -- Zoe, I think we're talking about point #6 treatment with all of these as being ineffective. I would not require a patient to go through all of them necessarily if they're meeting those criteria, again, for first-line treatment. But I guess a question for the Committee is, you know, as best as I know it's mixed results in terms of comparing romosozumab with PDH analogs. And so should we because PDH analogs -- I don't know if those [audio cuts out] cheaper, but they definitely have been around longer, so we know their side effect profile better. Should we include anything on here that PDH analogs should at least be tried before romosozumab?

Jon MacKay: This is Jon here. I think that would be appropriate. I think there are some cases where like Evenity might be preferred like parathyroid hormone disorders, hypercalcemia, or history of kidney stones. So I do think like there are some cases where going right to Evenity would be preferred.

Marissa Tabile: This is Marissa. So, Jon, are you proposing anything for 6? Did you want to make a proposal for any changes?

Jon MacKay: Kavita, do you recommend parathyroid hormone analogs first, and then remove romosozumab second unless it's not clinically appropriate or contraindicated? [Cross-talk] Is that -- what would you recommend?

Kavita Chawla: Yeah, those are my thoughts.

Jon MacKay: Okay, I would agree with that.

Kavita Chawla: So, I guess, yeah. So the D becomes that same D from the other one but with a trial of -- I'm getting the Committee's help here in the wordsmithing again as you do, Marissa, like how do we include in here? So [indistinct] will be considered when -- so we use this and then say, if these are not tolerated or contraindicated, then romosozumab. Does that make sense, Marissa?

Marissa Tabile: Uh, this is Marissa. So essentially, we would switch these, and I'll do a mockup of what that would look like.

Laura Beste: This is Laura. There is a typo there, too. There should be A-B-A-L-O, not L-A-O.

Marissa Tabile: And actually, this only applies -- I may actually change this [cross-talk] --

Laura Beste: I think it's just that one.

Marissa Tabile: This actually doesn't apply to everything.

Laura Beste: Okay.

Marissa Tabile: So I think what I hear you saying, Kavita, is this would be -- let me change -- I can spell. Romosozumab. I think that's a Q. A-Q-Q-G. I can't tell with the red. Q-G, like that I think is what I heard, what I think you were trying to convey.

Kavita Chawla: Yeah, I guess. And so may be consider medically necessary for first-line therapy for severe osteoporosis defined as one of the following, and PDH analogs are not tolerated or contraindicated. [Cross-talk] So that's the wordsmithing part. Does that make sense what we're proposing?

Marissa Tabile: Oh, I see what you're saying. Hmm. You -- this is Marissa -- for the DUR Board, you're recommending just for the severe osteoporosis that they step through the, um, the [cross-talk] --

Kavita Chawla: PDH [indistinct]?

Marissa Tabile: Yes, yeah. Is that correct? Just severe?

Kavita Chawla: Yeah, yeah.

Marissa Tabile: [Cross-talk] Okay.

Kavita Chawla: [Cross-talk] [Indistinct].

Jon MacKay: [Cross-talk] Can we cover that?

Kavita Chawla: [Indistinct] For several osteoporosis, if PDH analogs are contraindicated or not tolerated, period. And then it would say severe osteoporosis defined as. What does the Committee think about that? Does that look okay? I see some nodding. Yeah.

Jon MacKay: This is Jon again here. So in terms of the 12-month limit per lifetime, I think 12 months is like the limit of duration of therapy, but I don't know that sequential therapy is contraindicated. I mean, it's probably more inconsequential in terms of the number of patients, but I don't know that. You can get 12 months per series of doses, but you can get more than one series per lifetime as far as I'm aware.

Kavita Chawla: Yeah. Kavita here. I don't know enough about Evenity. I don’t think it has been out long enough to really know long-term that kind of going back and forth kind of stuff, so. It was -- Marissa, do you know if that was just derived from the FDA approval? Does the FDA approval say something about 12 months per lifetime?

Marissa Tabile: This is Marissa. I don't. This I got exactly from. -- let me, I can double-check.

Laura Beste: This is Laura. I have it up that the anabolic effects of romosozumab wanes after 12 monthly doses. Therefore, duration should be limited to 12-month doses. If osteoporosis therapy continued, continued therapy with antiresorptive agents should be considered. I've always heard that it's just 12 months only, too.

Kavita Chawla: I guess, yeah. Kavita here. I'm looking at Evenity website, and they're saying is taken for just 12 months. So would that be okay to leave it there, Jon, you think for now?

Jon MacKay: Yeah. I think that the data is newer data that is in terms of sequential therapy, where you would step down and step back up again in the future, so

there is probably not enough published data. But yeah, I'm okay with that at this time.

Peter Barkett: Yeah, I think in the absence of data showing safety, I would err on the side of being conservative. And I think everybody got surprised however many years ago when we started to see fragility fractures with more than seven years of bisphosphonate therapy. We can always come back and change this policy if it becomes clear that it's safe to take it again.

Kavita Chawla: Great. That sounds good. Any other edits on the policies Committee? This is -- I'm very proud of our work here today on this. And then if not, we can look at the final policies and the motions to approve them.

Marissa Tabile: Okay. This is Marissa. Let me go ahead and pull up the policies. Okay, so these are three different motions for all of them, and I did -- let me just make sure I save everything.

Laura Beste: This is Laura. Do we need to look at the form that needs to be checked off to make sure it matches what we just decided on? Or will that change accordingly?

Marissa Tabile: This is Marissa. So usually when we make changes, we do have our operations team go back because they do compare before the meeting and after the meeting, and then they do make the updates to make sure that it does match Yeah. So we'll make sure on our end that it matches what you all recommended. I can go back to the forms, though, if you just want to do your due diligence and look at them. Would that be helpful?

Kavita Chawla: Kavita here. Yeah, let's just look at it. [Cross-talk] --

Marissa Tabile: [Cross-talk] Okay.

Kavita Chawla: -- assume that the changes that we made this morning will get reflected but just making sure there is no other confusing language on there from a clinician standpoint.

Marissa Tabile: So this one is for the Parathyroid Hormone Form.

Kavita Chawla: Okay.

Marissa Tabile: I think here is where we would probably add if they have severe fracture. Somewhere here we would add that, either 4 or 5 to make sure. And then this is for teriparatide.

Kavita Chawla: Kavita here. Just, you know, using -- it's a question t for the Committee because I don't really know if it belongs here, but we know that the number one reason for treatment failure on any of these medications often tends to be patients actually just not getting enough calcium and vitamin D, and I know that Medicare requires, especially for things like denosumab, they will require that we document the patients are getting adequate amounts, not necessarily testing. Do you -- but at the same time, clinician burnout, as Zoe said, and so I don't want to add additional barriers. Is there any kind of framework or guardrails we want to put in here if the patient suffers a fragility fracture that we are making sure that is being checked? Or is that too much in the clinical realm, and so we don't need to add language here?

Marissa Tabile: This is Marissa. So Kavita, when I was drafting the policy, I was going back and forth of whether or not I should add like patient will be on sufficient -- and I'm making this up on the fly -- but something along the lines of that they'll be on adequate calcium and vitamin D supplementation. I did go back and forth on that, and I erred more on the side of not including it just because, one, I think it might have added another kind of layer, and then, two, you know, we do cover vitamin D products and calcium products on our PDL. But sometimes there can be issues with rebating and things like that and just claims processing things that we have issues with. So I did not want to include all of that yet if it's not completely -- we are kind of having issues right now with our PDL with some of those products, so that is kind of why I erred on the side of not including it. [Cross-talk] --

Jon MacKay: [Cross-talk] Kavita [cross-talk] --

Marissa Tabile: [cross-talk] patient that clinicians would be still prescribing those things in good practice.

Jon MacKay: This is Jon here. So, Kavita, I think that's a good point. But we do for some of our endo patients, we do hold calcium supplementation if they have like hypercalciuria, and so we do that. There are cases where we occasionally like hold calcium supplements.

Kavita Chawla: Yeah, I totally agree. Kavita here. Yeah, it's usually our emphasis is calcium from diet and not supplements because of all of those problems. Okay. It's fuzzy enough that we won't really include that in the policy and cause confusion. Okay. Any other comments about this form before we look at the motions from the Committee?

Marissa Tabile: This is Marissa. I'll go ahead and show the RANK ligand inhibitors form. I don't think I've shown that one. Keeping in mind that we would probably add, like I mentioned, the severe fractures somewhere in 4 and 5 is what I'm envisioning. And I think the IV bisphosphonate for the cancer would probably be somewhere here. It looks like it is already, but we'll make sure that that -- oh, there we go. Here we would add that. And then I'll move over to the last one, which is the romosozumab form, very short, luckily. And we would add that same severe osteoporosis probably in 4 or 5 here.

Kavita Chawla: Kavita here. I seem to recall that in previous forms we have also included contraindications. For example, in this one, I think you said if they're on another treatment, don't put them on like two antiresorptive treatments. Should we be including CKD as a contraindication or --? You know? Does the patient have CKD stage 3 or higher on the bisphosphonates form?

Marissa Tabile: [Cross-talk] Um, for the [cross-talk] --

Kavita Chawla: [Cross-talk] It’s more like a prompt for the provider to make sure they're getting an updated serum creatinine before they do an infusion with zoledronic acid. Something like that.

Marissa Tabile: Um, I would say if you wanted to do that, we probably should add that maybe to the criteria, just so that then it'll trigger that that is something that would get added to the pen form, so I would recommend adding that one to the criteria, that way it can get added here to the form. Because if we want to see the lapse, I'm sure we, as the pharmacists, would want to see them as well.

Kavita Chawla: What does the Committee think about the CKD criteria? Should we be including that for bisphosphonates?

Peter Barkett: I think the trick is it doesn't actually fall neatly to CKD like 3A or 3B, right? Isn't it a creatinine clearance, not GFR, and it’s 35, right? [Cross-talk] I could look that up.

Kavita Chawla: [Cross-talk] Yeah, that's [cross-talk] --

Laura Beste: [Cross-talk] you adjust -- you adjust it.

Kavita Chawla: Sorry.

Peter Barkett: Oh, are you talking about for dosing that for contraindications?

Kavita Chawla: Oh, sorry. I was talking about contraindications.

Peter Barkett: Yeah. So I think like, generally, -- it's creatinine clearance, and if your creatinine clearance is less than 35, then if you go to denosumab unless it's less than 30, and then you would stop. I'm going to look it up.

Kavita Chawla: Yeah, Kavita here. I believe is 35 for the EGFR.

Laura Beste: Yeah, I'm looking up now. It's creatinine clearance less than 35, which doesn't necessarily correlate to EGFR.

Kavita Chawla: And maybe that's something that -- I don't know. Do we -- I guess the question is for Marissa then. Is that for the agents that do need to be renally-dosed or are contraindicated if there is a renal failure or liver failure, that kind of stuff? Do you usually include that on the policy, or not necessarily? Because if we don't usually do that, we don't need to start doing it for bisphosphonates.

Marissa Tabile: I would say, traditionally in the policies that we have written, we have not, but it could be a good -- now that you mention it -- a good monitoring. We try to, if it's not like a complete contraindication, then we tend to kind of keep them off like the measures like that. Yeah, labs.

Kavita Chawla: Okay. So I think if that's not -- if the absolute contraindications are not typically included, then we can leave it alone and we can just go to the policy.

Marissa Tabile: This is Marissa. Sorry, Kavita. Did you want me to show the policy? Or are we good with the form?

Kavita Chawla: Sorry. Yes, we're good with the form. We can proceed with the motions.

Marissa Tabile: Oh, okay. Sounds good.

Kavita Chawla: I guess I'll get started. Kavita here, Kavita Chawla. I move that the Apple Health Medicaid Program implements the clinical criteria listed on Policy 30.04.40-2 as recommended.

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

Kavita Chawla: All in favor, please say aye.

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

Kavita Chawla: Any opposed or abstain? Okay, the motion carries.

Christy Weiland: This is Christy Weiland. I move that the Apple Health Medicaid Program implements the clinical criteria listed on policy 30.04.45-2 as recommended.

Zoe Taylor: Second. [Cross-talk] --

Jon MacKay: [Cross-talk] Jon MacKay, I second.

Zoe Taylor: I'm sorry.

Kavita Chawla: All in favor, please say aye.

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

Kavita Chawla: Any opposed or abstain? Great. And the motion carries.

Greg Hudson: I can take this one. I move that the Apple Health Medicaid Program implements the clinical criteria listed on policy 30.04.48-2 as recommended.

Zoe Taylor: This is Zoe Taylor, and I second.

Kavita Chawla: All in favor, please say aye.

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

Kavita Chawla: Any opposed or abstain? Great. And the motion carries.

Marissa Tabile: Perfect. Thank you so much, DUR Board. I have made sure that I saved everything. And thank you so much for a very thoughtful and insightful conversation. I definitely appreciate your feedback. So I will go ahead and stop sharing, and I [cross-talk] --

Kavita Chawla: That's a good job [cross-talk] --

Marissa Tabile: [Cross-talk] think we have drug class reviews now. [cross-talk] --

Kavita Chawla: Thank you. Okay, so on the schedule I see Nina is up next to go over the Antihyperlipidemics.

Nina Huynh: Yes. Marissa, are you going to pull that up for me?

Marissa Tabile: [Cross-talk] Marissa. Yes, um, let me just make sure I'm saving everything one more time. I do not want to lose any of this work, and then I will pull your slides up in just a minute.

Nina Huynh: Okay, thank you.

Marissa Tabile: I appreciate everyone's patience as I try to pull everything up. Okay. Let me get your slide. All right. And I did just want to note for the DUR Board, if you haven't all -- if you don't already know, so Magellan has actually undergone a change where now they are called Prime Therapeutics, so moving forward, we are trying to change everything that we have that is Magellan branded, whether that be on the agenda, the website, everything like that, you will notice that the slides do have Prime Therapeutics now. So if you're wondering why Nina is now Prime, it's because Magellan has gone through a rebrand. So moving forward, we will be referencing them as Prime, and we are trying our best to make sure that everything gets changed over to their new name. So just wanted to put that note out there for you all in case you get confused. So let me pull up your slides, Nina, and you should be good to go.

Nina Huynh: All right.

Marissa Tabile: So hopefully, you can all see it.

Nina Huynh: Okay. Hello, DUR Board. This is Nina Huynh, again from Prime Therapeutics. Thanks for the background information, Marissa, on that. And I will be going

over a few topics today. So for today's agenda topics, for the classes that will be reviewed, I will be going over the disease dates, any new updates from the past year, including guidelines, indication, dosages, and formulations. Okay, on the top in dark purple is the Prime Therapeutic Market Basket classes, and listed below that in light purple is the Apple Health Drug classes. So our first agenda topic will be Antihyperlipidemics : Adenosine Triphosphate-Citrate Lyase Inhibitors, Angiopoietin-like Protein Inhibitors, Microsomal Triglyceride Transfer Protein (MTTP) Inhibitor, and PCSK-9 Inhibitors. Okay. Cardiovascular is our first disease state. So many clinical trials have demonstrated that high serum concentration of low-density lipoprotein cholesterol (LDL-C) and low levels of high-density lipoprotein cholesterol (HDL-C) are major risk factors for coronary heart disease. The National Health and Nutrition Examination Surveys (NHANES) reported that in 2015 to 2018 approximately 11.4% of adults in the United States had high total cholesterol, and 17.2% had low HDL-C. The prevalence of elevated total cholesterol was higher in women compared to men, but the difference was not significant. The prevalence of low HDL-C was higher in men compared to women, and in 2015 to 2018, there were no significant race or Hispanic origin differences in the prevalence of high total cholesterol in adults. The NHANES analysis was based on measured cholesterol only and did not consider whether lipid-lowering medications were taken. Okay. Between 2013 and 2019, the American College of Cardiology (ACC) and the American Heart Association (AHA) in combination with the National Heart, Lung, and Blood Institute (NHLBI) releases four new consensus guidelines regarding cholesterol management, cardiovascular risk assessment, obesity, and lifestyle. ACC, AHA emphasizes lifestyle modification, including a reduced-calorie diet and aerobic physical activity as a critical component of atherosclerotic cardiovascular disease risk reduction both prior to and in conjunction with cholesterol-lowering drug therapies. In June 2021, the AHA published a scientific statement on physical activity as a crucial component in the first-line treatment for increased blood pressure and cholesterol. The statement details mild-to-moderate risk patient groups appropriate for lifestyle-only treatment of increased cholesterol as well as descriptions of the recommendations, usual effects, and considerations for lifestyle management with physical activity. Guidance and resources were also provided for evaluating, prescribing, counseling, and referring to assist an increased physical activity. In 2023, the AHA published a scientific statement which reports that resistant training has a favorable [audio cuts out] effect on total cholesterol, triglycerides, and HDL. Evidence for the effect of resistant training on LDL cholesterol is more variable. Okay. In March 2024, a new

indication was approved for Praluent (alirocumab). It was FDA-approved for adjunct to diet and other LDL cholesterol-lowering therapies in pediatrics at least 8 years old with heterozygous familial hypercholesterolemia to reduce LDL. The recommended dose is stratified by indication, age, and weight. For the new indication in pediatric patients less than 50 kg, the recommended dose is 150 mg subcutaneous every four weeks. And if LDL cholesterol-lowering response is inadequate, we will adjust the dose to 75 mg subcutaneous every two weeks. For patients, at least 50 kg and above, the recommended dose is 300 mg subcutaneous every four weeks. And if LDL cholesterol-lowering response is inadequate, we'll adjust the dose to 150 mg subcutaneous every two weeks. LDL cholesterol-lowering effect can be measured as early as four weeks after initiation. And a caregiver should administer treatment for pediatric patients between age 8 to 11 years old. Next, we have Nexletol and Nexlizet. So in March 2024, a new indication was approved for Nexletol (bempedoic acid), and Nexlizet, which is a combination of bempedoic acid with ezetimibe. It was FDA-approved to reduce the risk of MI and coronary revascularization in adults who are unable to take recommended statin therapy, including those not taking a statin, with one established cardiovascular disease, which I will refer to CVD, and a high risk for CVD event but without established CVD. Okay. The Nexletol is available as 180 mg oral tablets, and Nexlizet is available as 180 mg bempedoic acid/10 mg ezetimibe oral tablets, and the recommended dose is one tablet once daily with or without food. And then in April 2024, Amgen announced that it will discontinue the manufacture of the Repatha Pushtronex system on June 30th of 2024. Other Repatha devices, including the SureClick Autoinjector will remain available. And Amgen stated that this decision was made to maintain its high standards for the patient experience. And that is all for I have for Lipotropics. I can take any questions.

Kavita Chawla: Thank you, Nina. Any questions from the Board for Nina? And I do see one stakeholder listed. Oh, Marissa, do we want to review the PDL before we get the --

Marissa Tabile: This is Marissa. Yeah. Let me go ahead and pull it up. I apologize I don’t have it [cross-talk] --

Kavita Chawla: [Cross-talk] No worries.

Marissa Tabile: -- pulled up.

Kavita Chawla: You're orchestrating a lot of tabs [cross-talk] [laughter] --

Marissa Tabile: So let me show you the classes. All right. So let me get rid of these bone density regulators, actually. All right. There we go. So these are the Antihyperlipidemics drug classes that we [cross-talk]. Oh, I'm not showing it. [laughter] Thank you. Let me -- you would think by 2024 I would know how to show my screen by now but, hopefully, you can see that now. Is it good? Okay, good. So here I have the Antihyperlipidemic drug classes that Nina was mentioning. So for the first one, I'll go through the Adenosine Triphosphate Citrate Ligase Inhibitors. So we have the Nexletol and the Nexlizet, and in that class we do have the Nexletol, which is just the bempedoic acid as the preferred product. For the Angiopoietin-like Protein Inhibitors, we do have Evkeeza. That one is a carveout, so it doesn't have a preferred status, but we do include it on the PDL just for communicating what is carved in and carved out. So that's why you won't see a status there, but we do cover it. For Microsomal Triglyceride Transfer Protein Inhibitor, we just have Juxtapid, and that product we do have preferred. And for the PCSK-9 inhibitors, our preferred products in that class are all of the Repatha formulations. So I know Nina had mentioned the Pushtronex is being discontinued, but it still shows up on our drug file. So until that actually gets discontinued and out of the system, then it'll just pretty much automatically disappear, but for now it's still here. But we do have the Repatha SureClick and Repatha Syringe. The other two products, Leqvio and Praluent, are non-preferred. And I can take any questions from the Board about the PDL.

Kavita Chawla: Marissa, Kavita here. If you scroll over all the way to the right -- so yes, we see the -- for example, the very top one right, so bempedoic acid, it is preferred, but it has a prior auth requirement. So, yes, exactly where you're at. There is no policy though, so how is the prior authorize determined? Or what is required for the prior auth?

Marissa Tabile: Typically, if you don't see what the -- so if there is no policy, it probably won't populate here. But in that case, since we do not have a clinical policy for it, it would just be reviewed for medical necessity per the labeling. So that's really what we would be looking for.

Kavita Chawla: So is that to say, for example, with bempedoic acid, the labeling, or FDA approval said that is for individuals who either haven't achieved the LDL lowering as needed on statins, or they're statin intolerant, so is [cross-talk]

if the patient is statin intolerant that would be covered? Like that would meet the criteria for prior auth?

Marissa Tabile: That would be one of them, yeah. So we would make sure in those reviews that we are the LDL if it is called out in the label, the statin use, whether they have used it. Are they intolerant? And then also if there are any other kind of clinical reviews, clinical labs that might be of relevance for these particular drugs that we might want to look at. So any particular drug-drug interaction, things like that, we would also take those into consideration. But we don't have any like set criteria. You would just be kind of looking for those hallmark kind of labs or markers that are called out in either the label or important clinically, you would think.

Kavita Chawla: Okay. Thank you.

Marissa Tabile: Yeah.

Kavita Chawla: Other questions from the Board? Okay, hearing none. We can proceed with stakeholder input. Nonye, I see Josh Wageman from Amgen on the list. Is Josh here?

Nonye Connor: Yes, Josh. [Cross-talk] --

Josh Wageman: [Cross-talk] I'm here. Can you hear me?

Kavita Chawla: Yes, we can. Give us one moment, Josh. I'm going to allow either Nonye or Marissa -- I don't know who's controlling the timer -- to get that on the screen.

Marissa Tabile: This is Marissa. Yeah. I'm going to go ahead and pull up the timer and the questions, so let me get that all squared away.

Kavita Chawla: And Nonye, we do have the COI form already completed, right? So [cross-talk] --

Nonye Connor: [Cross-talk] Yes. Josh completed the COI form, so you can have the timer. Perfect. Thank you.

Kavita Chawla: Thank you for doing it ahead of time, Josh, and the floor is yours.

Josh Wageman: All right. Well, thanks for having me. And it's always good to see Repatha as the preferred PCSK-9 inhibitor on the Apple Health PDL, particularly in light of the 2022 ECDP update on behalf of the ACC/AHA that actually says that LDL-C thresholds should be less than 55 now for very high risk patients. So as a lipid specialist myself, it warms my heart to see all the available tools in the toolbox now for people to get them living in a safer neighborhood where there are fewer criminals, given that every LDL particle is potentially a criminal, and if you want to get living in a nice, safe, gated community, there is nothing more potent and cleaner than PCSK-9 inhibition. And so I just wanted to give you guys just a little brief update on some of the new things that we have seen with Repatha because one of the criticisms from the early FOURIER trial is that even though it reduced heart attacks and strokes over a very short time, 2.2 years, it was just a very short trial, and so it was like, Okay, we need to see what goes on with the long-term here. And now we have open-label extension data from almost nine years now. And what do we see? We see less new onset diabetes over time, less myalgias, no signals for cognitive concerns, and no signal for hemorrhagic stroke. Really, there were no side effects that emerge other than the occasional injection site reaction, which is very, very reassuring when it comes to the safety of these things for our patients. Additionally, there was an exploratory analysis on cardiovascular mortality, and, in fact, there was a 23% reduction in cardiovascular mortality for people who started Repatha sooner than people who were late to the party. And this really fits a nice, nice framework because first we see within 4 hours of injection, we see LDL-C start to drop with Repatha. And then, if we have LDL-C dropping, we would expect to see benefit on plaque stability and even plaque regression, and we do see that. And then we would expect if plaque characteristics are improving, there would be a reduction in cardiovascular events, and we do see that. And then over time we would expect to see a benefit in cardiovascular mortality, and now we have the data [audio cuts out]. And so really exciting stuff. And like I always say, Repatha is a clean and potent way to get living in a nice safe gated community if you have been broken into, when it comes to cardiovascular disease, given that it lowers LDL cholesterol 60% and lowers the risk of heart attack and stroke, particularly for these high risk patients to get them under LDL cholesterol goals of 55. So thanks for your time. I really appreciate it and look forward to chatting again in the future when we have even more cool stuff to share.

Kavita Chawla: Thank you, Josh. Any questions from the Board for Josh? Okay. Any other stakeholders that were not registered, Nonye?

Nonye Connor: I do not see any hands raised.

Kavita Chawla: Right on. Okay. So then we can proceed to the motion.

Marissa Tabile: And this is Marissa. So I'm just pulling them up now, so let me go ahead and just share it over here.

Kavita Chawla: So I guess -- Kavita here -- so when do we expect those policies to come out? [Cross-talk] --

Marissa Tabile: This is Marissa. For the Nexletol product that you referenced earlier, I don't have an ETA on when that policy will be presented, at least to you all. So we are in the process right now of kind of prioritizing the policies that we do want to bring forth to you in 2025, so that schedule is pending. It was not as far as priority-wise, I will be very transparent, it did not seem like it was a very high priority policy that needed to be created. So it may or may not show up next year, but we are trying to prioritize the higher priority ones for 2025. So I guess more to come on that.

Kavita Chawla: Okay, thank you.

Marissa Tabile: Mm-hmm.

Laura Beste: This is Laura Beste. I motion that all products in the drug classes listed on Slide 2 are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in these classes may require prior authorization to determine medical necessity. All 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.

Peter Barkett: Peter Barkett. I second the motion.

Kavita Chawla: All in favor, please say aye.

Multiple Speakers: Aye. Aye. Aye. Aye.

Kavita Chawla: Any opposed or abstain? Great. And the motion carries. Thank you. And back to Nina for agents for substance use disorder.

Nina Huynh: All right, thank you. So next is Substance Use Disorders. We're going go over agents for Opioid Withdrawal, Opioid Antagonist, Opioid Partial Agonist Subcutaneous, and Opioid Partial Agonist, Transmucosal. So next, we'll be going over opioid abuse and misuse. So prescription and illicit opioid abuse and misuse has reached national interest and was declared a National Public Health Emergency by the Department of Health and Human Services Acting Secretary in 2017. The 2022 National Survey on drug use and health reported that there was at an estimated 46.6 million Americans aged 12 years and older who were current illicit drug users, and approximately 8.5 million people each 12 years or older in the United States who misused opioid in the last year. Approximately 48.7 million people aged 12 years and older in 2022 were considered to have substance use disorders in the past year, including 29.5 million people with an alcohol use disorder, 27.2 million people with a drug use disorder, and 6.1 million with an opioid use disorder, and I'll refer to that as OUD. In 2020, the US Preventive Service Task Force issued a final recommendation statement on screening for unhealthy drug use. For adults, the recommended screening implemented when service for accurate diagnosis, effective treatment, and appropriate care can be offered or referred, and for adolescents, current regimen is insufficient to determine the benefits and harm of screening for unhealthy drug use. Okay. Next, we have the 2022 CDC Guidelines. So when opioids are prescribed, the CDC advises clinicians to evaluate for risk factors for opioid overdose in the patient and household members and offer naloxone. Their recommendations emphasize the careful tapering of opioids to avoid withdrawal symptoms in current pain patients and individualized assessment of risks and benefits for continued high-dose treatment. Regarding medications for opioid dependence, the CDC states prescriber should offer treatment for OUD, such as medication-assisted treatment such as buprenorphine or methadone. Buprenorphine alone or in combination with naloxone and methadone treatment have been associated with reduced overdose deaths and reduced all-cause mortality. Naltrexone is also an effective option, particularly for highly motivated individuals, but it has not been evaluated in persons with concomitant pain. Adherence is a consideration with injectable naltrexone as individual must be motivated to follow through with monthly long-acting injections. Because the effectiveness of oral naltrexone is limited by poor medication adherence, oral naltrexone should not be used except under very limited circumstances, such as patients who would be able to apply with

observed daily dosing. Naltrexone also requires full withdrawal from opioids prior to initiation, which may present a challenge, and the CDC state there is no duration limit for the treatment of OUD with buprenorphine, methadone, or naltrexone. Okay. In January 2024, following the FDA request, emergent extended the shelf life of newly produced naloxone, Narcan 4 mg nasal spray to four years, which was previously only three years shelf life. The extension is only applicable to products manufactured after January 17th of 2014 -- I mean 2024. In August of 2024, a new generic was approved for Lucemyra 0.18 mg tablet, and it is anticipated to launch immediately. And that is it for substance use abuse. I'll pass it back to the Committee.

Kavita Chawla: Thank you, Nina. Kavita here. Questions from the Board for Nina. And we'll wait for Marissa to load the Apple PDL.

Marissa Tabile: All right. This is Marissa. So I am showing our substance use disorder drug classes. This isn't -- I will caveat this. Clearly, it's not the whole -- well, I think it is. Actually, I was thinking of the opioids in general. I'm sorry. So I'll actually -- I withdraw what I said. I'll just go through these class by class. So for the first one, we have the agents for Opioid Withdrawal. In this class, we do have the Lucemyra and the generic lofexidine. That one is non-preferred, and it looks like there is PA on that. For substance use disorder, opioid antagonists, for this one we have -- it's easier for me to just say what is preferred. So we have the Kloxxado, which is a naloxone spray. Various naloxone, we have the spray, the syringe, the vial all preferred without PA. We have naltrexone auto-injectors, tablets. We have Opvee, which is nalmefene, and then we also have other kinds of branded naloxone as well. And then we have Revive, Vivitrol, and Zimhi. Those are all preferred without PA. For the opioid partial agonist subcutaneous, we do have Brixadi and Sublocade. Those are Brixadi is preferred without PA, and then Sublocade, we do have. It looks like it's preferred with a PA. We do have a policy for that. And then for Opioid Partial Agonist, Transmucosal, these are the suboxones. We do have brand Suboxone film preferred without PA as well as it looks like the generic tablets preferred.

Zoe Taylor: I just wanted to correct. I think. So Brixadi and Sublocade are both without PA [cross-talk] --

Marissa Tabile: [Cross-talk] Oh, it is. Yes. [Cross-talk] I'm sorry. [Cross-talk] --

Zoe Taylor: [Cross-talk] And so the Subutex, the buprenorphine HCL tablet sublingual that does have a PA, and that is like a thing that is a big deal for us, and so I just want to make sure that's really clear.

Marissa Tabile: Yes. Thank you for correcting that. It is for the buprenorphine tablets that we have the PA. And I can take any questions from the Board about [audio cuts out] the PDL.

Kavita Chawla: All right. And Nonye, do we have any stakeholders? I don't see any listed.

Nonye Connor: And I don't see anyone's hand raised.

Kavita Chawla: Okay. So then if no questions for Nina or for Marissa, we can look at the motion.

Zoe Taylor: Is now the time that we would talk about removing the PA from Subutex, or would that be a different meeting? Because that's like a huge agenda item for like WSMA, WFP, like every group that I am a part of, and if this is the meeting to do it then I want to do it. But I'm [cross-talk] --

Donna Sullivan: So this is Donna. You're, um, Subutex, meaning which one?

Zoe Taylor: Buprenorphine HCL sublingual tablets.

Donna Sullivan: The monotherapy? I think we're already in the process of doing that, Zoe. [cross-talk] --

Zoe Taylor: [Cross-talk] Great.

Donna Sullivan: It just hasn't been done yet.

Zoe Taylor: Okay.

Donna Sullivan: And that's for monotherapy, right?

Zoe Taylor: Yes.

Donna Sullivan: Yeah.

Zoe Taylor: That's definitely the biggest barrier for saving lives right now.

Donna Sullivan: It’s on our radar.

Zoe Taylor: Okay, awesome. Is that relevant to this motion, or is it not part of [cross-talk]

Donna Sullivan: I don't think so.

Zoe Taylor: Okay. Sounds good. Because it's listed as preferred, that wouldn't affect the wording of the motion, I think. Okay. I'm happy to do this motion if other people don't have any other objections. I think that the correct things are preferred on the list. Okay. So I move that all products in the drug classes listed on Slide 4 are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in these classes may require prior authorization to determine medical necessity. All 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.

Greg Hudson: [Cross-talk] This is Greg. I second. [cross-talk] --

Michael Corsilles: [Cross-talk] This is Michael Corsilles. [cross-talk] --

Kavita Chawla: Go ahead, Greg.

Greg Hudson: Yeah, sorry. This is Greg Hudson. I second.

Kavita Chawla: Great. All in favor, please say aye.

Multiple Speakers: Aye. Aye. Aye. Aye.

Kavita Chawla: Any oppose or abstain? Great. And the motion carries. Okay. Next item is Movement Disorder Agents. Is the Board okay doing that before we take our break? Yeah? I see some nodding heads. Okay. Let's do that one more, that topic, and then we can take our break. Over to you, Nina.

Nina Huynh: Thank you. Okay, Movement Disorders. Okay, on the next slide, we'll be going over Huntington's Disease. So chorea and abnormal involuntary twisting and/or writhing movement are characteristic features of Huntington's

disease, a rare and fatal genetic disorder resulting in neurodegeneration of the brain, which affects roughly 4.1 to 8.4 per 100,000 people in the US. Chorea affects approximately 90% of people with Huntington's disease and often develops early, gradually worsens, and plateaus in late stages. Chorea symptoms may be aggravated by stress and anxiety, and as the disease progresses it can interfere with patients' function and chorea is replaced by dystonia and parkinsonism. No therapy currently exists to delay the onset of symptoms or prevent the progression of the disease. However, symptomatic treatment may improve the quality of life and prevent complications. So here we have the 2022 International Parkinson's and Movement Disorders Society use the grading of recommendation, assessment, development, and evaluation approach, and appraised 22 randomized controlled trials involving 17 interventions, targeting several predetermined questions. However, the high-quality data was limited. The data found that both deutetrabenazine and tetrabenazine are likely efficacious for chorea. Deutetrabenazine is likely efficacious for motor impairment, while tetrabenazine is unlikely to be efficacious. Deutetrabenazine is likely efficacious for dystonia, but data was too limited for tetrabenazine. And deutetrabenazine and tetrabenazine were determined unlikely efficacious in functional capacity improvement as well as gait imbalance. Regarding safety of interventions, the group categorized deutetrabenazine as unlikely to be harmful and worsening depression, while tetrabenazine was considered likely to be harmful. Deutetrabenazine extended-release Austedo XR was not approved at the time of this publication, and valbenazine, Ingrezza and Ingrezza Sprinkle, was not yet approved for this indication at the time of publication. Okay. On the next slide, we have Austedo XR (deutetrabenazine). So in May 2023, FDA-approved higher strength ER tablets 30 mg, 36 mg, 42 mg, and 48 mg. And then in July 2024, FDA-approved a new intermediate strength ER tab 18 mg. And a new four-week titration kit was also approved, which contains seven ER tabs of each of the following strengths: 12 mg, 18 mg, 24 mg, and 30 mg. Okay. Next, we have Ingrezza (valbenazine). In May 2024, FDA-approved Ingrezza Sprinkle capsules for patients who have dysphagia or difficulty swallowing. The capsule contains one oral granule that can be sprinkled onto soft food, and the capsule content should not be mixed with milk or water and should not be administered via enteral tubes. The Ingrezza Sprinkle will be available as 40 mg, 60 mg, and 80 mg capsules. And that is all I have for Movements Disorders. I can take any questions.

Kavita Chawla: Thank you, Nina. Kavita here. Questions from the Board for Nina. Okay. And I do see we have two stakeholders listed as Omar Aziz. Oh, sorry. Let's look at

the formulary first, and then we will have the stakeholders. Thank you, Marissa.

Marissa Tabile: This is Marissa. No worries. It's pretty straightforward. So this is our Movement Disorder class. We have the products that Nina mentioned. So we have Austedo, Ingrezza, tetrabenazine, and brand name Xenazine. In this class, our preferred products are Austedo. All the different formulations, the tablets, the titration packs, the XR formulation, and the generic tetrabenazine, and Ingrezza is non-preferred. We do have a policy for that product. I think it's going live here in the next couple of months if not next month, which you did all review, I think sometime this year. So I can take any questions from the Board.

Kavita Chawla: Thanks, Marissa. Questions from the Board.

Peter Barkett: This is Peter. I just wanted to clarify about the -- I think there was a point about risk for depression with tetrabenazine versus deutetrabenazine. It looks like deutetrabenazine had the more favorable safety profile and is also preferred on here. I just wanted to confirm.

Marissa Tabile: This is Marissa. Yes, we do have Austedo preferred without PA, which is the deutetrabenazine. Hopefully, that was to me, Peter. I thought that was to me or Nina.

Peter Barkett: Yeah. Yeah. Thank you. Yeah, I was just trying to recall for the safety profile from earlier slides and make sure that matched up. I thought it did. And thanks for confirming.

Marissa Tabile: This is Marissa. No problem.

Kavita Chawla: Okay, great. Thank you. Any other questions for Marissa? And if not, we can start with Omar Aziz from Teva Pharmaceuticals. We have your COI form. Thank you for filling that out.

Omar Aziz: Hello, [indistinct]. It’s afternoon where I am, but it’s probably morning where you are. So thank you so much. My name is Omer Aziz. I'm with the Field Value and Evidence and Outcome scene, part of the Medical Affairs at Teva. I just wanted to provide some quick updates around Austedo and deutetrabenazine. As Prime so eloquently stated before, Austedo XR was approved and launched with strengths of 6 mg, 12 mg, and 24 mg, and is here

in additional strengths of 18 mg, 30 mg, 36 mg, 42 mg, and 48 mg strengths are approved. Now what this means is that they're now seven different one pill, once-a-day dosing options for deutetrabenazine, which allows providers to give a dose as flexible to find the optimal dose for the patient that controls the symptoms and minimizes effects. I just want to let you know that Austedo b.i.d. formulation is still available in the market for patients who require this. Austedo does not have clinically important drug-drug interactions with CYP3A4 inhibitors or inducers. I also will note that the Austedo and Austedo XR have a box warning for patients with Huntington's disease for depression or suicidality, but that does not apply to the tardive dyskinesia indication that is consistent with the Box Warning across the class for VMAT inhibitors, I want to refer the Committee to the full prescribing information for Austedo XR as well as Austedo. And in closing, I thank you so much for your time. I respectfully ask the Committee for maintained access to Austedo and Austedo XR. I'm available for you if you have any questions. Thank you so much for your time.

Kavita Chawla: Thank you, Omar. Any questions from the Board? Okay. Thank you. And then we have Anna Nepomuceno. I might be mispronouncing your last name, I apologize. Are you online?

Anna Nepomuceno: Yes. Can you hear me?

Kavita Chawla: Yes, we can. [Cross-talk] --

Nonye Connor: And if you can do [cross-talk]. If you can do a favor, please answer the questions on the screen, please, Anna. Thank you.

Anna Nepomuceno: Okay, so my name is Anna Nepomuceno. I'm speaking on behalf of NAMI Washington. And I am not a provider or a patient. And there is no conflict of interest.

Nonye Connor : Thank you.

Anna Nepomuceno: Can I go ahead and start?

Nonye Connor: Yes.

Anna Nepomuceno: Okay, great. Thank you. On behalf of NAMI Washington, I am asking for preferred status for all FDA-approved medications for the treatment of

tardive dyskinesia (TD). There are currently two FDA-approved medications for treating TD, and only one has a preferred status, leaving people with TD no other options for treatment. It is critical that people with TD have treatment options based on their individual needs and that they are not restricted to a single compound. These medications have different drug interactions, metabolizer statuses, and side effect profiles. In light of these variances, we strongly support patients and their prescribers continuing to have both options available to them. Before diagnosis and treatment, having TD is a deeply challenging reality, especially considering that many people develop TD as a result of a long-term use of certain antipsychotics used to treat serious mental illness, which has its own effects on functionality. TD is estimated to affect over 600,000 people in the US, about one in four people who take antipsychotic medications for many years can develop TD. People experiencing symptoms are often confused about and unsure of what is happening to them. Many people with untreated TD will find themselves breathing harder, making uncontrollable clicking sounds with their tongue, and experiencing face switching, voice wavering, and an inability to be physically still. They may be uncomfortable in social situations. They'll often have difficulty securing and sustaining employment. The impact of TD, if untreated, can devastate a person's ability to face the world and cause extreme social isolation. Thankfully, the availability of TD medications has given patients new hopes. TD treatment can change people's lives in ways that they and their loved ones never thought possible. This year, NAMI Washington received feedback from an individual experiencing the challenges associated with TD. Her symptoms compelled her to pull away from society, putting her livelihood at stake, so she was also unable to continue her career as an attorney. Once the patient started receiving treatment, she reported very positive results, to the point where she felt empowered to re-enter society. With treatment this patient experienced a renewed confidence to live her life and continue on with her career. To people whose lives have been impacted by TD, access to treatment means acceptance. It means feeling comfortable in their own skin. It means achieving professional goals in the workforce. To put it differently, access [audio cuts out] to TD treatments means feeling human again. Washington is one of only four states that do not provide parity for TD medications, meaning that they are not preferred medications. There are no generics for treatment of TD, just these two approved medications. On behalf of NAMI Washington and our members across the state, I strongly encourage the Board for parity and open access to both TD medications as preferred agents within the Movement Disorder class. Thank you very much for your time.

Kavita Chawla: Thank you, Anna. Questions from the Board for Anna? Okay. Any other stakeholders, Nonye?

Nonye Connor: Yes, we have Anna Marie. Anna Maria, you can unmute yourself and answer the question on the screen please. Thank you.

Anne Marie: All right. Anne Marie. Um, I am speaking on behalf of AAPPN. I am a provider. I see almost exclusively Medicaid clients. I do have a potential conflict of interest to report. I am a paid speaker for long-acting injectable for Teva Pharmaceuticals and Austedo, but I'm not going to speak about Austedo, specifically. All right. So I'm a Psych NP. I serve Community Metal Health Clinics in Thurston, Mason, and Gray's Harbor Counties. I've had the privilege of treating patients with serious mental illnesses, including schizophrenia, schizoaffective disorder, and other psychotic disorders for the past seven years. Many of these patients are covered by state health insurance and rely on antipsychotic medications as a cornerstone of their treatment. I'm testifying today to bring your attention to the critical healthcare challenges faced by my patients and to advocate for legislative changes that support the well-being of rural population. In these communities, access to healthcare is severely limited. Many of my patients struggle with transportation, often unable to afford the gas or lacking reliable vehicles. Compounding this issue is limited availability of internet and cell phone access, which hinders telehealth options that could otherwise bridge the gap in care. The small rural hospitals in our area experience a high turnover of physicians, which exacerbates the lengthy wait times for patients to see a primary care provider ranging from three to six months or more. In this environment, I'm often the healthcare provider who sees my patients most frequently, routinely every three months at a minimum. My consistent presence allows me to develop a deep understanding of their health needs, providing continuity and personalized care that is otherwise lacking. Despite the critical role that ARNP's like myself play in these communities, there is a proposed requirement for physician oversight on a specific medication, Ingrezza. This is particularly problematic when there are no local psychiatrists and scarce neurologists, often requiring travel to Olympia or beyond. Requiring a physician who has had no prior contact with the patient to approve certain medications, such as VMAT2 inhibitors, is not only impractical but also punitive. It places an unnecessary burden on patients who are already struggling to access care. I urge the Committee to consider reforms that recognize the capabilities of ARNPs and allow us to practice to

the full extent of our training and expertise. By removing unnecessary barriers to prescribing medications, we can ensure timely and effective treatment for our patients, reducing the strain on an overburdened healthcare system, and improving healthcare outcomes in rural communities. Thank you for your attention to this pressing issue. I am committed to working collaboratively to find solutions that enhance healthcare access and quality for all residents in Washington State.

Kavita Chawla: Thank you, Anne Marie. Any questions for Anne Marie from our Board? Okay. Any other stakeholders, Nonye?

Nonye Connor: Yes. We have John Deason. John, if you can please go ahead and read and answer the questions on the screen, and you can give your testimony. Thank you.

John Deason: Yeah, absolutely. Thank you. As mentioned, my name is John Deason, and I'm here representing Neurocrine Biosciences Medical Affairs department. I am not a provider or a patient, and I am an employee, as I mentioned, of Neurocrine Biosciences. So good morning.

Nonye Connor: Okay.

John Deason: Awesome. Thank you. So good morning. I appreciate the opportunity to join the Board here today. I just had two quick items that I wanted to bring to the Board's attention. As Nina had mentioned, there is a new FDA-approved formulation for Ingrezza, Ingrezza sprinkle capsules, or a new oral granules formulation, and it received FDA approval on April 30th of this year for the treatment of tardive dyskinesia (TD) and chorea associated with Huntington's Disease in adults. It's important to note that many patients with TD and HD chorea experience dysphagia or difficulty swallowing. The Ingrezza sprinkle capsule is easy to open, and the contents or the granules can be easily sprinkled on soft foods such as apple sauce, yogurt, or pudding for oral administration. In a survey of 250 patients with TD experiencing moderate-to severe involuntary movements, 37% of patients reported that their movements impacted their ability to eat and drink. Most people living with chorea associated with Huntington's disease will also experience swallowing issues. The availability of a treatment for chorea that can be easily sprinkled on a food is very helpful in reducing the burden of taking a pill for these individuals as well as their caregivers, especially as the majority of these patients will experience dysphagia as their disease progresses.

Ingrezza sprinkle offers the same dosage strengths of 40 mg, 60 mg, and 80 mg as well as the same once-daily dosing as the Ingrezza capsule. I would also like to let you know I appreciate the opportunity to respectfully request that the Board consider moving Ingrezza to preferred on the state PDL to allow patients and providers in the State of Washington choice when considering FDA-approved options for the effective treatment of their TD or Huntington's disease-associated chorea. TD is often irreversible, and it requires unique management. It's important to keep in mind that when we're discussing the treatment of TD, the underlying condition that the majority of patients with TD are receiving antipsychotic treatment for is due to a serious mental illness. This could be schizophrenia, schizoaffective disorder, or a mood disorder. In these patients with both a serious mental illness as well as TD, it must not only deal with the stigma associated with a serious mental illness but also the additional stigma associated with -- the involuntary movements, making access to FDA-approved VMAT2 inhibitors for the treatment of TD, including Ingrezza, important. In summary, Ingrezza is an effective treatment for adults with tardive dyskinesia and adults with [audio cuts out]-associated chorea providing simplicity for both patients as well as providers, as there will always be one capsule once daily, and this is regardless of a patient's maintenance dose. Ingrezza can be safely used in patients with no dosage adjustment required for mild, moderate, or severe renal impairment, and it is the only FDA-approved VMAT2 inhibitor that can be used safely in patients with moderate or severe hepatic impairment at a reduced dose of 40 mg once daily. Again, appreciate the Board's time and attention today. And we are to again respectfully request the Committee consider adding Ingrezza to the state PDL. I'm happy to answer any questions you may have.

Kavita Chawla: Thank you, John. Questions from the Board or John? Okay. Other stakeholders, Nonye?

Nonye Connor: No. No one else's hands were raised.

Kavita Chawla: Okay, so we can have a look at the motion. Can you go back to the PDL for a second? Just because we heard so much about that.

Greg Hudson: And this is Greg Hudson. I think I have a question. Maybe this is for Marissa. I know the guidelines we reviewed today were for Huntington's and Parkinson movement disorders. I'm wondering if we're -- if there is a separate guideline for tardive dyskinesia or if this is sort of included in this overview.

Marissa Tabile: This is Marissa. You might have been referencing maybe Nina's presentation.

Greg Hudson: Yes, excuse me.

Marissa Tabile: Yeah, no worries. I'm looking at it and, Nina, feel free to chime in. It doesn't look like there is anything specific in your slides about the tardive dyskinesia. So I don't see anything specific about guidelines in that. But feel free to elaborate if I'm missing anything, Nina.

Nina Huynh: Okay. So yeah, I did not mention anything of tardive dyskinesia, but it is part of the class overview. I'm checking real quick if there is any -- there wasn't any guideline updates in the past year, but I want to look at the most current guidelines, and I can pull that up. Yes, the most recent guideline was in 2020. APA updated the guidelines for the treatment of schizophrenia. The recommended routine assessment for TD in patients using antipsychotics, they recommended that patients who have moderate-to severe or disabling TD related to antipsychotic therapy be treated with a reversible VMAT2 inhibitor, specifically deutetrabenazine, tetrabenazine, or valbenazine. A patient with mild TD can also be considered for treatment with a VMAT2 inhibitor following an assessment of several factors such as patient preference, impairment, and psychosocial functioning impact. They state that deutetrabenazine or valbenazine is preferred over tetrabenazine due to the data supporting their use, efficacy, safety, and pharmacokinetic considerations. Other factors should also be considered when selecting which agent is most appropriate for a specific patient. Such as hepatic impairment, renal impairment, metabolizer status, drug interactions. And then deutetrabenazine ER and valbenazine Ingrezza sprinkles were not approved at the time of the publication.

Jon MacKay This is Jon McKay here. I had a question regarding our stakeholder referencing the -- is there a policy that requires a behavioral health expert or psychiatrist to prescribe this class?

Marissa Tabile: This is Marissa. I can speak to that. We don't have a policy that's alive right now. There was a policy that you all did review. The date is escaping me. Let me actually see when it will be going live. It's in the final stages. Let see. And I will double-check. Okay. So actually, it should. It actually should have just gone live October 1st, so technically, this policy is supposed to be live right now. In our current policy, we do have criteria where it's prescribed by or in

consultation with a neurologist or a psychiatrist. And that goes for both the Huntington's disease, chorea, and tardive dyskinesia. We do have that in our policy.

Laura Beste: So this is Laura, just a quick question. So based on that policy, if a provider went to prescribe Ingrezza over Austedo, would they have to fail tetrabenazine first before using [indistinct]? [cross-talk] they would have to see [cross-talk] --

Marissa Tabile: [Cross-talk] They would have to step through [cross-talk] Austedo first.

Laura Beste: Okay. But they would have to fail two agents, just the Austedo?

Marissa Tabile: It's either or. If they have [cross-talk] stepped through deutetrabenazine or tetrabenazine, I believe. Let me see the way it's written. I might have misspoken. [Cross-talk] Let me check [cross-talk] --

Donna Sullivan: Hi, Marissa. I think they have to go through deutetrabenazine [cross-talk].

Marissa Tabile: Yes.

Donna Sullivan: Hi, Marissa, I think it I think they have to go through deutetrabenazine, so [cross-talk] --

Marissa Tabile: [Cross-talk] Yes, it's just due to [cross-talk] - -

Donna Sullivan: [Cross-talk] So if they have tried tetrabenazine, they will also have to try deutetrabenazine.

Zoe Taylor: Is there any sort of like cost information about why?

Donna Sullivan: It's a -- Ingrezza is extremely more costly than [cross-talk] --

Zoe Taylor: [Cross-talk] Okay.

Donna Sullivan: -- Austedo [cross-talk] --

Peter Barkett: [Cross-talk] Yeah.

Donna Sullivan: -- which is why we have it on PA. [cross-talk] So if they are relatively equally effective, we want you to try [cross-talk] --

Zoe Taylor: [Cross-talk] Yeah.

Donna Sullivan: -- the least costly one first.

Zoe Taylor: [Cross-talk] And I just got [cross-talk] --

Peter Barkett: [Cross-talk] And the cost differential is a little over $3000 per month between the two.

Zoe Taylor: Okay. I just found a Systematic Review from 2024 that they're both like extremely similar in terms of effects and side effects, so I wasn't able to find anything in that to make it seem like one is better than the other.

Jon MacKay: This is Jon MacKay, and I just wonder about with an established diagnosis of a movement disorder, if it would be, you know, preferable or allowed to have like primary care take over the prescribing like in conjunction if maybe Psychiatry made the initial diagnosis, if it's necessary to have that ongoing requirement just to improve access to care, I just kind of hear [cross-talk] what one of our stakeholders said. [cross-talk] --

Peter Barkett: [Cross-talk] I think that one [cross-talk] I think that would be allowed for with this policy. I don't remember the exact language, but I thought it said something like in conjunction or consultation with a neurologist or psychiatrist.

Zoe Taylor: Yeah. When I've done that for rheumatology, which is like a similar phenomenon, I just write the name of the person on the form, and I don't tend to have to have them -- see them again.

Greg Hudson: This is Greg Hudson. I think speaking to our stakeholders' concern about access to care, I mean I believe there has been past criteria that's been adjusted to include psychiatric ARNP's to include this in their scope of practice. I don't see a reason why this couldn't be included as well.

Kavita Chawla: Marissa, is the policy, I guess, addenda or adjustments something that we would do now? Is that up for discussion now?

Marissa Tabile: This is Marissa. No. So we wouldn't be changing the policy because it is already live. I can take it back for a possible update. And I'm sorry, I must have missed what the amendment was to the policy, but I can take it back for a future update. It wouldn't be something that would be reflected as soon as possible. It would be a little bit. I actually can't tell you how long it would take depending on the update, but I can take it back for consideration.

Kavita Chawla: I don't think we're necessarily proposing any -- or maybe we are proposing the change yet, but it's what's being brought up for discussion is in point #2 prescribed by or in consultation with a neurologist or psychiatrist or psychiatrist ARNP, or psychiatric ARNP. That is I think what's up for discussion right now to allow for access to care. So maybe that can be on the agenda at one of the future meetings.

Greg Hudson: Yeah, but -- this is Greg Hudson. I would recommend that that be included as a recommendation for future items just in terms of adequate scope of practice for psychiatric ARNPs.

Marissa Tabile: This is Marissa. Yeah, I can definitely take that back for updating. Not even just for the valbenazine policy, but probably across the Board just to take that into consideration for the different provider types that we do have.

Kavita Chawla: That sounds fair. And I think, yeah, if in general it seems like the rule of thumb would be if the state allows it, would we just follow state laws? But yes, that sounds like a great agenda item for one of our future meetings. I think that'd be very beneficial.

Marissa Tabile: This is Marissa, and I will say as a clinical reviewer, myself, for some of these requests that we get, if I did see a -- and I think this is the expectation -- if we did see a request come from a psychiatric ANRP, I would certainly count that. I wouldn't discount that as not meeting criteria. You know? I definitely would take that and, you know, if it's still provable, prove it, but still take that into consideration for sure.

Kavita Chawla: That's helpful to know. Thank you, Marissa. Other questions from the Board. I know one of you had asked to look at the formulary. Did you get your question answered about that? Maybe it was Zoe, I think.

Zoe Taylor: Yep, yeah.

Kavita Chawla: Okay. All right. Yeah. Any other questions for Marissa, for Nina, or for any of our stakeholders? And if not, then we'll look at the motion. Okay. Kavita Chawla. I move that all products in the Movement Disorders Agents Class 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 this class 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, non-clinically appropriate, or one product is preferred.

Peter Barkett: Peter Barkett. I second the motion.

Kavita Chawla: All in favor, please say aye.

Multiple Speakers: Aye. Aye. Aye. Aye.

Kavita Chawla: Any oppose or abstain?

Laura Beste: Actually, this is Laura. I just have one question.

Kavita Chawla: Please.

Laura Beste: So it says at least two preferred products, but aren't we saying there is only -- they only have to try one product?

Peter Barkett: It depends on which preferred product they tried. So if they tried tetrabenazine, they still have to try deutetrabenazine. If they tried deutetrabenazine then they can move on to Ingrezza. And I think the reason why that one's kind of carved out is because it's written that way in the prior auth for Ingrezza.

Laura Beste: Okay. So since it's in the prior auth, it's okay for it to say at least two, even though technically, it wouldn't be.

Peter Barkett: Yeah, because we made an exception in the policy.

Laura Beste: The prior auth.

Marissa Tabile: Yeah. This is Marissa. Whatever is in the policy would certainly override that behavior because we would be very specific about what non-preferreds they would have to try.

Laura Beste: Okay.

Marissa Tabile: Yeah.

Laura Beste: I'm in agreement with that.

Marissa Tabile: Good question.

Kavita Chawla: Were you starting to say something, Greg?

Greg Hudson: No. I think I had my question answered. Thank you.

Kavita Chawla: Okay. Any oppose or abstain? Okay. And with that, the motion carries. Okay. I am doing a time check and looking at the schedule. So we're at 11:40. Our plan was to take a break right now. Does that still sound good to everybody? The next chunk of topics, which is the Oncology agents, is a 2 and 1/2 hour potentially topic, so we'll probably break in the midst of that to take a lunch break as well. Does that sound reasonable? Yeah? Okay. All right. So 10-minute lunch break, Nonye, please. Or not lunch, just break. Break.

Nonye Connor: No problem.

Marissa Tabile: Okay, Nonye, I'll put the sign up on my computer, so don't worry about it.

Nonye Connor: Okay, thank you.

[break]

Kavita Chawla: Welcome back, Board. Just making sure we have a quorum. Okay, great. All right, Nina. So before I have you get started, I think we have planned on splitting up the Oncology agents portion maybe somewhere, Marissa? Correct me if I'm wrong. So maybe do about like an hour and 15 minutes-ish before lunch, and then the remaining after.

Marissa Tabile: This is Marissa. Yep, unless the DUR Board wants to do something different, but that sounds like a good plan to me.

Kavita Chawla: Okay. So approximately go until 1:00?

Marissa Tabile: Yeah. That works for me if it works for everyone else. I don't want to speak for the rest of the Board.

Kavita Chawla: Yeah, okay. I see nodding. All right, sounds good. Thank you, Nina. Take it away.

Nina Huynh: Okay. Next, we're going to go over Oncology Agents : Antibodies - Injectable.

Marissa Tabile: Sorry, this is Marissa. Hey, Nina, you can just go straight from section to section, so you don't have to stop if you don't need.

Nina Huynh: Okay, sounds good.

Marissa Tabile: Yeah.

Nina Huynh: Thank you. Okay, on the next slide, we'll be going over multiple disease states first, and then we'll go into the drug updates after. So the first one we have is Lung Cancer. So lung cancer is the leading cause of cancer death in both men and women in the United States. Current five-year survival is estimated to be 23%, an increase from 15% reported in 2019. Decline in lung cancer mortality in the US has been accelerating in recent years, but there has been a steady decline in the incident of lung cancer diagnosed in the US. The number of diagnoses declined 2.3% in the most recent measurement. Despite these encouraging trends, there are still more US lung cancer deaths annually than deaths from breast cancer, prostate cancer, and colorectal cancer combined. The primary risk factor for the development of lung cancer is smoking tobacco is accounting for approximately 85% to 90% of all cases of lung cancer. While chemo prevention agents are not yet established, lung cancer screening using low-dose computerized tomography (LDCT) is recommended by the US Prevention Service Task Force, who expanded their lung screening cancer guidelines in 2021. The guidelines now recommend annual screening with LDCT for our patients 50 to 80 years of age who are current smokers with at least 20-pack-year smoking history and former smokers who have quit within the past 15 years. On the next slide, lung cancer is divided in two major classes, non-small-cell lung cancer and small-cell lung cancer (SCLC). These two types of lung cancer differ in their biology, treatment, and overall prognosis. NSCLC accounts for more than 80% of all

lung cancer cases. There are two major types of histology subtype of NSCLC, squamous cell and non-squamous cell. Non-squamous cell includes adenocarcinoma, which is the most common type of lung cancer diagnosed in the US and is also the most common subtype occurring in non-smokers. Depending on the state of the disease at diagnosis and the histology subtype, the treatment of lung cancer may involve surgery, radiation, chemotherapy, targeted therapy, immunotherapy, or a combination of these approaches. Okay. The next disease state is Cholangiocarcinoma, also known as Biliary Tract Cancer, which I will refer to as BTC. The tumors originate in the epithelium of the bile duct and are typically classified as either intrahepatic or extrahepatic, depending on their location within the biliary tree. BTC is rare in the United States, with approximately 8000 people diagnosed each year. This may be an underestimate because these cancers can be difficult to diagnose and may often be classified as other types of cancers, such as hepatocellular carcinoma or cancer of unknown origin. The average age of diagnosis is between 70 and 72 years of age. Treatment includes a surgical consultation to assess if the patient is a candidate for resection or possible organ transplantation. And for a patient with unresectable or metastatic disease, there is an increasing role for molecular profiling. Intrahepatic cholangiocarcinoma harbors IDH1 mutations in 10% to 20% of cases, and mutation in FGFR2 fusions occur in about 9% to 15% of cases. These mutations provide an opportunity for targeted therapies. Okay, next we have Gastric Cancer. The incident of gastric cancer has been declining steadily since the 1930s, yet it remains a major cause of cancer death in the United States and globally. The high mortality rate reflects the prevalence of advanced disease at presentation. In population-based series of Western populations, the five-year survival rate for patients with completely resected stage 1 gastric cancer is approximately 70% to 75%, and it drops to 35% or less for stage 2B disease and beyond. Efforts to improve treatment results beyond those obtained with surgery alone have included adjuvant and neoadjuvant strategies. The positive impact of such therapies on survival in patients with resected gastric cancer have become clearer over time, although there is no consensus as to the best approach. Next, we have Bladder Cancer. So in 2023, an estimated 82,290 new cases of bladder cancers will be diagnosed in the United States, and an estimated 16,710 deaths will occur in 2023 due to these malignancies. It is the fourth most common cancer in US men, but it is less common in women. The average age of diagnosis is 73 years, and as a result patients commonly have coexisting medical conditions. Urothelial carcinoma, also known as transitional cell carcinoma, is the most common type of bladder cancer. Other much rarer

bladder cancers include squamous cell carcinoma, adenocarcinoma, small-cell carcinoma, and sarcoma. Risk factors for bladder cancer include smoking, which is responsible for about half of all bladder cancers. Male gender, white race, personal family history of bladder cancer, radiation of the pelvic region, environmental exposure such as occupational or drug-related, and chronic urinary tract infections. Okay, moving along we have Cervical Cancer. So almost all cervical cancer cases are linked to infection with high-risk human papilloma virus (HPV), an extremely common virus transmitted through sexual contact. Although most infection with HPV resolves spontaneously and cause no symptoms, persistent infection can cause cervical cancer in women. Cervical cancer is the fourth most common cancer in women globally, and in 2022 an estimated 660,000 women were diagnosed with cervical cancer worldwide, and about 350,000 women died from the disease. Effective primary and secondary prevention approaches will prevent most cervical cancer, such as HPV vaccination and screening for and treating precancerous lesions. When diagnosed, cervical cancer is one of the most successfully-treated forms of cancer as long as it is detected early and managed effectively. Cancers diagnosed in late stages can also be controlled with appropriate treatment and palliative care. And with the comprehensive approach to prevent, screen, and treat, cervical cancer can be eliminated as a public health problem within a generation. Next, we have Uterine Cancer. So over 90% of uterine cancer are endometrial [audio cuts out] originating in the epithelium. The major risk factor for endometrial carcinoma, which I'll refer to as EC, is the presence of a clinical scenario associated with an excess of endogenous or exogenous estrogen without adequate opposition by a progestin. EC develops in approximately 3% of females in the United States and is the fourth most common cancer among females in the United States after cancer of breast, lung, and colon. The incident peaks between ages 60 and 70 years, but 2% to 5% of cases occur before age of 40. Most patients are diagnosed when disease is still confined to the uterus and thus have a greater than 90% five-year survival rate. EC typically present with abnormal uterine bleeding, and other presentations include abnormal cervical cytology findings on cervical cancer screening, abnormal finding on imaging, or discovered incidentally when hysterectomy is performed for benign disease. Next, we have Melanoma Skin Cancer. So the incident of melanoma skin cancer in the US is increasing, but the death rate due to melanoma is declining. Melanoma is increasing more rapidly than any other malignancy, except for lung cancer in women. Recently, there have been recent declines in mortality for melanoma. The median age of diagnosis is 65 years old, and risk factors for the development of melanoma include both genetic factors such as

skin type, inherited germline mutations, and environmental factors such as excess sun exposure, and UV-based artificial tanning. Despite the relationship to the exposure, melanoma can also occur in areas of the body without substantial sun exposure and can occur in any ethnic groups. There are also noncutaneous forms of melanoma arising from melanocytes present in mucosal membranes or the uveal tract of the eye. And the treatment of noncutaneous melanoma may differ from that of cutaneous melanoma, and treatment should be individualized in those patients. Okay. Next, we have Nasopharyngeal Carcinoma, which I will refer to as NPC. NPC is the predominant tumor type arising in the nasopharynx. Although NPC is rare in most part of the world, it is endemic in Southern China, Southeast Asia, North Africa, and the Arctic, where undifferentiated and nonkeratinizing squamous cell carcinoma is the predominant histology. The major theological factors for endemic NPC are genetic susceptibility, early age exposure to chemical carcinogens, and Epstein-Barr Virus infection. Analysis of Epstein-Barr Virus DNA and plasma is useful for screening at-risk populations for NPCs. It can detect the cancer at an early stage with a superior treatment outcome compared with those that are unscreened. Okay. Next, we have Acute Lymphoblastic Leukemia, which I will refer to as ALL. So ALL is the most common form of childhood leukemia, with 53.5% of patients diagnosed before the age of 20 years old. Approximately 29.6% of cases of ALL are diagnosed at age 45 years or older, with 13.7% of cases diagnosed at 65 years or older. Overall survival outcomes for children with ALL have improved dramatically in the last decade, such that five-year overall survival is estimated to be 89% in children. Unfortunately, as age of diagnosis increase, the overall survival rate decreases, so adolescents and young adults have an estimate of 61% overall survival, while adults diagnosed with ALL have only a 20% to 40% overall survival rate. Aside from the patient's age, prognosis is also influenced by cytogenetic markers or genetic abnormalities, and newly diagnosed pediatric ALL patients are often classified for the purpose of treatment as being low risk, standard risk, high risk, or very high risk. All treatment regimens for ALL are generally divided into phases. These phases often include an induction phase, consolidation phase, and a maintenance phase. Okay. Moving on to Esophageal Cancer. So squamous cell carcinoma and adenocarcinoma accounts for over 95% of esophageal malignant tumors. In the 1960s, squamous cell carcinoma accounted for more than 90% of esophageal tumors in the United States, and adenocarcinomas were considered uncommon. However, adenocarcinoma now accounts for more than 60% of all esophageal cancers in the US. Patients with advanced thoracic or cervical esophageal carcinoma usually present

with progressive dysphasia and weight loss. The diagnosis of esophageal and esophagogastric junction cancer is usually established by endoscopic biopsy. Early cancers may appear as superficial plaques, nodules, or ulcerations. Advanced lesions may appear as strictures, ulcerated masses, circumferential masses, or large ulcerations. The endoscopic appearance of a large mucosal mass is frequently diagnostic of esophageal cancer. Biopsies confirm the diagnosis in more than 90% of cases. The prognosis of esophageal cancer is strongly associated with the disease stage, accurate clinical staging of both local tumor extent and the presence or absence of distant metastasis is critical for estimating prognosis and selecting the appropriate treatment strategy. Okay. Now, we have Ovarian Cancer, which includes fallopian tube or primary peritoneal cancer. The risk of ovarian cancer increases with age, with the medium age of diagnosis of 63 years. The five-year survival rate is 50.8%, and more than half of the patients present with advanced disease. Ovarian cancer has been shown to have a higher prevalence in families with BRCA1 or BRCA2 genotypes, and in these patients, the onset of disease is usually at a younger age. However, patient with these mutation accounts for only 15% of all ovarian cancers. Primary treatment for advanced ovarian cancer usually begins with cytoreductive surgery to remove as much gross disease as possible because patients with more complete debulking have better outcomes. Majority of patients, excluding those with very early stage disease, are recommended to receive postoperative adjuvant systemic chemotherapy. Recommended protocols generally include a taxane and a platinum agent. Okay. Moving along, we have Follicular Lymphoma. This is the most common subtype of indolent non-Hodgkin's lymphoma and accounts for approximately 22% of all newly diagnosed cases of non-Hodgkin's lymphoma. While the clinical course of follicular lymphoma is usually indolent, with about 90% of diagnosed patients surviving to five-year post diagnosis and about 50% of patients surviving to 20-year post diagnosis. About 3% of patient progressed to a more aggressive lymphoma such as diffuse large B-cell lymphoma. Okay. Next, is Multiple Myelomas, which I will refer to as MM. So MM is a malignant neoplasm of plasma cells that accumulate in the bone marrow leading to bone destruction and marrow failure. MM accounts for approximately 1.8% of all malignancies and 18% of all hematologic malignancies in the US. The median age of diagnosis is 69 years old, and the five-year relative survival rate is 57.9%. The overall survival rate now is estimated to be 8 to 10 years among patients with standard risk disease, but it is significantly lower in patients that exhibit high risk features. Patients with symptomatic MM must have at least one myeloma-defying event, which may include hypercalcemia, renal

insufficiency, anemia, or lytic bone lesions. This constellation of effects is often referred to by the acronym, CRAB, and is likely an indicator of an organ dysfunction associated with MM. MM is sensitive to a variety of agents, but the disease is not considered curable with current available drug therapies. The clinical course of MM usually involves initial response to chemotherapy, but these responses may be transient. Best retreatment with multiple rounds of therapy with different agents may be required to treat relapse. Next, we have on the next slide is Hepatocellular Carcinoma, which I will refer to as HCC. The incidence of liver cancer stabilized in the past few years, particularly in men. However, the stabilization followed decades of increases. Rates for younger adults less than 50 years decreased from 2015 to 2019 by 2.6% per year for liver cancer. In March 2024, American Society of Clinical Oncology updated its guidelines on the use of systemic therapy for advanced HCC. The recommended first-line treatment and patients with Child-Pugh Class A advanced HCC who have an ECOG performance score of 0 to 1 or atezolizumab plus bevacizumab or durvalumab plus tremelimumab. Alternatives are sorafenib, lenvatinib, or durvalumab. Second-line treatment is based on first-line treatment use and includes tyrosine kinase inhibitor, nivolumab, ipilimumab, as well as durvalumab plus tremelimumab or atezolizumab plus bevacizumab if not used as first-line. For third-line treatment, any of the previously mentioned agents may be used if they do not have an identical mechanism of action as a previously used agent. Okay. Next, we have Alveolar Soft Part Sarcoma, which I will refer to as ASPS. So ASPS is a rare slow-growing soft tissue tumor of an unclear cause. It is among the least common sarcoma, representing 0.2% to 1% of large studies of soft tissue sarcomas. ASPS is characterized by a painless mass that most commonly arises in the leg or buttocks, with a particular affinity to travel to the lungs as multiple [audio cuts out] nodules, presumably while the sarcoma itself is still small. This disorder is very rare because it involves a specific breaking and joining event between two chromosomes called an unbalanced translocation. This finding is observed in essentially all patients with ASPS examined so far and cannot be passed on to children. There are no families in which multiple family members have this disorder. ASPS tends to occur more often in younger individuals, specifically adolescents and young adults, and treatment is with surgery for the primary place where the sarcoma arises. Radiation therapy is sometimes considered as an adjunct to surgery, depending on the tumor characteristics. For disease that travels to the lung, sometimes surgery is possible to remove nodules, but often systemic therapy is the only option for treatment. Okay. We finally made it through the disease states, and now we're going over the drug updates. So first we have Keytruda

(pembrolizumab), which has multiple updates in the past year. So the first one is in October of 2023, FDA approved a new indication for treatment of patient with resectable tumors greater or equal to 4 cm or node-positive. NSCLC in combination with platinum containing chemotherapy as neoadjuvant treatment, and then combined as a single agent as adjuvant therapy after surgery. In November 2023. Keytruda had three updates on indications. So it was approved for use in combination with gemcitabine and cisplatin for locally advanced unresectable or metastatic biliary tract cancer. And it revised the indication of pembrolizumab with trastuzumab with fluoropyrimidine, and platinum-containing chemotherapy first-line treatment of patients with locally advanced unresectable or metastatic HER-positive gastric or gastroesophageal junction adenocarcinoma to restrict use in patients whose tumor express program death-ligand 1 as determined by an FDA-approved test. It was also approved for use in combination with fluoropyrimidine and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma. In December of 2023, FDA expanded the advanced metastatic urethral cancer indication to include the following: Keytruda in combination with enfortumab vedotin-ejfv for treatment of adults with locally advanced or metastatic urethral cancer. They removed the limitation of ineligibility versus platinum-containing chemotherapy. They also granted this indication full approval from Accelerated Approval. In January of 2024, FDA approved a new indication for use in combination with chemoradiotherapy for treatment of patient with FIGO 2014 Stage III-IVA cervical cancer. And then in June 2024, FDA approved a new indication for use in combination with carboplatin and paclitaxel followed by Keytruda as a single agent for the treatment of adults with primary advanced or recurrent Endometrial Carcinoma. On the next four slides I have listed out the full list of FDA indication for Keytruda. So again, it covers melanoma, non-small-cell lung cancer, malignant pleural mesothelioma, head and neck squamous cell cancer, classical Hodgkin's lymphoma, primary mediastinal large B-cell lymphoma, urothelial cancer, microsatellite instability-high or mismatch repair deficient cancer, microsatellite instability-high or mismatch repair deficient colorectal cancer, Merkel cell carcinoma, hepatocellular carcinoma, gastric cancer, esophageal cancer, cervical cancer, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high cancer, triple-negative breast cancer, adult [indistinct] classical Hodgkin's lymphoma, and adult primary mediastinal large B-cell lymphoma, biliary tract cancer, and cutaneous squamous cell carcinoma. Okay. The recommended dosing is stratified by indication and age and is administered as an intravenous

infusion over 30 minutes after dilution. Here I've listed the recommended doses for the new and revised indication, which happened to all be 200 mg every three weeks or 400 mg every six weeks. Our next drug is Opdivo (nivolumab). So in October 2023, FDA approved an expanded indication for melanoma stage 2b and stage 2c. Updated indication is for adjuvant treatment of patients greater or equal to 12 years old with complete resected indication for melanoma stages 2b, 2c, 3, or 4 melanoma. In March of 2024, a new indication was approved for in combination with cisplatin and gemcitabine for first-line treatment of adults with unresected or metastatic urothelial carcinoma. On this slide and the next two slides, I've listed the full indication. So there is melanoma, non-small-cell lung cancer, malignant pleural mesothelioma, renal cell carcinoma, squamous cell carcinoma of the head and neck, classic Hodgkin's lymphoma, and urothelial carcinoma. We also have colorectal cancer, hepatocellular carcinoma, esophageal cancer, and gastric cancer. The recommended dose for Opdivo is stratified by indication, age, and weight, and is administered by IV infusion after dilution based upon recommended infusion rate for each indication. Here I listed the dosing for the updated indications. So for adjuvant therapy of melanoma in pediatric patients less than 40 kg, the recommended dose is 3 mg/kg every two weeks or 6 mg/kg every four weeks. For adults and pediatric at least 40 kg, the recommended dose is 240 mg every two weeks or 480 mg every four weeks. For adjuvant treatment of urothelial carcinoma, the recommended dose is 240 mg every two weeks or 480 mg every four weeks. Okay. On the next slide, we have Loqtorzi. So in October 2023, FDA approved Loqtorzi (toripalimab-tpzi) a PD-1-blocking antibody as a first FDA-approved medication for the following indications: So it was approved for in combination with cisplatin and gemcitabine for first-line treatment of adults with metastatic or recurrent locally advanced nasopharyngeal carcinoma and as a single agent for treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after platinum-containing chemotherapy. Warnings include immune-mediated adverse reactions, infusion-related reactions, complications of allogenic hematopoietic stem cell transplantation, and embryo fetal toxicity. The recommended dose for in combination with cisplatin and gemcitabine is 240 mg IV every three weeks, and the recommended dose as a single agent is 3 mg/kg IV every two weeks. The first infusion can be infused over 60 minutes, and if there are no infusion-related reactions during the first infusion, then the subsequent infusions can be administered over 30 minutes. Loqtorzi is available as 240 mg/6 mL solution in a single-dose vial. Okay, next, we have Padcev (enfortumab vedotin-ejfv). So in December 2023, FDA approved expanded

indication for use in combination with pembrolizumab for the treatment of adults with locally advanced or metastatic urothelial cancer. For the expanded indication, the recommended dose is 1.25 mg/kg up to a maximum dose of 125 mg given as an IV infusion over 30 minutes on day 1 and 8 of a 21-day cycle, until disease progression or unacceptable toxicity. Okay. Next, we have Besponsa (inotuzumab ozogamicin). So in March 2024, FDA approved for an expanded indication for treatment of relapsed or refractory CD22-positive B-cell precursor ALL in adults, in pediatrics at least one year old. Previously, this was only approved for adults with this indication. The recommended dose is based on patient's body surface area, and the first cycle for all patients is 1.8 mg/m^2 per cycle administered as three divided doses on day 1, day 8, and day 15. Cycle one is three weeks in duration but may be extended to four weeks if the patient achieves a complete remission, or complete remission with incomplete hematologic recovery, and/or to allow recovery from toxicity. Okay, on the next slide we have Rybrevant (amivantamab-vmjw). In March 2024, FDA approved indication for combination with carboplatin and pemetrexed for first-line treatment of adults with locally-advanced or metastatic NSCLC with EGFR exon 20 insertion mutation as detected by an FDA-approved test. FDA has also granted traditional full approval as a single agent for treatment of adults with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations as detected by an FDA-approved test, whose disease has progressed or after platinum-based chemotherapy. In August of 2024, a new indication was approved for in combination with lazertinib for first-line treatment of adults with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon L858R substitution mutation, as detected by an FDA-approved test. On the next slide, the recommended dose is based on baseline body weight and is administered as an IV infusion after dilution. It is for the use in combination with carboplatin and pemetrexed. The recommended dose is administered every three weeks, and the order of administration is Pemetrexed first, carboplatin second, and then Rybrevant last. For use in combination with lazertinib, is administered weekly from Week 1 to 5 then every two weeks starting Week 7 and onward. No doses should be given during Week 6. Treatment should be administered until disease progression or unacceptable toxicity, and when given on the same day, Rybrevant should be administered after lazertinib. And for this indication, it is recommended to administer anticoagulant prophylaxis during the first four months of treatment to prevent venous thrombotic events. Okay. In March of 2024, FDA approved Tevimbra (tislelizumab-jsgr), a PD1-blocking antibody as monotherapy for treatment of adults with unresectable or metastatic

esophageal squamous cell carcinoma after prior systemic chemotherapy and did not include PD-L1 inhibitor. Warnings are similar to the previous drugs, so immune-mediated adverse reactions, infusion-related reactions, complications of allogenic hematopoietic stem cell transplantation, and embryo-fetal toxicity. The recommended dose is 200 mg as an IV infusion once every three weeks until disease progression or unacceptable toxicity. And -- the first infusion can be administered over 60 minutes and, if tolerated, subsequent infusions may be administered over 30 minutes. Tevimbra will be available as 100 mg/10 mL solution in a single-dose vial. Okay. Next, we have Elahere (mirvetuximab soravtansine-gynx). So in March of 2024, FDA converted the Accelerated Approval to full approval for adult patients with folate receptor alpha-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. On the next slide, we have Enhertu (fam-trastuzumab deruxtecan-nxki). So in April of 2024, FDA granted an Accelerated Approval for treatment of adults with unresected or metastatic HER2-positive immunohistology chemistry (IHC 3+) solid tumors, who have received prior systemic treatment and have no satisfactory alternative treatment options. And for the new indication, the recommended dose is 5.4 mg/kg given as an IV infusion once every three weeks until disease progression or unacceptable toxicity. And next, we have Tivdak (tisotumab vedotin-tftv). So in May of 2024, FDA granted traditional approval for recurrent or metastatic cervical cancer with disease progression on or after chemotherapy in adult patients. Tivdak was previously approved for Accelerated Approval for this indication. Okay. Moving along, we have Imdelltra (tarlatamab-dlle). The FDA granted an Accelerated Approval for treatment of adults with extensive stage small-cell lung cancer with disease progression on or after platinum-based chemotherapy. Imdelltra carries a Blackbox Warning for cytokine release syndromes, including serious or life-threatening reactions, and neurologic toxicity, including immune effector cell-associated neurotoxicity syndromes (ICANS), and require patient monitoring for approximately 24 hours during and after the first two doses, and patients should remain within one hour of the healthcare settings for a total of 48 hours. The observation period can decrease for subsequent doses. Other warnings include cytopenia, hepatotoxicity, and embryo-fetal toxicity. Imdelltra is administered through IV infusion over 1 hour, with step-up doses given on cycle 1. Day 1 is 1 mg, day 8 is 10 mg, and day 15 is 10 mg, followed by administration of 10 mg every two weeks until disease progression or unacceptable toxicity. And it will be available as 1 mg or 10 mg of lyophilized powder in a single-dose vial for reconstitution and further

dilution. Okay. Next, we have Blincyto. So in June 2024, FDA-approved a new indication for Blincyto (blinatumomab) for treatment of CD19-positive Philadelphia chromosome-negative B-cell precursor ALL in the consolidation phase of multiphase chemotherapy in adults and pediatric patients at least one month of age. For the new indication, Blincyto should be administered as a single cycle of 28 days of continuous infusion, followed by a 14-day treatment-free interval, a total of 42 days. For patients weighing greater than or equal to 45 kg, the recommended dose is 28 mcg/day, and for patients less than 45 kg, the recommended dose is 15 mcg/m^2 per day, not to exceed the 28 mcg per day. Okay. Next, we have Imfinzi (durvalumab). So in June 2024, FDA approved a new indication for use in combination with carboplatin and paclitaxel followed by Imfinzi as a single agent for treatment of adults with primary advanced or recurrent endometrial cancer that is a mismatch repair deficient. And then in August 2024, FDA approved another indication for use with a platinum-containing chemotherapy as neoadjuvant treatment, followed by single agent Imfinzi as adjuvant treatment after surgery for adults with resectable tumors greater or equal to 4 cm or node-positive NSCLC, and no known EGFR mutations or anaplastic lymphoma kinase rearrangement. On the next slide, we can see the recommended dose as indicated by the indication, patient weight, and schedule. So dMMR Endometrial Cancer patients greater or equal to 30 kg, the recommended dose is 1120 mg in combination with carboplatin and paclitaxel every three weeks for six cycles, followed by 1500 mg every four weeks as a single agent. Patients less than 30 kg for the dMMR endometrial cancer, the recommended dose is 15 mg/kg every three weeks in combination with carboplatin and paclitaxel for six weeks, and then you would follow as a single agent 20 mg/kg every four weeks. For resectable and SCLC patients greater than or equal to 30 kg, the recommended dose is 1500 mg. And for patients less than 30 kg, the recommended dose is 20 mg/kg. It should be administered every three weeks if it's neoadjuvant treatment, and if it's for adjuvant treatment, then it will be every four weeks. Okay. Next, we have in Epkinly (epcoritamab-bysp). In June 2024, FDA granted Accelerated Approval for the treatment of adults with relapsed or refractory follicular lymphoma after at least two lines of systemic therapy. The recommended dose for follicular lymphoma requires step-up dosing over the course of 10 cycles. Each cycle length is 28 days to a 48 mg dose given on day one of each cycle by the 10th cycle. Okay. In August 2024, a new indication for Darzalex Faspro, which is a combination of daratumumab and hyaluronidase-fihj, was approved in combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in patients with newly diagnosed multiple

myeloma who are eligible for autologous stem cell transplant. There is a limitation. It is not indicated and is not recommended for the treatment of patient with light chain amyloidosis who have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB outside of controlled clinical trials. Okay. The recommended dose is 1800 mg of daratumumab and 30,000 units of hyaluronidase administered subcutaneously into the abdomen over approximately 3 to 5 minutes according to recommended schedule. Next, we have Jemperli (dostarlimab-gxly). The FDA has approved it in combination with carboplatin and paclitaxel, followed by Jemperli as a single agent for all patients with primary advanced or recurrent endometrial cancer. Jemperli was previously only approved for this indication in patients with mismatch repair deficiency or microsatellite instability-high tumors. Recommended dose for this indication is 500 mg IV every three weeks for six cycles in combination with carboplatin and paclitaxel, and then 1000 mg IV every six week as monotherapy until disease progression or unacceptable toxicity for up to three years. Okay. Lastly, we have Tecentriq Hybreza (atezolizumab with hyaluronidase-tqjs), and this was approved as the first and only PD-L1 inhibitor for subcutaneous injection in the United States. It has been approved for all the adult indications of IV atezolizumab, Tecentriq, including treatment of certain patients with NSCLC, SCLC, HCC, melanoma, and ASPS, which I listed out under FDA indications. Okay. Warnings include immune-mediated adverse reactions, infusion-related reactions, complication of allergenic HSCT and embryo-fetal toxicity. It is available as 1875 mg atezolizumab and 30,000 units hyaluronidase per 15 mL solution in a single-dose vial. And the recommended dose and administration is different than the IV Tecentriq (atezolizumab) product. So the recommended dose for Tecentriq Hybreza is 115 mL injection administered subcutaneously into the thigh over approximately 7 minutes every three weeks by a healthcare professional. Okay, that's it for the Antibodies IV, so we're going to go over to our Oral Oncology Agents now. So this one is Oncology Agents : Gamma Secretase Inhibitors. Okay, so first we'll go over Desmoid Tumors. So for every 1 million people worldwide, two to four are diagnosed with a desmoid tumor per year. In 5% to 10% of cases, desmoid tumors may run in families and is also known as aggressive fibromatosis or desmoid-type fibromatosis. It is most common in people between the age of 15 and 60 years old and are more common in females than males. Desmoid tumors grow from the connective tissue in the body and can occur anywhere in the body, and while the cells of the desmoid tumor do not travel to other parts of the body like cancer can, they can invade nearby tissue and are often very painful. Desmoid tumor can be hard to predict. They can shrink and go away on their

own, or they can remain the same size, or they can grow very quickly. Treatment options include watch and wait for the cases that where the tumor grows very slowly or even shrinks without any treatment. Surgery has been the standard treatment for desmoid tumors in the past, but this is changing given that the tumor often returns to the same location after surgery. The doctors are looking for other treatment options. Radiation therapy is also an option for some desmoid tumors; however, it may cause other cancers in the future. And the chemotherapy, there is no standard chemotherapy for desmoid tumors, but promising new drugs have been shown to shrink these tumors. Okay, on the next slide, we have Ogsiveo (nirogacestat). So in November 2023, FDA approved for adults with progressing desmoid tumor who require systemic treatment. Warnings include severe diarrhea, so is recommended to monitor and dose and modify for Grade 3-4 diarrhea. Ovarian toxicity may occur, so it's recommended that female reproductive function and fertility may be impaired and to advise females of reproductive potential of the potential risk prior to treatment and monitor routinely. Hepatotoxicity, so elevated AST and ALT can occur, so it's recommended to monitor AST and ALT regularly, and modify dose as recommended. It can also cause non-melanoma skin cancer, so it's recommended to perform dermatologic examination prior to initiation and routinely during treatment. Electrolyte abnormalities may occur. It is recommended to monitor phosphate and potassium regularly and modify dose as recommended. And then it also may/can cause embryo-fetal toxicity. Recommended dose is 150 mg twice daily until disease progression or unacceptable toxicity, and it is available as 50 mg oral tablets. Next, we're going over Oncology Agent HIF-2-Alpha Inhibitors. Okay. So we're going to go over Renal Cell Carcinoma, which I will refer to as RCC. So cancer of the kidney and renal pelvis account for approximately 4% of all newly diagnosed cancers in the United States with a 5% incident in male and a 3% incident in females. The median age of diagnosis is 65 years, and greater than 75% of cases are diagnosed in patients ages 55 years or older. The overall five-year survival for patients diagnosed with RCC was 77.6% from the period of 2013 to 2019. If the disease is localized at time of diagnosis, outcomes are excellent with the five-year survival of approximately 93%. However, patient diagnosed with advanced metastatic disease account for approximately 15% of diagnoses have much poorer outcomes with approximately a 17.4% survival rate at five years. Approximately 85% of kidney tumors are renal cell carcinoma, and approximately 70% of all RCC have a clear-cell histology. Other less common histologies are usually grouped together as non-clear-cell tumors. The incidence of RCC in men is more than twice of that in women in the United

States. And the most common presenting triad of symptoms include hematuria, flank mass, and flank pain. However, as the use of routine imaging has become more widespread, the frequency of incidental detection of RCC has increased, and only about 30% of patients are now diagnosed on the basis of symptoms. Okay, here we have the 2023 NCCN Guidelines. So for first-line systemic therapy of favorable risk, clear-cell histology, relapse or stage 4 RCC, they recommend a tyrosine kinase inhibitor plus an immune checkpoint inhibitor as a Category 1 preferred option. Specifically, axitinib plus pembrolizumab, or cabozantinib plus nivolumab, or lenvatinib plus pembrolizumab are the three TKI/CPI regimens included. Other recommended regimens for the same group of patients include monotherapy with sunitinib or pazopanib or the combination of axitinib plus avelumab, or ipilimumab plus nivolumab. Axitinib monotherapy is an NCCN category 2B recommendation and is listed as useful in certain circumstances. For the same group of patients with poor or immediate risks rather than favorable risk, ipilimumab plus nivolumab and the three TKI/CPI regimens are listed as category 1 preferred along with single agent cabozantinib being a category 2A preferred option. Other options largely mirror the favorable risk options defined above. For subsequent therapy of RCC with clear-cell histology, no preferred options are provided. Then other recommended regimen options are based on whether the patient is immuno-oncology therapy naive or has received prior IO therapy, which are all category 2A. And here, I've listed the list of options for IO therapy for these patients. For patients with non-clear-cell histology, single agent cabozantinib, sunitinib, axitinib, pazopanib, and everolimus are all category 2A recommendations, though cabozantinib and sunitinib are the preferred regimens. Okay, here we have Welireg (belzutifan), which had an FDA expanded indication in December 2023. FDA approved for patient with advanced RCC, PD-1, or PD-L1 inhibitor with a vascular endothelial growth factor tyrosine kinase inhibitor. And then the recommended dose for the expanded indication is 120 mg administered orally once daily with or without food. Okay. Next, we have Oncology Agent : KRAS Inhibitors. So we will be going over the disease state Colon Cancer. In the US, colon cancer is the third most diagnosed cancer as well as the second leading cause of death from cancer in both men and women. In 2023, an estimated 106,970 cases of colon cancer will be diagnosed, and an estimated 52,550 deaths will occur in the US. Colon cancer typically affects older adults, though it can happen at any age. Treatments include surgery, radiation therapy, and medicines such as chemotherapy-targeted therapy and immunotherapy. Okay. So we have Krazati (adagrasib), which has a new indication in June 2024. So FDA-approved accelerated approval for use in

combination with cetuximab for treatment of adults with KRAS G12C-mutated locally advanced or metastatic colorectal cancer as determined by FDA-approved test who have received prior treatment with fluoropyrimidine-oxaliplatin and irinotecan-based chemotherapy. The recommended dose is 600 mg orally twice daily. Okay. And this is our last Oncology class, Oncology Agents : Ornithing Decarboxylase Inhibitors. So we will be going over Neuroblastoma, and this is cancer that starts in very early forms of nerve cells, most often found in an embryo or fetus. This is the most common cancer in infants, mainly younger than one years old. There are about 700 to 800 new cases of neuroblastoma each year in the United States, and some neuroblastomas grow and spread quickly, while others grow very slow. Sometimes in very young children, the cancer cells die for no reason, and the tumor just goes away on its own. And then in other cases, the cells sometime mature on their own and then grow into normal ganglion cells and stop dividing. Treatment depends on the risk group of the cancer, the child's age, and other factors and might include more than one type of treatment. So treatment options include surgery, chemotherapy and related drugs, radiation therapy, high-dose chemotherapy, and stem cell transplant, retinoid therapy, and immunotherapy. Okay. And we have Iwilfin (eflornithine). So in December 2023, FDA approved to reduce the risk of relapse of high-risk neuroblastoma in adults and pediatric patients with at least a partial response to prior multiagent multimodality therapy, including anti-GD2 immunotherapy. Warnings include hearing loss, myelosuppression, and hepatotoxicity. A baseline audiogram, CBC, and liver function tests should be performed prior to starting therapy. Iwilfin may also cause embryo-fetal toxicity as well. The recommended dose is based on surface area and should be taken orally twice daily with or without food until disease progression, unacceptable toxicity, or a maximum of two year, and it is available as oral tablets 192 mg. And that concludes our Oncology section. I'm happy to take any questions.

Kavita Chawla: Kavita here. Amazing marathon run there, Nina. It is especially difficult to pronounce medication names, too.

Nina Huynh: Yes.

Kavita Chawla: All right, questions for Nina as Marissa is pulling up our PDL? Okay. All right. Go ahead, Marissa.

Marissa Tabile: Hi, this is Marissa. Great job. Nina marathoning through that. Definitely kudos to you. We are actually, I think, right on schedule, so that's perfect. So I'll be going through the Oncology agents that Nina just went through in very deep detail, but I'll just do the overview of the AHPDL. For the Oncology Agents : Antibodies : Injectable drug class, you will see that for the preferred status. A lot of them have X. And to be completely honest with you, we do have to re-examine this class. Some of these products on here we do include on the PDL, some of them we don't, so there are some discrepancies. But for the sake of our DUR Board Meeting today, I will just consider us reviewing this class as a whole. These are typically medically administered or professionally administered drugs. That's why you don't see that they have a preferred status because we would only allow these through the medical benefit. You wouldn't typically see these through point of sale. So we do cover them on the medical side, most likely. I would assume that a lot of these probably do have PA on them, just as like a general rule of thumb. So I can't really speak too much on that, but that's really all that's going on in that class. We don't have any that are preferred over the other at this time, but just wanted to caveat that we are still taking a look at this class. And we will determine whether or not we do truly want to include it on the PDL or not because a lot of the IV drugs are medically administered drugs. We typically don't include them on the PDL unless there is some carve out or some type of circumstance where we would see it. But that's just kind of what's going on right now. For the Gamma Secretase Inhibitors, we have Ogsiveo, and actually just with all of the other Oncology agents, we pretty much have them all preferred with PA. We don't have any clinical policies for them, so they would be reviewed for medical necessity per the labeling. But that's generally what's going on, nothing too exciting in this class as far as utilization management, but we do cover them on our AHPDL.

Kavita Chawla: Marissa, Kavita here. I see Peter has a question.

Peter Barkett: Yeah. Thanks, Peter. Do any of these medications have [indistinct] care associated with them in addition to medical necessity review? Or is that the way that the contracts are written, is that not taken into account any differential cost for site of care?

Marissa Tabile: This is Marissa. I don't believe we do take that into account. Yeah, I don't. I don't believe we do look at that. Unless there is maybe some circumstance where we would have to look at that, like inpatient versus outpatient or [cross-talk] --

Peter Barkett: Right and [cross-talk] --

Marissa Tabile: Yeah, in that regard, then yes, we would definitely take that into consideration, but if it's like a regular kind of covered outpatient drug, then not really.

Peter Barkett: Right. The reason I bring it up is I think more often site of care has been implicated as a utilization management strategy than actually medical necessity criteria. A lot of these medications for other health plans that have been moved into kind of site of care restrictions to -- when appropriate, have people treated in say like an outpatient physician office as opposed to an outpatient hospital setting, and that gets really tricky. And so, anyway, I was -- I know that Medicare doesn't -- the way that the Medicare contracts work, actually, there is just no such -- they don't recognize site of care, and so I was curious how that worked for Apple Health.

Marissa Tabile: Yeah. I will say as far as medical drugs go, when we do review them, like when they come out, we do take into consideration, like, do we want to allow it through an outpatient hospital or professional setting. So that might be like maybe one of them. I guess it is like you were saying, a utilization management, but that is really the extent, and then also considering if it is inpatient only. That's real the extent to -- what we consider for those. I guess that's all I could speak to. It does get kind of tricky sometimes. There are some drugs that are coming out nowadays where I think they are considered covered outpatient drugs, but they are administered inpatient, and everything for that has been kind of tricky for those types of drugs that have been coming out. So it's kind of unchartered territory or new territory that we're having to maneuver around when those do happen.

Kavita Chawla: Thank you for that. Marissa. Other questions for Marissa or for Nina? Okay. And then, Nonye, do we have any stakeholders? Sorry, I'm pulling up.

Nonye Connor: We did not have any pre-registered stakeholders, and I do not see anyone's hands up.

Kavita Chawla: Okay. So I guess with that we could look at the motions.

Marissa Tabile: And this is Marissa. I'm actually going to add the Antibodies because that was not on here initially. 1, 2, 3, 4, 5, yep. All right. And that should be good to go.

Laura Beste: I think there's a typo under antibodies.

Kavita Chawla: Laura's got a really good eye.

Laura Beste: I thank you for catching, and that did come up, actually, and I'm surprised I caught that very quickly. Thank you.

Michael Corsilles: This is Michael Corsilles. [Audio cuts out] I'll read the motion. I move that all products in the drug class listed on Slide 7 are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products [audio cuts out] 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 [audio cuts out] 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 second the motion.

Kavita Chawla: Thank you. All in favor, please say aye.

Multiple Speakers: Aye. Aye. Aye. Aye.

Kavita Chawla: Any oppose or abstain? Okay, great. With that the motion carries. And after that marathon, Nina deserves a break for lunch. Nonye, does that sound okay?

Nonye Connor: Sounds good.

Kavita Chawla: Okay. See you all back in 30 minutes. Thank you.

Nonye Connor: Thank you.

[lunch break]

Kavita Chawla: We can hand it -- 1, 2, 3 -- yes. All right. I see most of our Board is back. So Nina, whenever you are ready to resume.

Nina Huynh: Okay, thank you. Next, we have Endocrine and Metabolic Agents : NH3 Inhibitors.

Marissa Tabile: Hey, this is Marissa. Um, Nina, for the next two for the NH3 and I think the Parathyroid, you can just go straight to Parathyroid after since we'll be doing a motion for both of them, one motion for both.

Nina Huynh: Okay, perfect. All right. So first, we're going to go over Hyperphosphatemia. Hyperphosphatemia is a risk factor for cardiovascular disease (CVD). Studies have shown an increased risk of mortality in patients with CKD stage 5 receiving dialysis with hyperphosphatemia. Long-term hyperphosphatemia along with elevated calcium times phosphorus product values greater or equal to 55 mg^2/dL^2 is linked to an increased risk of vascular, valvular, and other soft tissue calcifications in patients with CKD. Soft tissue calcification occurring in vascular and cardiac tissue can lead to increased morbidity and mortality, and patients with elevated calcium phosphorus product values are at a significantly higher risk of death. The calcium phosphorus product is calculated by using the patient's corrected serum calcium level and serum phosphorus level. On the next slide is the 2017 KDIGO Guideline. Since it's well over a year, I just included it here for completeness' sake. So on the next slide, we have Xphozah (tenapanor), which is a new drug that was FDA approved in October 2023 to reduce serum phosphorus in adults with CKD on dialysis as an add-on therapy in patients who have inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. It is contraindicated in pediatric patients under 6 years of age and patient with known or suspected mechanical gastrointestinal obstruction. It can also cause severe diarrhea. The recommended dose is 30 mg orally twice daily before the morning and evening meals. It is recommended to monitor serum phosphorus and adjust the dose as needed to manage gastrointestinal tolerability. And it's not recommended to take it right before a hemodialysis session, and it's recommended to take it right before the next meal following dialysis. It is available as 10 mg, 20 mg, and 30 mg oral tablets. Okay. Next, we have Endocrine and Metabolic Agents : Parathyroid Hormones. And to point out on the previous slide, the medication that we're going over is under the Prime Therapeutic Market Basket Hyperparathyroidism, but the agent we're covering is actually indicated for hypoparathyroidism. So hypoparathyroidism is a rare disease most often caused by damage to the parathyroid glands from surgery or autoimmune disease. Patients with hypoparathyroidism has low level of parathyroid hormone which leads to hypocalcemia. Patients with hypoparathyroidism are typically treated with

active vitamin D and calcium to raise blood calcium into the low normal range and can require large doses of calcium taken more than once a day. Symptoms of hypoparathyroidism vary depends on blood calcium levels and can include tingling or numbness in the fingertips, toes, and lips, muscle cramps, spasms, and seizures. So we have here Yorvipath (palopegteriparatide), which was FDA approved in August 2024 for the treatment of hypoparathyroidism in adults. For limitation, it was not studied for acute postsurgical hypoparathyroidism, and the titration scheme was only evaluated in adults who first achieve an albumin corrected serum calcium of at least 7.8 mg/dL using calcium and active vitamin D treatment. Warnings include unintended changes in serum calcium level related to number of daily injections, so make sure to use only one daily Yorvipath injection. Using two injections to achieve the recommended once-daily dosage increases the variability of the total delivered dose. It can also cause serious hypercalcemia and hypocalcemia, so it is recommended to periodically measure serum calcium and monitor for signs and symptoms and can cause a potential risk of osteosarcoma as well. The dosing is individualized based on serum calcium and may be administered by patient or caregiver after proper training. Recommended starting dose is 18 mcg subcutaneously once daily and is titrated in 3 mcg increments [audio cuts out] or decrements, with the goal of maintaining serum calcium within the normal range without the need of active vitamin D or therapeutic calcium doses. The maximum dose is 30 mcg once daily, and if adequate response is not achieved with the 30 mcg dose, consider adding or restarting calcium and/or vitamin D therapy and/or seek other treatment options. It is available as 168 mcg/0.5 mL, 294 mcg/mL, or 420 mcg/1.4 mL in a single patient use prefilled pen. And that concludes the Endocrine and Metabolic agents. I'll answer any questions.

Kavita Chawla: Should we go ahead with the medications, or do we have any stakeholders?

Marissa Tabile: This is Marissa. Sorry about that, Kavita. Okay. I'll go through the Endocrine Metabolic Agents : NH3 Inhibitors and Parathyroid Hormones. The two drugs of note are really just the two drug products that Nina just went over, so Xphozah and Yorvipath. And as you can see on our PDL, we do have them both preferred with PA. We don't have a policy for them, so just follow our usual medical necessity reviews. And I can answer any questions about the PDL.

Kavita Chawla: There we go. [cross-talk] I think we have two -- let's see here -- we have two stakeholders listed. Paul Miner, are you here?

Nonye Connor: Yep. So Paul if you can answer [cross-talk] the question on the screen?

Paul Miner: [Cross-talk] Yes, hello. Hello? Can you hear me?

Nonye Connor: Yes, I can hear you.

Paul Miner: [Cross-talk] Oh great.

Nonye Connor: [Cross-talk] If you can answer the question on the screen, please.

Paul Miner: Um, I thought I did. I don't see a question on the screen.

Nonye Connor: Uh oh.

Paul Miner: Oh, um, name or you speak on behalf of a company and organization? Yes, I am. I'm an employee of Ascendis Pharma.

Nonye Connor: Okay.

Kavita Chawla: And if you can, yeah, the remain [cross-talk] --

Paul Miner: Right [cross-talk] --

Kavita Chawla: [Cross-talk] The remainder of the questions on there.

Paul Miner: Oh, other questions? Um, are your provider? No, I'm not. I'm not a patient. I do not have any conflicts of interest to report other than I am an employee of the Ascendis Pharma, which is the manufacturer of Yorvipath. My name is Paul Miner.

Nonye Connor: Thank you.

Paul Miner: Sorry about that.

Nonye Connor: No, it's okay. Okay?

Paul Miner: Great. Well, thank you, and good afternoon, everyone. My name is Paul Miner. I'm a Pharmacist and National Director with Medical Affairs for Ascendis Pharma, and I realize that you already thoroughly reviewed the Parathyroid Hormone Analogs and was uncertain as to how this review would go with the Endocrine Metabolic Agents. So I know that you have introduced the product and that you have it available for patients in a preferred positioning. So rather than reiterate many of the things that were already addressed, I would make myself available to any questions. I did want to just take the opportunity to share with you that this is the first and only product available, and that while approved in August of this year, August 9th, it is not yet commercially available. Anticipate it sometime in December or early part of 2025. Um, the point I wanted to raise is that there is no other therapy available. There was a product Takeda had, Natpara, which was being made available for some patients through a special use program, which will be sunsetting this year. So I just wanted to make that available information. I'm sure you knew it, but that you may have been getting some requests when it's commercially available prior to a review. But since you are reviewing it and you have made it preferred and available, I will defer the remainder of my time back to Committee. And thank you for the consideration. I will make myself available for any questions that you may have.

Kavita Chawla: Thank you, Paul. Any questions from the Board for Paul? Okay, great. Next, I see Michelle Reyes. Are you online?

Nonye Connor: Okay, Michelle?

Michelle Reyes: Can you hear me?

Nonye Connor: [Cross-talk] Yes, we can.

Kavita Chawla: [Cross-talk] Yes, we can hear you.

Michelle Reyes: Okay, there we are. Hi.

Kavita Chawla: Hi. Please go ahead and answer the questions and [cross-talk] --

Michelle Reyes: [Cross-talk] Um, for those questions -- yes. My name is Michelle Reyes. I am speaking on behalf of the Hypoparathyroidism Association. I am not a provider. I am a patient. And I don't have any conflicts of interest to report.

Kavita Chawla: Thank you.

Michelle Reyes: Hi, my name is Michelle Reyes, and I'm a two-time cancer survivor in a rare disease patient. The rare disease I have is called hypoparathyroidism, and it is why I am here today. Although I have had this disease for 30 years, we have not had an approved drug for treatment until August of this year. This drug is now trying to come to market, and I'm here to tell you why we so desperately need it to be approved to be covered. My journey began after my thyroid cancer diagnosis and the inadvertent removal of all of my parathyroid glands during surgery for my cancer. I was told I would just need to take one calcium pill a day, and I would lead a normal life, no big deal. Well, that couldn't have been further from the truth. I experienced debilitating muscle cramps, my jaw locking up, my throat tightening to the point where I couldn't breathe correctly, constant pins and needles, and at times the inability to do everyday tasks like carry my groceries, pick up my child. Heck, there were days where my child basically had to pick me up as I was unable to walk unassisted out of her school assemblies. I was hospitalized over 240 times in a four- to five-year period due to this disease. I also want to talk today about the way this disease is currently treated. The current standard of care is to take over the counter calcium and active vitamin D, sometimes also magnesium and potassium in large quantities. For me, this turned into 64 pills a day every three hours around the clock, never getting a full night's sleep for years. But I did not have a choice if I missed one single dose, I risked ending up in the ER. I also want to mention that taking this much calcium does further damage to your body by causing kidney disease, the calcifications in other areas of your body, including your heart and brain. Three and a half years ago I was lucky enough to begin a trial that changed my life. Now I take two pills a day, and one of them has absolutely nothing to do with this disease. My kidney disease has been completely reversed, and my quality of life is now amazing. I don't have to think about my disease on a daily basis, and I don't have to depend on others now to function. I want to stress that I'm not the worst case scenario, I'm somewhere in the middle. What I can tell you is without a doubt that far too long we have treated this as a calcium disorder when it is first and foremost a PTH disorder, and until we treated my PTH, I never had relief. After 30 years with this disease, I finally feel like I have quality of life. The thought that I may lose this drug because it's too costly is terrifying. The thought that others may never realize what it's like to live because this drug won't be approved is heartbreaking. I thank you for your time today and for your consideration.

Kavita Chawla: Thank you, Michelle, for sharing your story. Questions from the Committee for Michelle? Okay. Thank you, Michelle. Nonye, any other stakeholders?

Nonye Connor: No. No other hands are raised.

Kavita Chawla: Okay. Okay, Board, are we ready to look at the motion or any other discussion?

Laura Beste: This is Laura Beste. I make a motion that I move that all products in this drug class listed on Slide 9 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.

Peter Barkett: Peter Barkett. I'll second that motion.

Kavita Chawla: Thank you. All in favor, please say aye.

Multiple Speakers: Aye. Aye. Aye. Aye.

Kavita Chawla: Any opposed or abstain? Okay. With that the motion carries. And back over to Nina for Hematopoietic agents.

Nina Huynh: Okay. Next is Hematopoietic Agents : CXCR4 Receptor Antagonists. The next we'll be going over a WHIM syndrome, which is a rare genetic disease that causes the body's immune system to not function properly. It reduces the numbers of mature neutrophils and lymphocytes circulating within the body, and it is estimated to occur in about 1:5 million live births, with approximately 60 cases have been reported in the medical literature. While symptoms vary, patients with WHIM syndrome can have recurrent infections, including pneumonia, sinusitis, skin infections, and are at high risk for life-threatening bacterial and viral infections. Here we have Xolremdi (mavorixafor), which is a new drug. The FDA approved it as the first drug for patients greater or equal to 12 years old with warts, hypogammaglobulinemia, infections, and myelokathexis, also known as WHIM syndrome, to increase the number of circulating mature neutrophils

and lymphocytes. The drug is contraindicated with drugs that are highly dependent on CYP2D6 for clearance. It can cause embryo-fetal toxicity and can cause QTc interval prolongation. The recommended dose for patients less or equal to 50 kg is 300 mg once daily. For patients over 50 kg, the recommended dose is 400 mg orally once daily, and it should be administered on an empty stomach after an overnight fast and at least 30 minutes before food, and it will be available as 100 mg oral capsule. And that is all that I have for Stem Cell Mobilizers. I'll take any questions.

Kavita Chawla: Thank you, Nina. Questions for Nina from the Board. Okay. It looks like a quick formulary review, Marissa.

Marissa Tabile: Yeah. This is Marissa. So this is the CXCR4 Receptor Antagonist drug class. We just have one product, which is Xolremdi, and it is preferred, and there is PA on that product. I can answer any questions about the PDL.

Kavita Chawla: Any questions for Marissa? Otherwise, Nonye, if there any stakeholders.

Nonye Connor: I'm trying to unmute myself and share my camera. No, I do not see any hands up. No.

Kavita Chawla: Okay. All right. Then we can look at the motion. Okay. It's Kavita Chawla. I move that all products in the Hematopoietic Agents CXCR4 Receptor Antagonist class 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 this class 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 as in this case, only one product is preferred.

Jon MacKay: This is Jon McKay. I second.

Kavita Chawla: All in favor, please say aye.

Multiple Speakers: Aye. Aye. Aye. Aye.

Kavita Chawla: Any opposed? Okay. With that the motion carries. And back to Nina to review Pulmonary Hypertension Agents.

Nina Huynh: Thank you. So next is Pulmonary Hypertension Agents : Activin Signaling Inhibitors. So next, we'll go through Pulmonary Arterial Hypertension, which I will refer to as PAH. So it is a progressive disorder characterized by increased pressure in the pulmonary artery, which carries oxygen-poor blood from the right side of the heart to the lungs. This is defined by the American Heart Association as a resting mean pulmonary arterial pressure of 20 -- greater than 20 mmHg. Approximately 500 to 1000 new cases of PAH are diagnosed in the United States each year. The prevalence of PAH is estimated to range from 15 to 50 per million in the US and Europe; however, pulmonary hypertension is heterogeneous and underdiagnosed. Although the number of approved therapies for PAH has grown in the past year, the prognosis is still poor, with a three-year mortality rate estimated at 21%. Symptoms include dyspnea, lightheadedness, syncope, fatigue, peripheral edema, chest pain, palpitations, and visible or enlarged veins on the side of the neck, which may be exacerbated by exertion. Management of PAH should be limited to specialized centers where clinicians are experienced in the evaluation and treatment of patients with PAH. Okay, there are many causes of PAH, including idiopathic or underlying disease and hereditary causes cellular changes in the walls of the pulmonary arteries, and it appears that mutations in the bone morphogenic protein receptor type 2 gene plays a key role in the pathogenesis of heritable PAH. Other etiologies in PAH includes drugs and toxins, collagen vascular resistance, HIV, portal hypertension, chronic thromboembolism, and congenital heart disease. The World Health Organization (WHO) classifies PAH patients into five categories based on the etiology. Group 1 refers to PAH, and the other four groups describes PAH. So here we have Winrevair (sotatercept-csrk), which is a new drug. So in March 2024, FDA approved it for the treatment of adults with PAH WHO Group 1 to increase exercise capacity, improve WHO functional class, and reduce the risk of clinical worsening events. Warnings include erythrocytosis, and if severe may increase the risk of thromboembolic events and hyperviscosity syndrome. It is recommended to monitor hemoglobin before each dose for the first five doses or longer if values are unstable and then periodically, thereafter, to determine if dose adjustments are required. It can also cause severe thrombocytopenia, which increases the risk of bleeding, so it's recommended to monitor platelets before each dose for the first five doses or longer if values are unstable and periodically, thereafter, to determine if dose adjustments are required. Again, it can cause serious bleeding and then may cause embryo-fetal toxicity and impaired fertility. The recommended starting dose is 0.3 mg/kg subcutaneously to a targeted dose of 0.7 mg/kg subcutaneously every three weeks. This may be administered by the patient

or a caregiver with proper training and is available as a 45 mg or 60 mg lyophilized cake or powder in a single-dose vial. Okay. And then here we have Pulmonary Arterial Hypertension Agents, Oral and Inhaled. So these are the combinations. Okay. And this is Opsynvi (macitentan with tadalafil). So in March 2024, FDA approved Opsynvi, a combination of macitentan and tadalafil for chronic treatment of PAH WHO Group 1 in adults and WHO functional Class 2 and 3. Macitentan reduces the risk of clinical worsening events and hospitalization, and tadalafil improves exercise ability. There is a Blackbox Warning for embryo-fetal toxicity for all female patients. This is available only through the REMS Program. And then it's contraindicated in pregnancy, hypersensitivity, concomitant organic nitrates, concomitant guanylate cyclase stimulators. And then it may cause fluid retention and hepatoxicity. The recommended dose is 1 tablet taken once daily with or without food, and it is available as a film-coated tablet with macitentan 10 mg and tadalafil 20 mg or 10 mg per 40 mg. And that concludes the PAH Agents.

Kavita Chawla: Thank you, Nina. Okay, now we'll allow Marissa to pull up the PDL.

Marissa Tabile: So this is Marissa. I will be going through our Pulmonary Hypertension Agents, the Activin Signaling Inhibitors, and the Combinations. So it's pretty straightforward for these two classes. We just have Winrevair and Opsynvi, which you can see on our PDL, we do have them non-preferred with PA, and we do have a policy that corresponds to the pulmonary hypertension agents. I don't have the other pulmonary hypertension agents included in this publication, which is like the tadalafil, sildenafil. There are other ones that are slipping my mind, but I do know that we do have those types like the PDE4 inhibitors preferred. So it's the expectation that they would step through those preferred products before they would be eligible for these newer products on the market. So I can answer any questions that you might have about the PDL. And I apologize I don't have the other PAH drug classes displayed.

Kavita Chawla: Thank you, Marissa. Questions from the Board for Marissa? If not, I see some stakeholders listed starting with Andy Kim. Are you online?

Andy Kim: Yes. Can you hear me?

Kavita Chawla: Yes, we can.

Andy Kim: Perfect. Thank you. [Cross-talk] --

Kavita Chawla: If you can answer the questions on the screen, please, and then we'll start your time.

Andy Kim: Yes. My name is Andy Kim, and I will be speaking on behalf of United Therapeutics Corporation. And then for the other question, I am not a provider, nor a patient, and I do not have any conflicts of interest to report. Okay. Good afternoon. My name is Andy Kim. I'm a Medical Science Liaison with United Therapeutics Corporation. In May 2022, FDA approved Tyvaso DPI for the treatment of patients with pulmonary arterial hypertension (PAH) and pulmonary hypertension due to interstitial lung disease (PHILD) to improve exercise ability. Tyvaso DPI is a new formulation and inhalation device for Tyvaso and is the only dry powder inhaler approved by the FDA for use in PAH and PHILD. Tyvaso DPI was evaluated in the BREEZE study, and the primary objective was to evaluate the safety and tolerability of Tyvaso DPI during a three-week treatment phase in 51 PAH patients on the stable regimen of Tyvaso inhalation solution who were transitioned to Tyvaso DPI. Patient to transition from Tyvaso to DPI demonstrated safety and tolerance. 96% of patients completed the three-week treatment phase, while two subjects discontinued due to treatment-related adverse events. Adverse events were consistent with studies of inhaled treprostinil in patients with PAH, and there were no study drug-related serious AEs. Significant improvements in secondary study objectives were also observed at Week 3, including six-minute walk distance of 11.5 meters compared to baseline. Overall patient satisfaction with the Tyvaso DPI inhaler as measured using the preference questionnaire for inhaled treprostinil devices, and PAH [audio cuts out] patient reported outcome questionnaire were observed in physical impacts and cognitive and emotional impacts. The 49 patients who completed the treatment phase of Breeze opted to continue in an optional extension phase. Improvements in six-minute walk distance compared to baseline versus staying in the optional extension phase through the data cutoff date up to 51 weeks. Given these findings, we ask that you maintain Tyvaso and Tyvaso DPI as preferred on the Washington State Medicaid PDL for PAH and PHILD patients that depend on your services for their medications. I thank you for your attention, and I'm happy to answer any questions.

Kavita Chawla: Thank you, Andy. Any questions from the Board for Andy? Okay. Let's see, next we have Nirmal Ghuman. Are you online? Do you see them, Nonye?

Nonye Connor: Yes.

Kavita Chawla: Yes? Okay. Can you unmute yourself, Nirmal?

Nonye Connor: Sorry, talking while muted. It looks like they must have logged out or maybe have technical difficulties.

Kavita Chawla: Okay, maybe we can come back to them. Other [cross-talk] --

Marissa Tabile: Nonye, this is Marissa. It does look like in the Q&A Amy Hale said she would be speaking for Nirmal.

Kavita Chawla: Oh, okay.

Nonye Connor: Okay. Thank you.

Marissa Tabile: I just saw that pop up. No worries.

Kavita Chawla: Amy, are you online?

Amy Hale: Hello. So sorry about that. We had to have a last minute change.

Kavita Chawla: Good job of tag teaming. You can go ahead, please, and answer the questions on the screen.

Amy Hale: Yes. My name is Amy Hale. I'm a Principal Scientific Account [indistinct] at Johnson & Johnson Innovative Medicine. I'm neither a provider nor a patient. I have no additional conflicts of interest to report. Okay. Thank you for the opportunity to speak to you today about Opsynvi, a combination of macitentan and tadalafil. A DUE, a Phase III study evaluated the efficacy and safety of Opsynvi compared to macitentan 10 mg and tadalafil 40 mg monotherapies in patients with PAH, including treatment-naive patients and patients previously on ERA or PDE5 inhibitor monotherapy at baseline. The primary endpoint was a change in PVR from baseline to week 16. And the patient who randomized to Opsynvi versus macitentan monotherapy, Opsynvi was associated with a 29% reduction in PVR. In the patient who randomized to Opsynvi versus tadalafil monotherapy, Opsynvi was associated with a 28% reduction in PVR. In treatment-naive patients, Opsynvi was associated with a 30% and 34% reduction in PVR compared to

macitentan and tadalafil monotherapies, respectively. And in patients receiving prior ERA therapy. Opsynvi was associated with a 32% reduction in PVR compared to macitentan monotherapy, and patients receiving prior PDE5 inhibitor therapy, Opsynvi was associated with a 19% reduction in PVR compared to tadalafil monotherapy. The most common adverse events observed with Opsynvi were edema and fluid retention, anemia, and headache or migraine. Qualitative one-on-one semi-structured Web-assisted interviews were conducted with the A DUE trial participants and site investigators about their experience with the single-tablet combination therapy, adherence, convenience, and the impact of a reduction in pill count. All participants preferred the open-label single-tablet combination therapy to the four tablets in the double-blind phase. Patients stated the single-tablet combination therapy was convenient, aided adherence, and had a positive impact on their day-to-day lives. Patients also expressed how taking more tablets made them feel more sick compared with single-tablet combination therapy. Additionally, patient acknowledged that single-tablet combination therapy improved their psychological well-being and reduced the stress of managing multiple tablets. Clinicians cited that the high pill burden in PAH causes their patients emotional distress, whereas patients had higher treatment satisfaction with the single-tablet combination therapy. Clinicians from the interview predict the single-tablet combination therapy will be well received in clinical practice and endorsed prescribing single-tablet combination therapy for treatment-naive patients. For these reasons, please consider adding Opsynvi to the Washington Medicaid Preferred Drug List. Please refer to the Full Prescribing Information for complete information. I want to sincerely thank you for your time and consideration today, and I'm here for any questions you may have.

Kavita Chawla: Thank you, Amy. Any questions from the Board for Amy?

Amy Hale: Thank you.

Kavita Chawla: Okay, thanks. And then any other stakeholders?

Nonye Connor: No other hands are raised.

Kavita Chawla : Okay, great. So then we can go ahead and look at the motion, please.

Peter Barkett: Peter Barkett. I can make the motion. I move that all products in the drug classes listed on Slide 12 are considered safe and efficacious for their

medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in these classes may require prior authorization to determine medical necessity. All 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: Zoe Taylor, second.

Kavita Chawla: All in favor, please say aye.

Multiple Speakers: Aye. Aye. Aye. Aye.

Kavita Chawla: Any oppose or abstain? Okay. With that the motion carries. Okay. And then back to Nina for the final big chunk, I think. Or are we doing that piece meal? Marissa and Nina guide us.

Marissa Tabile: This is Marissa. So this section that we're getting into is the drug classes that have no big clinical updates. Or we did do a little something new where we're only mentioning the classes where there might be small drug updates, so it's like a quick 1-minute overview for some of these, but for the large part, a lot of them don't have any updates. So for I guess, Nina's specific section, there are just some callouts that we wanted to make, specifically, in the Ulcerative Colitis Agents and Multiple Sclerosis. They're not very major updates, but we're just going to mention them just for completeness' sake. So I'll let Nina get into that, and then after that I will get into the actual Apple Health PDL so you can see what the statuses are of all of the drug products that fall within these classes. So as you can see, there is quite a bit. It might take me a little bit of time to just go through each class one by one, and then after that we just have the motion. Any stake -- well, stakeholders, the motion, and then that should be it for the rest of the meeting.

Kavita Chawla: Great. Thank you for that outline. So I'll -- yes, I'll let Nina take over, and then --

Marissa Tabile: Yep.

Kavita Chawla: Let us know when we need to come back on camera [cross-talk] if you could.

Marissa Tabile: Okay, will do. So Nina, whenever you're ready to just go through your small updates, I'll display them here for you.

Nina Huynh: Okay, perfect. Thank you. So our first one is Ulcerative Colitis Agents. So just one update. There is a discontinuation in October 2023 for Delzicol (mesalamine). So FDA posted that AbbVie will discontinue Delzicol 400 mg delayed-release capsule, and it's generic. The generic version by Teva will still be available. And for Multiple Sclerosis Agent, there was just an FDA communication in May 2024, indicating Copaxone generic (glatiramer acetate) FDA alerted patient, caregivers, and healthcare professionals of labeling update for glatiramer acetate injection products that include a new Warning that using an autoinjector that is not compatible with the specific glatiramer acetate injection product may increase the risk for medication errors, such as a missed dose or administration of a partial dose. The availability of optional compatible autoinjectors for each glatiramer acetate injection drug product may change with time. The FDA will no longer update this information on their website, and patients can continue to confirm the compatibility other autoinjector by speaking with their HCP visiting the drug manufacturer patient's information website or contacting the drug manufacturer for more information or referring to the autoinjector labeling. And that's all the updates I have for you guys.

Marissa Tabile: All right. And then this is Marissa, so I'll go ahead and get straight into the AHPDL review for these classes. Let me just get my bearings right. It's going to be a little bit of moving that I have to do. Okay. So the first one -- oh, let me put my stuff on camera. All right. So the first class that I'll be going through with not a lot of updates is the Antifungals : Topical. So this class is really where you'll see like the clotrimazoles, miconazole. There is just a whole bunch of different antifungals in here. As you can see, we do have quite a bit of mix in this, so we have some that are noncovered, we have some that are preferred, and then we also do have it looks like some non-preferreds in the mix. It's probably easier for me to just point out what is actually preferred in this class so you can see. That's probably going to be a little bit cleaner to go through, so I'll just go through them pretty quickly. We have a clotrimazole cream, miconazole cream, tolnaftate cream, same thing, clotrimazole, tolnaftate. We have some ciclopirox. It looks like we have a shampoo, cream, and suspension, solutions, more creams, more miconazole nitrate cream, and the list can go on and on. But I would say just looking at our list, it's probably miconazole, clotrimazole. Do we have ketoconazole? We do have some ketoconazole cream and shampoo, and nystatin, we have creams, ointments,

powders. I apologize for the scrolling. And it looks like that is the gist of what are our preferred products for this class. So go ahead. I know that was a lot. I'm just going to skip through, but feel free to stop me if you want me to go back to any specific class. The next one I'm going to go through is our Antivirals, which is going to be our Influenza Agents and our Smallpox Agents. For these classes for the preferred, we do have generic oseltamivir phosphate, so we have the capsule and suspension preferred. We have Rapivab preferred, rimantadine tablet. And then for the Smallpox Agents, we have Tembexa. That's the only product in the class that is preferred as well. Moving into our Cardiovascular Agents. So for this one for Sinus Node Inhibitors : Transthyretin Stabilizers and Vasoactive Soluble Guanylate Cyclase Stimulators. Wow, that was a mouthful. Everything is pretty much preferred in all of these classes. We do have PA it looks like for the Corlanor and the Ivabradine or the generic. We do have an applicable policy, but for the Vyndamax, Vyndaqel, and Verquvo, we don't have any policies yet that we have created for those, but there is PA. Okay, moving into our Endocrine and Metabolic Agents. Let me get into these. The Acid and Pituitary. All right. For the Fabry disease injectable, Fabry disease oral, fatty acid, metabolism agents, and pituitary suppressants. You can see that everything is pretty much preferred in all of these classes with PA. We don't have any applicable policies for them yet, but still have that PA on them for those. Getting into the Gastrointestinal agents, I did not list -- well, actually, here. It might not be on the agenda. So we have the Inflammatory Bowel Agents and the Irritable Bowel Syndrome Agents or GI Motility. So for the Inflammatory Bowel Agents, the preferred products in this class are -- oh, it won't let me click. We have balsalazide capsules, olsalazine. We have mesalamine rectals and tablets. We have mesalamine, more capsules and tablets as well, the ERs. And then we have sulfasalazine tablets and DR tablets as well. For the Irritable Bowel Syndrome drug class for this, our preferred products are brand name Linzess and then also generic lubiprostone capsules. And it looks like this is Movantik, and there are applicable policies for the irritable bowel syndrome products. Then moving into our Genitourinary : Overactive Bladder. For these, our preferred products, we have generic bethanechol, generic festoterodine, oxybutynin, solifenacin, and brand name Toviaz, and those are pretty much all preferred without PA. Then moving into our Hereditary Angioedema Agents, our preferred products in this class are Icatibant syringe and Kalbitor vial, those are both injectables. And then for Multiple Sclerosis, for this class we have Avonex syringe and pen injector that is preferred without PA. We have Betaseron, which is interferon beta-1B preferred. It looks like that's a kit. We have brand name Copaxone, generic dimethyl

fumarate. We have Kesimpta Pen preferred without PA. We have Tascenso ODT, which is fingolimod lauryl sulfate that is preferred with the PA. We don't have an applicable policy at this time. And then we do have the Zeposia, which is preferred with PA as well. So those are our preferred. Then for the Neuromuscular Agents. So for Freidrich's Ataxia Agents and Rett Syndrome agents, we have Skyclarys and Daybue. For those they are both preferred with PA. No policies yet as of this time. Then for some of the Oncology Agents [indistinct] at these. [Indistinct] I apologize if you can hear the yard people outside. It's always good timing when you have a meeting, right? So for Allogenic Cellular Immunotherapy, for that class, we have Omisirge or omidubicel. That one, I believe, is a carve out. That's why it's included on our PDL. That's why it doesn't have a status, but it is included. It's probably most likely on medical with PA. For Gonadotropin-Releasing Hormone Receptor Antagonists, we have Orgovyx or relugolix that is preferred with PA. For everything else, pretty much, for Interferons, LHRH Injectable, and Urinary Tract Protective Rescue Agents, everything is pretty much preferred with PA, especially for the LHRH injectables. So the Leuprolide, Lupron, Trelstar, Eligard, Fensolvi, Mesnex is the only product in the Urinary Tract. That one is preferred, and that one does not have PA. Then moving into our Ophthalmic Agents, which is Cholinergic Agonist and Complement Inhibitors. For these ones -- for the Cholinergic Agonist I should say, it's Tyrvaya and Vuity. I hope I'm pronouncing those correctly. Those are preferred with PA. We don't have any policies yet. For the Complement Inhibitors, we have Izervay and Syfovre. Hopefully, I'm pronouncing that one correctly. That one is a carve out, most likely. You won't see any preferred statuses -- well, similar to what you have seen, but we do, most likely, allow it through medical, there is probably PA on that product. And then the last one is our Vitamin D, which this can get a little confusing as well. So we do have various non-covered reasons. So sometimes we have non-covered OTC, and then we also have non-covered vitamin D. So you might see that on our AHPDL, which you'll see here, but we do have preferred products that we do have in this class, so I'm going to try to call out the ones that we have. So we have cholecalciferol vitamin D3 drops. We have various ones here. We have Calcitriol capsule and solution, various D3's that we have depending on the formulation. Lots of drops and tablets and some capsules. We do have a vitamin D2, which is the ergocalciferol. We do have the capsule and tablet. I believe, for the most part, it's mostly just D2 and D3 that live in this class, but we do cover -- have some products that we cover for vitamin D. And I think that was it. I know I went through a lot. Let me know if you have any questions. I'll go ahead and open up the floor.

Kavita Chawla: Go ahead, Peter.

Peter Barkett: Yep. Thanks. Peter Barkett here. I was wondering if we could go back to the Overactive Bladder Agents for a second. I noticed that a few of the anticholinergic agents that have not been associated with cognitive issues we're not on the Preferred Drug List. So I was wondering why just because they think they're pretty inexpensive, and I think trospium was the one I had picked out in here. Like Oxybutynin and some of the other anticholinergics have been associated with cognitive declines, but [indistinct] [cross-talk] --

Zoe Taylor: [Cross-talk] We talked about this before, too, like a few months ago.

Peter Barkett: And then the one other thing that I noticed on this list, I think mirabegron was listed on here as not available as generic, and I wonder if that will end up at some point on the Preferred Drug List as a totally different mechanism of action being a Beta-3 agonist. I think it's still pretty expensive, even though it's technic -- even though there is a generic available, but it's a different mechanism of action that avoids the antimuscarinic pathway.

Marissa Tabile: This is Marissa. So to answer your question about the mirabegron, we're probably still just keeping an eye on it, so we haven't really made any changes. I think it's kind of been a while, to be quite honest with you, since we have reviewed this class just because I think, in general, there hasn't really been very much that we have seen going on. So I think this is a good trigger to re-evaluate it. So any recommendations that you have, I can definitely take back as we review this class.

Zoe Taylor: In June, we did it. We did edits to the motion, I know, to talk about how we needed at least two of that we're not. I remember us talking about this in the past. Am I going crazy?

Marissa Tabile: This is Marissa. Um, I'm going to have to double-check in June what that was looking like. So I'm trying to pull up the motion. [Cross-talk] --

Laura Beste: [Cross-talk] Zoe, I remember discussing it, too. [cross-talk] You’re not that crazy. [laughter]

Zoe Taylor: Okay [audio cuts out] yeah, I remember having a whole discussion with Peter about how we needed to have two options besides oxybutynin besides Myrbetriq that were preferred.

Marissa Tabile: This is Marissa. I don't see it in the list of classes for [audio cuts out] June that we went over for motions unless it was another meeting.

Zoe Taylor: I was probably P&T rather than DUR.

Marissa Tabile: Yeah. So -- that is a little different as far as for the P&T section. Yeah, it does look like in June, you did go through that for the P&T section, which doesn't apply to our Apple Health.

Zoe Taylor: So the decisions we make in P&T don't get reflected on this Preferred Drug List in terms of what's P and what's N?

Marissa Tabile: No, they do not. [cross-talk] --

Zoe Taylor: Oh.

Marissa Tabile: That is -- yeah, that's only for -- correct me if I'm wrong. I don't think Ryan P. is on the line. I believe that is for the Washington PDL, which is specific for L&I, and I think it's our UMP.

Zoe Taylor: So okay. So I would just say it would be easiest probably to start from whatever decision we made there, and have it match what our recommendation is here rather than trying to come up with something new.

Peter Barkett: I don't know that we can tell them what to [indistinct]. We can only say like what is eligible, but I would strongly advocate for having a couple of anticholinergics not associated with cognitive decline on the Preferred Drug List, and then at some point consider whether to put mirabegron on the Preferred Drug List now that it's generic and realize [audio cuts out] it's still more expensive. But I think that might have to do with the branded generic, but when true generics are available and the cost comes down, then I really don't see a reason not to have mirabegron at that point on the Preferred Drug List.

Marissa Tabile: Yeah. This is Marissa. So you, as the DUR Board, are more than welcome to add recommendations to -- I believe you guys may have done it before in the

motion. I can add like a little bullet here in the motion saying, “recommend adding a, I don't know, overactive bladder, or what have you, product to the PDL without cognitive decline, something along those lines. You are allowed to do that as well.

Zoe Taylor: Would Nonye have the language from June that we decided on already so that we could copy and paste that into this motion?

Marissa Tabile: So this is actually what you all came up with at the meeting. It was a little different. So let me see. So I think a once daily formulation must be included as a preferred drug on the Washington Preferred Drug List. Of course, I only read that last sentence, but there is more. But this is what was voted on at that June Meeting.

Zoe Taylor: Thank you for pulling this up. That's exactly what I was thinking about. So something about trospium and darifenacin, maybe we could add to this one and then also something similar to that last sentence.

Kavita Chawla: Do we want to -- Kavita here -- do we want to take that sentence regarding the trospium and the darifenacin [cross-talk] --

Donna Sullivan: This is Donna. We don't do therapeutic interchange [cross-talk] --

Kavita Chawla: [Cross-talk] Right, yeah. [cross-talk] --

Donna Sullivan: [Cross-talk] PDL, so I think that's not relevant. What would be relevant is the last sentence.

Zoe Taylor: We would want the once daily, yeah. I think the once daily thing and then also if we can get at the [cross-talk] thing that we’re talking about. Yeah.

Kavita Chawla: -- cognitive side effects would be -- something like that? Go ahead.

Peter Barkett: I think, yeah. I think I would include a line maybe that says at least two neuroselective anticholinergic agents (e.g., darifenacin and trospium) should be included on the Preferred Drug List.

Zoe Taylor: I agree with that.

Donna Sullivan: Are those the only ones that are, um?

Peter Barkett: Well, I think those are the ones that like chemically speaking, they should be neuroselective, and they have not been associated with cognitive decline, depending which study you look at, there are some others that have not been associated with cognitive decline. Like I think tolterodine and glycopyrrolate were looked at, and they did not see the cognitive decline. But it doesn't make sense why they wouldn't because they're not neuroselective, so it kind of depends on how confident you would want to be.

Donna Sullivan: So I would rather you say formulations that are not neural, that are mot associated with cognitive decline, so that we can look at the evidence and then pick the least costly alternatives that do not have cognitive decline.

Peter Barkett: I would be comfortable with that.

Zoe Taylor: Do you think cognitive decline is the right term?

Kavita Chawla: Yes, I think saying an agent that is not associated with [cross-talk] --

Zoe Taylor: [Cross-talk] Adverse cognitive outcomes, I think, is maybe the -- what the Urology guidelines language is. Or cognitive impairment is another -- adverse cognitive outcomes I'm seeing in a lot of different papers. So maybe that's the way to put it.

Marissa Tabile: All right. This is Marissa. I kind of was trying to listen and paste and do things at the same [cross-talk] time, so I'm ready to wordsmith whenever someone is ready.

Kavita Chawla: Okay. So at least a once daily formulation and it must be included -- sorry, remove the “and” so it'll be as a freestanding sentence. And then at least one agent that is not associated with adverse cognitive outcomes would have preferred status. Or -- yeah. The rest I look to the Board.

Zoe Taylor: We probably want to say, “at least one once daily formulation must be included.” And then should it say, “included as a preferred drug on the AHPDL” for both? Okay. At least one agent is not associated with adverse cognitive outcomes must be included. Can you add, “must be included as”? Okay, perfect. And then I still would love to do something about mirabegron as well though. I don't know if we can do anything about that here.

Kavita Chawla: Any ideas Donna?

Donna Sullivan: I think, I mean, it'll be -- it's still just because it's non-preferred doesn't mean patients don't have access to it through prior authorization. And, you know, looking at the cost, I think we would still want to try less costly alternatives unless there was a clinically appropriate reason to jump right to mirabegron.

Marissa Tabile: This is Marissa. Yeah, it does look like the way that it is, I don't think it's listed here, but there is no PA on it, so most likely there are probably step-throughs. I'm going to assume it may be two. Don't quote me on that, but there is probably step-through one or two to get to it, so it's not a full PA.

Kavita Chawla: All right. And then, Jon, you also have your hand up.

Jon MacKay: My comments about the ATTR cardiomyopathy for the Vyndamax. Do you mind bringing that up?

Marissa Tabile: All right. This is Marissa. I just want to make sure for this language for the Overactive Bladder, is everyone good for now? And then we can go back.

Peter Barkett: It looks good to me.

Marissa Tabile: Okay. I will go ahead then, Jon, and skip over to yours. You said it was the Vyndamax and Vyndaqel, right? [cross-talk] I don't remember.

Jon MacKay: [Cross-talk] Correct.

Marissa Tabile: There we go. Okay.

Jon MacKay: So we administer some of these medicines for cardiomyopathy, and I was just wondering, the Amvuttra, I don't see that in there. There is kind of two analogs that are frequently used. That's a healthcare administered med. I'm not sure if that's like a carve out, the Amvuttra.

Marissa Tabile: This is Marissa. I will have to double-check. Do you mind spelling that drug for me? I can actually [cross-talk] --

Jon MacKay: [Cross-talk] Yeah.

Marissa Tabile: [Cross-talk] this is not the PDL. Go ahead.

Jon MacKay: A-N-V-U-T-T-R-A.

Marissa Tabile: Okay. So that product actually lives in a different class on our PDL. It's called the Neurological Agents : Transthyretin Amyloidosis Agents drug class. That one, it is included on the PDL, and we do have it just for reference as preferred with PA. We do have a policy for that, which is posted online, so you can reference that as far as any kind of clinical criteria for that. But it is in a different class.

Jon MacKay: Okay.

Marissa Tabile: And that's why you don't see it.

Kavita Chawla: Any other questions for Marissa?

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Marissa Tabile: This is Marissa. And also, sorry, Jon. To answer your question, the other product that you were referencing, the Anvuttra, that one is a carve out, so that's why it is probably separated from these products.

Jon MacKay: Okay, great. Thank you.

Marissa Tabile: Mm-hmm.

Kavita Chawla: Any other questions for Marissa? And if not, Nonye, do we have any stakeholders?

Nonye Connor: Hi. I was trying to unmute myself. Let me see. I know we have hands raised, but I think we had some stakeholders that pre-registered. Let me see here. The first one I have is Sharon.

Kavita Chawla: Oh, I see that, Shannon Payne.

Nonye Connor: Yes.

Kavita Chawla: Hey there.

Shannon Payne: Yeah. Hi. Can you hear me?

Kavita Chawla: Yes, we can.

Shannon Payne: Hi, I'm Shannon Payne. I'm speaking on behalf of BioCryst, and I'm neither a patient nor a provider. So thank you, everyone, for the opportunity to present to the Board today. I'm Shannon Payne, and I'm your principal MSL at BioCryst, the manufacturer of berotralstat, brand name Orladeyo. In support of Washington Medicaid patients with hereditary angioedema, BioCryst asked the Board for Orladeyo to be placed on the Preferred Drug List without barriers to access. Now, I would like to give a brief update on berotralstat data, including guideline updates, confirmation of efficacy and safety, and, importantly new published data showing reductions in healthcare resource utilization following berotralstat initiation. Orladeyo was FDA-approved in December 2020, becoming the first oral targeted agent prophylaxis to prevent attacks of HAE in adults and pediatric patients 12 years of age and older. Orladeyo is the only oral first-line treatment and does not require additional supplies for storage or administration. Patients treated with berotralstat in the pivotal double-blind, placebo-controlled APEX 2 trial experienced a statistically significant reduction in HAE attack rates compared with placebo at six months. Quality of life improvements were also seen. Newly published data shows that berotralstat also demonstrated continued safety and effectiveness over the long term. Patients on berotralstat 150 mg experienced a 90.8% average reduction in monthly attacks at 24 months. In addition to significant decreases in attack rates and improvements in quality of life, patients treated with Orladyeo in clinical trials also used fewer doses of rescue medication and treated fewer attacks after four weeks on Orladyeo. Newly published retrospective data using 2015 to 2022 administrative claims showed significant reductions in the overall rates of all-cause and angioedema-related hospitalizations after initiation of berotralstat. Orladyeo is generally well-tolerated with the most common adverse events seen being GI-related, graded as mild-to-moderate, short-lasting and self-limited. Patients report fewer adverse events over time, and this is confirmed across clinical trials and real-world evidence. These data reinforce that Orladyeo is generally well-tolerated and effective in reducing HAE attack rates, use of rescue medication, and other healthcare resources in patients with HAE. Today, Orladyeo is the only oral option for targeted HAE prophylaxis and is recommended in the World Allergy Organization 2021 Guidelines as first-line long-term prophylaxis in HAE. Thank you for your time, and I'm happy to take any questions.

Kavita Chawla: Thanks so much, Shannon. Any questions for Shannon? Okay. Thank you. And then I see Mandy Champ listed.

Mandy Champ: Hi. Thank you so much for the opportunity. I'm happy to give my time back to the Committee.

Kavita Chawla: Okay. Thank you. Any other stakeholders, Nonye?

Nonye Connor: Lynda.

Lynda Finch: Yeah. Can you hear me?

Kavita Chawla: Yes, we can.

Lynda Finch: So good afternoon. I'm going to speak first about Tysabri for the MS class and then Skyclarys for Friedreich ataxia. Is that okay to go ahead and do it that way?

Kavita Chawla: Yeah, that'd be fine. If you could please answer the questions on the screen really quick [cross-talk] --

Lynda Finch: Sure. My name is Lynda Finch. I'm speaking on behalf of Biogen. I am not a patient or a provider. So, as I mentioned, I'll be discussing Tysabri today. So I have supported Tysabri along with Biogen's portfolio of MS Therapies for over 17 years now. And over that period of time there has been a significant shift in how MS is treated. There is now a large number of therapies available to treat MS, but Tysabri remains a critical tool for neurologists, especially for rapidly stabilizing patients with highly active regressive MS and for treating patients with MS-related cognitive impairment. Patients treated with Tysabri have experienced clinically meaningful improvements in cognitive tests. Risk mitigation strategies for Tysabri have also continuously evolved, and neurologists can now identify who is at highest risk of developing PML and reduce that risk through the use of tools such as JC virus testing, JCV index, and extended interval dosing, which has significantly reduced the risk of PML in JC-positive individuals. During the COVID-19 pandemic, other attributes of Tysabri such as the preserved response to vaccines and its mechanism of action, which doesn't deplete lymphocytes, have made Tysabri an essential first-line option amongst the high-efficacy therapies. MS therapies which deplete lymphocytes led to more severe COVID-19 infection and a higher risk of hospital, and therapies which impact the response to immunization, such as S1P inhibitors and B-cell depleters, present a real challenge and dilemma in our post-pandemic era, where regular vaccine boosters are needed. Your

current criteria require that MS patients fail two therapies prior to using Tysabri, and these criteria don't account for the heterogeneity of MS and that some patients do have aggressive disease early on, and they can sustain permanent disability with each relapse, and cognitive impairment can begin early in the disease course and can be even more disabling than physical disability. Patients with highly active MS can't afford to try and fail less effective therapies before stabilizing the disease. That could -- failing a less effective therapy could mean that the patient has ongoing disease activity and could have some permanent neurologic disability. So while you may allow for medical exceptions, that does take time and a dedicated provider, and in MS, time loss equals brain cells lost. So there are national guidelines supporting the use of Tysabri as an option for early aggressive disease characterized by frequent relapses with incomplete recovery and the accumulation of focal lesions on MRI. And so I respectfully request that Oregon Medicaid follow these national guidelines for the treatment of MS and allow for the use of Tysabri as a first-line option for patients with highly active or early aggressive disease, including manifestation of MS-related cognitive impairment. So thank you very much for your time. I'm happy to take any questions, and if there are no questions, then I will go to the Skyclarys testimony.

Kavita Chawla: Any questions for Lynda? Okay. Go ahead, Lynda.

Lynda Finch: Okay, so my interest is the same, and I don't have any other conflict of interest other than I am an employee of Biogen, the manufacturer of Skyclarys. So thank you for the opportunity to discuss Skyclarys. I know you haven't developed a policy yet, so my goal today is really to give you some key considerations in terms of developing a policy. So Skyclarys is the first and only treatment indicated for Friedreich ataxia (FA), which is a rare progressive neurodegenerative disease that affects about 5000 individuals in the US. For the sake of time, we're going to refer you to the PI for Warnings and Precautions, and I'll focus on these key clinical policy considerations. So FA is a relentlessly progressive neurodegenerative disease. It leads to loss of coordination, lower limb movement, independence, and ambulation, and even after wheelchair dependence, this progressive multisystem disease continues to affect motor strength, reflexes, hearing, vision, cognition, and cardiac function, ultimately leading to death around age 37 on average. Untreated FA patients experience disease progression about 2 points per year as assessed by the Modified Friedreich Ataxia Rating Scale or the MFARS, and Skyclarys has been shown to slow down this progression.

Patients treated with Skyclarys achieved statistically significantly lower MFARS scores compared to placebo at week 48 in the clinical trial and slowed progression up to three years compared to matched untreated patients from a large ongoing natural history study. I do want to share that while the MFARS is a validated neurologic assessment tool in Friedreich ataxia, it is used as an outcome measure in registries as a clinical trial. It has not been used in clinical practice even by specialists, so FA is generally diagnosed and managed by pediatricians and primary care providers, and then they're not familiar with this tool. Is a heterogeneous disease, and patients have a lot of variability in their disease progression and symptoms, so providers use specific neurological assessments to individually monitor their patients. So I recommend that you don't require the MFARS to monitor disease progression. It's not an appropriate tool for this purpose. It lacks sensitivity to change over short periods of time, and it was designed to evaluate FA at a population level, not individual patient level. It presents a barrier to patients due to the lack of provider familiarity, and it requires a significant investment time, and it [indistinct] inappropriate for assessing non-ambulatory patients, since it's heavily weighted towards upright stability. We do know that individuals afflicted with FA can often maintain their upper body strength even after they require a wheelchair due to ataxia. So this is an important consideration when designing a policy. It means maintaining upper body strength is critical for maintaining independence and quality of life, and non-ambulatory patients have shown benefit from treatment with Skyclarys. So I think I'll end there and just request that you allow patients to receive Skyclarys, and then we recommend an initial authorization period of 12 months to allow sufficient time for response to treatment. We did see response to treatment by about nine months in the clinical trial. And then if you can allow for repeated treatment if patients have shown response to therapy by stabilization or slowing of the natural course of the disease. Thank you for your time today. I'm happy to address any questions.

Kavita Chawla: Thank you, Lynda. Any questions for Lynda from the Committee? Okay. Any other stakeholders, Nonye?

Nonye Connor: No other stakeholders have their hands raised.

Kavita Chawla: Okay, then we can have a look at the motion.

Laura Beste: This is Laura. I had one question regarding the MS agent. So for Tysabri, I was surprised to see that it was an N and not an X because it's primarily given in the clinic setting. So when did it fall under different criteria?

Marissa Tabile: This is Marissa. So we probably -- let me see if we actually allow it through both. I would imagine we do. We may have had some experience where it came through either some type of infusion pharmacy or something like that, so that's why we usually would include that. Yeah. So we do allow it through both Medical and Pharmacy, and there is probably some type of experience we have had where it's been billed through some type of infusion pharmacy or whatnot, so that's why it does have a status for it.

Zoe Taylor: Does anyone else have enough experience to know that there are drugs on this list that should be preferred or that we should argue about it all? Like, I have patients on some of these, but I don't know how much the neurologist had to go through to get them, or if there is any -- I feel like with the urinary retention ones we had personal experience, and with this one, I just -- does anyone on the Committee have thoughts about that?

Peter Barkett: This is Peter. So last I did a big overhaul of MS drugs for another health plan. The way that we had done it is we split it into the moderately-active and like highly-active and then made sure we had medications from each group. Kind of first glance over this it seems appropriate, but I probably need to do some comparison against the rest of the market to confirm.

Kavita Chawla: Are there any changes you would propose, Zoe?

Zoe Taylor: No, not in particular. I just, I don't know enough, and I don't know if we have any neurologists here, so I just, you know --

Kavita Chawla: No, that's a good call out. Okay. So in the absence of that, other questions or changes to the motion? Okay. So then I am hearing that maybe the motion is okay to proceed with.

Jon MacKay: This is Jon McKay. I move that all products in the drug classes listed on Slides 14, 15, 16, and 17 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 clinically appropriate, or only one product is preferred. For the Genitourinary Agents : Overactive Bladder Agents, at least one once daily formulation must be included as a preferred drug in the AHPDL. At least one agent that is not associated with adverse cognitive outcomes must be included as the preferred drug on the AHPDL.

Christy Weiland: Christy Weiland [Cross-talk] --

Michael Corsilles: [Cross-talk] This is Michael Corsilles. I second that.

Kavita Chawla: Great. All in favor, please say aye.

Multiple Speakers: Aye. Aye. Aye. Aye.

Kavita Chawla: Any opposed or abstain? Okay. With that the motion carries. And I think I see that's the end of the agenda for today. Marissa, Nonye, am I missing anything?

Marissa Tabile: This is Marissa. Yep. That is the end of our DUR Agenda, so I'll hand it off to Nonye for anything -- any other logistics we need to go over.

Kavita Chawla: An amazing job today, team. And I'm so proud of, like, how much we are also advocating for access to these treatments for our patients as clinics -- with our clinical brains and also the clinical expertise on this team. But yes, go ahead, Nonye.

Nonye Connor: [Laugh] Yes. Thank you, guys so much for all the work that you guys have done today. With that, Kavita, it's your last meeting with us today.

Donna Sullivan: Kavita, I just wanted to thank you for participating in the P&T Committee, DUR Board, and for your leadership for this last year, and we will definitely miss you next month and in the future. So thank you for your participation. We really appreciate all the work that you have done and looking forward to working with you, maybe in the future if so, you should return.

Kavita Chawla: Thank you so much. It's been such a privilege. And again, I echo what an amazing team we now have, all of the advocating voices, and so much clinical expertise in these twelve boxes here on my screen. So, yes, thank you so much. It's been an honor.

Nonye Connor: Thank you. With that, if there are no -- any comments, concerns, or questions? If not, that's it for today, you guys. Thank you, again. Thank you, Kavita.

Kavita Chawla: Okay. We adjourn the Board then.

Donna Sullivan: Thank you.

Laura Beste: Thank you.

Donna Sullivan: Bye-bye.

Zoe Taylor: Thank you. Bye.

Greg Hudson: Thank you.

Laura Beste: Have a great day.

Nonye Connor: Bye. Thank you.

Laura Beste: Bye.

[end of audio]