Washington State Pharmacy and Therapeutics Committee
Drug Utilization Review Board
Meeting Transcription
August 14, 2024

Nonye Connor: Okay, Kavita.

Kavita Chawla: All right. Good morning. Hello, everybody. I am Kavita Chawla, the Chair of the P&T Committee. I will start off by reading the names of all of the participating attendees, so please say "here" when I call your name. Peter Barkett.

Peter Barkett: Yep, I am here.

Kavita Chawla: Hi, good morning. Um, well, I can't open two things at the same time. Hold on one second. Let me just pull it up. All right, Kevin Flynn.

Kevin Flynn: Yep, I am present.

Kavita Chawla: Good morning, Kevin. Gregory Hudson.

Greg Hudson: Here.

Kavita Chawla: Good morning. Jon MacKay.

Jon MacKay: Good morning. I am here.

Kavita Chawla: Good morning, Jon. Um, Zoe Taylor.

Zoe Taylor: Here.

Kavita Chawla: Good morning. And Christy Weiland.

Christy Weiland: Good morning.

Kavita Chawla: Good morning. All right. Our Health Care Authority members, Nonye Connor.

Nonye Connor: Hello, good morning.

Kavita Chawla: Leta Evaskus.

Leta Evaskus: Here.

Kavita Chawla: Amy Irwin.

Amy Irwin: Good morning. Amy's here.

Kavita Chawla: Good morning, Amy. Ryan Pistoresi. Not quite on yet. Elizabeth Punsalan.

Elizabeth Punsalan: Not quite yet. Donna Sullivan. Marissa Tabile.

Marissa Tabile: I am here.

Kavita Chawla: Morning, Marissa. Ryan Taketomo.

Ryan Taketomo: Good morning. I am here.

Kavita Chawla: Good morning. I see Elizabeth Punsalan on. Are you here, Elizabeth? I saw her, I heard her.

Nonye Connor: [Laughter].

Kavita Chawla: And then Ryan Pistoresi.

Ryan Pistoresi: Good morning.

Kavita Chawla: Good morning. And Joey Zarate.

Joey Zarate: Good morning.

Kavita Chawla: Morning. All right, our Magellan Medicaid Administration presenters. We have got Nina Huynh.

Nina Huynh: Good morning, I am here.

Kavita Chawla: Good morning. Nina, how do I say your last name? Am I saying that right?

Nina Huynh: Yes. Huynh.

Kavita Chawla: Huynh? Okay. And Umang Patel.

Nina Huynh: He won't be joining us today.

Kavita Chawla: All right, Nina! [Laughter]. And then our Managed Care Organization representatives. We have got Greg Simas from Molina Healthcare, Heidi Goodrich from Molina Healthcare, Petra Eichelsdoerfer from United Healthcare, Omar Daoud from Community Health Plan of Washington, and Jeffrey Natividad from Community Health Plan of Washington. And now Nonye will go over the meeting logistics.

Nonye Connor: Yes. Hi. The Committee and presenters can mute and unmute themselves at any time, but please mute yourself when not speaking to limit background noises. Presenters, please share your webcams when presenting. Committee, please share your webcams during discussions and motion consideration. For stakeholder participation, the Chair will read the list of stakeholder names who pre-registered to speak, we will unmute you. Afterward, the Chair will ask if there are any other shareholders. If there are, please raise your hand, and we'll call upon you and unmute you. You can also use the Q&A box. We will address your questions during the stakeholder time. If you do not fill out our stakeholder conflict of interest form, please answer the questions we will post on the screen. Your three minutes will start after you answer the questions. Back to you, Kavita.

Kavita Chawla: Thank you, Nonye. Okay. So with that, we are diving right into the DUR Board, so we convene the DUR Board now, and I think we start with Ryan and Marissa going over the DUR utilization data.

Marissa Tabile: Yeah. So this is Marissa. So as Kavita said, the first agenda item is DUR utilization. I am not going to take any credit for this presentation because Ryan puts together a beautiful presentation that he will be going through with you all here shortly. So I will go ahead and drive your slides, Ryan, and kick it off to you. Let me go ahead and present them, and then we should be good to go. Let me know if it is not working. All right. It should be good to go, so I will go ahead and hand it off to you, Ryan, whenever you are ready.

Ryan Taketomo: Hi. This is Ryan Taketomo. Good morning, P&T and DUR Committee. This morning, we'll be kicking it off with another drug utilization presentation with the focus on the Antidiabetics drug class. Next slide, please. Okay. So just a quick overview of what we'll be covering. We'll do a little recap of what was

presented at the June P&T meeting, and then we'll start doing some -- a deeper dive into the antidiabetic side classes and then looking at the GLP-1 agonists. Next slide. So a little background about the data that is being presented. It is mainly using the pharmacy point of sale claims. The date ranges from January of 2021 to the end of 2023, and it includes both fee-for-service and managed care claims. Just some definitions for terms that we will be using throughout the presentation. When we say paid amount, this talks about the Total Paid Amount, but it does not include rebates. When we use the term Net Paid, this is the Total Paid Amount, but it includes rebates, and then we have terminology such as PMPM which means Per Member Per Month. And next slide, please. Okay, so some of these slides may look familiar from the last P&T meeting. This first slide is looking at the annual utilization focusing on the paid amount. And we can see that it does -- and we added a split to show how much of the paid amount is attributed to antidiabetics versus all the other Apple Health PDL classes. And so if we look at the right chart with the percentages, any diabetics make up approximately 15% of the paid amount. Next slide, please. Okay. And then here we're looking at annual utilization with the net paid. So, again, net paid includes the rebates. And with the antidiabetics, it makes up approximately 7% as of 2023. This was increased from around 4.67% in 2021. Next slide, please. And then on this slide, we'll be looking at the number of claims for each year. And it looks like for the antidiabetics, it has remained pretty consistent with maybe a slight increase of around 4% to 5%. Next slide, please. Okay. This was just an informational slide that helps define when we use the terms classes and subclasses. So when we say class, this is the piece before the colon when you look at the Apple Health Drug class. So, for example, Antidepressants : Tricyclic Agents Antidepressants is the class. There were, again, 64 classes as of 2023, and then when we talk about subclass, this is the component after the colon. So using the previous example, this would be Tricyclic Agents, and out of 2023, there were 494 full classes and subclasses. Next slide. Okay. On this slide, we're again just looking at the top ten classes by net paid for 2023, and since this presentation is going to be focused on the antidiabetics class, I will just kind of be calling that one out as we move throughout these slides. So Antidiabetics is the third most expensive class in 2023, and we spent about $70 million. Next slide. All right. On this slide, it shows the Net Paid PMPM over the years for those top classes, and the red that is kind of highlighted represents the Antidiabetics Apple Health class. We can see that throughout the years it is moved up, and what that means is the colors for each of the years are stacked by their actual PMPM. So in 2021, the Antidiabetics was the 6th most expensive class, and then in 2023, it moved

up to the third spot, representing the third most expensive class currently. Next slide. All right. And then now we'll be looking at the various antidiabetic classes. So next slide. Yeah. And so this is the breakdown of all the antidiabetics. This represents the most expensive ones. There are few classes not included, but they represent a very small amount. So we can see that some of our top classes currently include the GLP-1 agonists, the SGLT2 inhibitors, and then insulins, and then DPP4 inhibitors. Next slide, please. Okay, and then similar to the previous try we kind of talked about, this shows the net paid PMPM overtime and movement represents that a particular class is getting more expensive relative to other subclasses. So we can see that throughout the years the GLP-1 agonists remain the topmost expensive subclass of the antidiabetics. It has increased almost three times since 2021, with the PMPM of $0.36 in 2021 to a PMPM of a $1.13 in 2023. We also see a shift in the SGLT2 inhibitors moving up to the second most expensive subclass with this PMPM doubling between that timeframe. And then that looks like the other classes kind of remain [cross-talk] relative [cross-talk] --

Donna Sullivan: [Cross-talk] Sorry to interrupt. This is Donna. It looks like Chawla has a question. Kavita, I am sorry.

Ryan Taketomo: Yes, of course.

Kavita Chawla: Hey, Ryan. Sorry, I have a very basic question. Wait, I need to get my camera. It is when we're looking at these data points, this is just for -- since we have the DUR Board convened right now, is it just Medicaid, State Medicaid, or is it all of HCA?

Ryan Taketomo: Hi. This is Ryan Taketomo. And, yes, that is correct the first part. So right now we're only focusing on the Apple Health Medicaid Program utilization.

Kavita Chawla: Okay, thank you.

Ryan Taketomo: And then looks like we have another question from Dr. Barkett.

Peter Barkett: Yeah. Well, two questions, actually. First, the drop in the price of long-acting insulin, is that because of generics entering the market like Semglee?

Ryan Taketomo: Hi. This is Ryan Taketomo. So when we see the drop, we want to also look at kind of the number inside that blue line. So we see it going from like $0.33 to

$0.30 in 2022 and then up to $0.31. It is not a really big change throughout the years, but when you see it move down, it does mean that another class has become more expensive. The SGLT2s kind of overtook it with the PMPM.

Peter Barkett: And then a huge increase in GLP-1 cost, and I don't think that would be a surprise to anyone, but I am curious how those lines up with the rest of the market. Is the increase that Apple Health has seen in the GLP-1 cost, is that similar to what the rest of the market is experiencing or greater or less? Or are you able to comment on that at all?

Ryan Taketomo: Hi. This is Ryan Taketomo. I am not able to comment on that, but I am not sure if one of the other staff members can provide a perspective.

Ryan Pistoresi: This is Ryan Pistoresi. We are seeing something similar with the same drug classes for Uniform Medical Plan. I don't have the data analysis ready. We did look at this a couple of years ago and it was trending in this direction. There are some different dynamics that would maybe explain some of the differences between Uniform Medical Plan and Apple Health, but the general trend is this is the same.

Ryan Taketomo: Hi. This is Ryan Taketomo, and it looks like we have a question from Christy Weiland.

Christy Weiland: Yeah. Thanks, Ryan, for presenting all of this really interesting information. I am just curious on the subclasses. For instance, like SGLT2, is that specifically linked to the ICD 10 that was diagnosed for it, or could this also include like heart failure patients? I guess what I am asking, like, under [indistinct], is also SGLT2 listed as a subclass? Or is this all of the SGLT2s that are prescribed, assuming we have labeled them as anti-hyperglycemic?

Ryan Taketomo: Hi. This is Ryan Taketomo. So the data represents all the drugs in the Antidiabetics : SGLT2 Inhibitors class regardless of diagnosis. So if those products are used for cardiovascular indications, those would be included as well.

Christy Weiland: Okay. Thank you very much.

Ryan Taketomo: All right. This is Ryan Taketomo. I am not seeing any more questions, so I think we can move on.

Kavita Chawla: Ryan, Kavita here. Just to hop on Peter's question and also to the response Ryan Pistoresi gave. The trend, I am sure, that everybody is seeing the same trend with these two classes, but I am wondering percentage-wise, I think -- that 40% of the antidiabetic drug costs are attributable to the GLP-1 percentage-wise or proportion-wise, I should say, is that kind of similar in what we're seeing in with the rest of the payer -- rest of HCA buckets of expenses. And maybe that is not easily commentable.

Ryan Taketomo: Hi. This is Ryan. Yeah, I am not sure regarding the UMP numbers, and I think Ryan mentioned that. I don't know if he had current data available, but if he has anything in addition to input, they will chime in, I guess.

Ryan Pistoresi: Yeah, I mean without having looked at the data in a little bit more detail, I don't think I really have anything to add right now.

Ryan Taketomo: Hi. This is Ryan Taketomo. We can move on to the next slide. All right. So on this slide, we're looking at the absolute change in PMPM between 2021 and 2023. So looking at the first item, the GLP-1 agonists. It pretty much means that between 2021 and 2023 then that paid PMPM increased by $0.78 per member per month between those two time periods, and so kind of a general trend that we can get out of this graph is GLP-1 agonists and SGLT2 inhibitors have seen kind of the greatest increase within PMPM. Some activity with the rapid-acting insulins and the DPP4 inhibitors, but other than that, everything else kind of remained relatively stable throughout the years. Next slide, please. And then on this graph we're looking at the percent change between the two years and, again, we're kind of seeing a similar trend with the actual increase. By looking at -- just to go over some of the numbers, the GLP-1 agonists have seen an over 200% increase in the net paid PMPM attributed to them. SGLT2 inhibitors are seeing over 100% increase in net paid PMPM, rapid-acting insulins at a 45% increase, and the DPP4 inhibitors a 19% increase. The next slide, please. All right. So in summary, the SGLT2 inhibitor and the GLP-1 agonist have seen the greatest increase in expenses since 2021, and GLP-1 agonist continues to be the most expensive Apple Health antidiabetic subclass since 2021. And then compared to the second most expensive antidiabetic subclass, the GLP-1 agonists are more than double in expenses. Okay, next slide, please. All right. So now we'll be looking at the same classes, but we'll be focusing on the utilization. For utilization, we will be looking at the number of distinct clients that have utilized the subclasses. So as you might expect, we see the Biguanides having the greatest number of clients utilizing that class, and then it kind of starts to -- it drops

off and it kind of evens out when you look at the long-acting insulins, the GLP-1 agonists, and SGLT2 inhibitors, and then the rapid-acting insulin. We see sulfonylureas, then kind of dropping off again, and then the rest of the antidiabetic subclasses just have continued decrease in utilization versus the other subclasses. Okay. Next slide, please. In this slide, we're looking at the number of clients who have used the various subclasses over time. In general throughout it looks like most classes do see an increase in utilization. So, for example, metformin or biguanides, those products are increasing from 57,000 clients utilizing that class to 62,000 in 2023. The long-acting insulins appear to remain relatively similar throughout the years. And then I think one of the biggest changes, of course, we're seeing is with the GLP-1 agonists and the SGLT2 inhibitors. So the GLP-1 agonists, they are moving from the sixth most utilized class in 2021 to the third most utilized class in 2023, and then with the SGLT2 inhibitors they move from the fifth most utilized class in 2021 to the fourth most utilized class in 2023.

Kavita Chawla: Hey, Ryan, Kavita here. I guess just an observation that it also looks like -- are we also diagnosing more diabetes or just more of our members are developing diabetes but, yet that is all just like almost 40,000. Am I looking at that right? 30,000 uh more? Because it looks like in 2021 it was about 135,000, and now it is almost like 160,000 people if I am reading the math correctly.

Ryan Taketomo: Yeah. So this is Ryan Taketomo. One thing to consider with the slide is that it is looking at distinct clients by the class. So, unfortunately, when we use that type of metric or calculation, we're not able to kind of add them up. So what that means is a client could be on both a [cross-talk] biguanide and a GLP-1 [cross-talk].

Kavita Chawla: Okay.

Ryan Taketomo: Unfortunately, we're not able to add it up that way, but the way to properly use the graph is just to understand the number clients using each of these classes.

Kavita Chawla: Thank you for that clarification.

Zoe Taylor: And this is Zoe Taylor. Also, we don't know that all these patients are actually diabetic, right? We just know that they are on a drug that is in the antidiabetic class, so the other trend that I am seeing is a lot of patients being

put on an SGLT2 for heart conditions who aren't necessarily diabetic. So just consider those kinds of things as well.

Ryan Taketomo: Yep. This is Ryan. I absolutely thank you for that comment. And then it looks like Dr. Barkett has a comment or question.

Peter Barkett: Hi, Ryan. Thanks. I was just trying to put this into context. What has membership done over the same time period? Has it been pretty flat or is membership going up or down?

Ryan Taketomo: Hi. This is Ryan Taketomo. So I believe like in 2021 and 2022, there was an increase in membership with, like, the COVID pandemic and that, but I think in 2023 there was the start of the unwind, and so there may be a decrease in membership starting then.

Ryan Pistoresi: Ryan is right. So in May of 2023, we had our peak of about 2.3 million lives in Medicaid, but that is also when we started the unwind, then over the next three months we did see a pretty significant decrease. I think by the end of 2023 where we were just a bit above 2 million, and I think that is about where we are today. We might actually be just right under 2 million lives in Medicaid as of July. I think that is the last time that I looked at our enrollment data. So if we look at this again in 2024 and we see a drop, that is likely because of the unwind.

Ryan Taketomo: Okay. This is Ryan Taketomo. Is there any other question or comment, Peter? All right. It looks like we can move on to the next slide, please. All right. And so on this slide, again, and this one is, again, just the absolute change in number of clients using each of these subclasses, so we see the GLP-1 agonists and the SGLT2 inhibitor seeing a significant increase, and then the remaining classes remaining relatively stable with maybe a little increase in the rapid-acting insulins. Next slide. Okay. And then similar to the previous slide, this is the percent change in clients between 2021 and 2023. And as we would expect, we're seeing the GLP-1 agonists and the SGLT2 inhibitors showing again significant increases with a 98% increase with GLP-1 agonists from 2021 to 2023 and an 84% increase with the SGLT2 inhibitors from 2021 to 2023. Next slide, please. All right. So, in summary, between 2021 and 2023, the utilization of the SGLT2 inhibitors and the GLP-1 agonists have increased significantly, and the utilization of all the other subclasses have remained relatively stable. Next slide, please. Now we'll be moving on to -- oh, it looks like we have a question or comment from Dr. MacKay.

Jon MacKay: Hey, Ryan. This is Jon MacKay. So I just had like a high-level question or observation. So a lot of times pharmacy gets siloed just like a net cost center, and I differentiate cost versus value what you get per dollar per unit outcome. So just wondering if there is any -- I don't even know how you would model it, but just take for example like a long-acting insulin and a GLP-1, is it possible to look at cost per outcome in terms of decreasing cost system wide? Don't know just in terms of like decreased cardiovascular events and renal protection and things like that. I don't know how you would do that from a holistic approach, but I mean I think that seems to be some of the drivers behind the changes in classes too.

Ryan Taketomo: Yeah. This is Ryan Taketomo. That is a great comment, and I don't have anything to present around that today, unfortunately. I think it would be great to look at that and bring that back at a future meeting, maybe if there is some type of outcome that we can tie back to the class. It might be a little difficult with antidiabetics as they kind of wrap -- they kind of intermingle with, like, cardiovascular event. And so is it because of the antidiabetic drug, or is it because of [indistinct] the blood pressure, but maybe in the future we'll have access to, like, A1Cs, for example. Or maybe that is something we can start collecting, and that would be one way to kind of demonstrate that value.

Peter Barkett: Jon, I just [indistinct] has done some of this analysis. I haven't looked at data specifically for GLP-1s from [indistinct]. I think the last time I looked at their data was for the monoclonal antibodies for Alzheimer's. But in my other job, we have looked at some of this, and the GLP-1s are not great value, just strictly by the numbers as GLP-2s show -- present much better value.

Jon MacKay: Oh, that is interesting. Thank you.

Ryan Taketomo: All right. This is Ryan Taketomo. It doesn't look like they are any more questions or comments at this time, so we can continue on. So now we'll be looking again at the GLP-1 agonists. So here are the current -- here are all of the GLP-1 agonists, and it is currently sorted by the amount we pay. We can see that Victoza, which is our preferred GLP-1 product, is the number one GLP-1 agonist. We spend about $0.63 per member per month. The next GLP-1 agonist is Ozempic, with the net paid PM of about less than a third or $0.19 per member per month. And then we have Trulicity and Mounjaro at $0.12 PMPM. Those kind of wrap up -- or I guess the second most expensive to the

fourth most expensive mainly represent the weekly GLP-1s, and then the other remaining GLP-1s kind of fall off with how much we spend on those products. Next slide.

Peter Barkett: Ryan, I just wanted to confirm. So that net paid figure, that is a monthly cost?

Ryan Taketomo: So the net paid PM is the per member per month. The net paid would be the amount spent for 2023 or the annual cost.

Peter Barkett: That is an annual cost? Wow, those are great rates [Cross-talk] --

Ryan Taketomo: [Cross-talk] Yeah, for 2023. And then I would add -- this is Ryan Taketomo, sorry. And I would add that when we look at net paid per client, it may not necessarily represent like 12 claims per client. And ideally, we would have, like, net paid per claim. However, federal regulations prevent us from revealing those rates that the manufacturers give us, so we have to use other metrics to kind of represent the cost of these therapies. But I would say that at the end of the day and when Victoza or Byetta are lower than the other GLP-1 agonists, then the cost of those are cheaper versus the other products.

Kavita Chawla: Ryan, Kavita here. I have a couple of questions. One is though on the basis of what you just said, net paid per client, and this is for the year 2023, so would that be fair to, like, say for Victoza, a person who is on Victoza for the year 2023, Apple Health paid $900.00 for the entire year for the 12 months, and so the per month cost would be 900 divided by 12?

Ryan Taketomo: Hi. This is Ryan. So, again, when we think about a Medicaid population, they are not -- they don't have stable membership over the [cross-talk] course of the year, so most likely they are filling less than 12.

Kavita Chawla: Okay.

Ryan Taketomo: Ideally, when we want to compare the cost of these drugs, we would again use net paid per claim or something like that, but because of again the regulation, we're not able to provide those rates. So -- if a patient were to use these drugs for a full year, the cost would most likely, or they would be a lot higher than what is shown here.

Kavita Chawla: Got it. Okay. And then the second question is, Victoza being the highest net paid, but is that also a factor of what is preferred on the drug list and hence that is the one that gets approved most often?

Ryan Taketomo: Hi. This is Ryan Taketomo. And yes, that is correct. And as we'll see later, we'll move into utilization looking at the number of clients using each of these products. That will help give you an idea around that.

Kavita Chawla: Thank you, Ryan.

Ryan Taketomo: All right. This is Ryan Taketomo. It doesn't look like there are any other questions or comments, so we'll move on. And so on this slide, we're looking at the net paid between 2021 and 2023 for each of the products. We can see that the most expensive GLP -- or the GLP-1 that we're spending the most on is Victoza between the years. I think it is interesting to see just how much it has increased from around $5.26 million in 2021 to $16.6 million in 2023. We see Trulicity being the second most expensive, but it kind of falls to the third most expensive by 2023. And then we have Ozempic that the PM -- or the cost is so small in 2021, but it increases to $5 million in 2023. Overall trend for all these products though is at that they have typically seen an increase in utilization. With the biggest increase going to Victoza and Ozempic, I think. Okay, next slide, please. All right. And so this is the actual net paid change between the two time periods 2021 and 2023. Victoza has increased $11.35 million since 2021, Ozempic has increased $4.71 million, and Trulicity has increased $1.76 million. I do want to call out that Mounjaro is not listed because they came out in 2022, so that that medication is not listed here. But I think on the previous slide the cost in '23 for Mounjaro was a little over $3 million. Okay, next slide, please. And then this is just looking at the net paid percent change between the two time periods. Ozempic stands out significantly at 1300% increase. Part of it is due to it probably just came out around 2021, and so the utilization was a little bit low. That is why we can see a really big increase in percentage. And then Victoza, Trulicity, Rybelsus, they still all have pretty significant increases, and they have been out. For Victoza, it increased 215%, Trulicity increased 121%, and Rybelsus increased a similar percentage as well. Okay, next slide. All right. So, in summary, since 2021, we have seen the amount of expenses attributed to GLP-1 agonists triple. More than half of the GLP-1 agonist subclass expense is attributed to Victoza. It is 55.38%. One reason is that it is the preferred product -- it is one of our preferred products on the Apple Health PDL. And then just kind of looking at the most expensive GLP-1s. From 2021 to 2023,

the amount spent on Victoza increased 13 -- sorry, $11.35 million, and Ozempic increased $4.71 million. Okay, next slide, please. Okay, now we'll be looking at the utilization by the number of clients using each of these therapies. And kind of similar to what we have seen with the net paid graphs, we're seeing the same thing with the utilization. So Victoza remains kind of the most utilized GLP-1 agonist. We see just a lot of increase over our preferred product in the weekly GLP-1 products. And I think it is interesting to see that. I think we saw the costs of Victoza -- I am sorry, never mind. It looks like we have a question or some comment in the chat really quick. Let me address that. So Peter Barkett said has the liraglutide generic impacted the Apple Health strategy. For example, therapeutic interchangeability, or is the current rate better than generic prices? Net paid per claim would suggest that.

Peter Barkett: Yeah. So just for context. So Victoza (liraglutide) the generic came out, I think at the end of June and commercially available last month, and it is available at a lower price, although not hugely lower. So I am just wondering if that has impacted the strategy at all. It seems like you have probably already got a better rate than what the generic is selling for, so maybe not.

Donna Sullivan: Yeah. Peter, this is Donna. I agree that right now the generic liraglutide is probably net of rebate more expensive than the brand because of the way the federal rebates and cost the consumer price index penalties play out. However, I do believe that they are both preferred, so I imagine that we will see shifting to the generic.

Greg Hudson: Yeah. And this is Greg Hudson. I think there are more generics on the list for approval expected around like December. So this could look quite a bit different I wonder about around like 2025.

Kevin Flynn: Yeah. This is Kevin Flynn. Like Hickman's brand got approved, but they are still in the patent dance. The one that is generic now is actually an authorized generic from [indistinct].

Ryan Taketomo: All right. This is Ryan Taketomo. Thank you for all the comments and feedback. So moving on with the discussion, just looking again at the -- GLP-1s over time, again Victoza remains the top utilized product by number of clients. Ozempic increased from the four most utilized in 2021 to the second most utilized. Trulicity kind of remained the third most utilized, and then you kind of see this change with Bydureon Pen because that product isn't

available anymore. And so those people -- those clients were switched to the Bydureon Bcise product. And then I guess for that orange under the yellow, that represents Mounjaro starting to have some increase. Okay, next slide. Okay. On this slide, we're looking at just the absolute number of clients change from 2021 to 2023. Between those two time periods -- the number of clients using Victoza increased by 8800, Ozempic increased by 3000 clients, and then Trulicity, Rybelsus, Bydureon Bcise an increase of 500 or so or less. Next slide, please. And then here we're looking at the percent change between 2021 and 2023. Ozempic increased almost 400%, Rybelsus increased 221%, Victoza increased 91%, Trulicity increased 63%, and Bydureon increased 31%, so just increases in utilization of all these different products between the years. Okay, next slide, please. Okay. In summary, since 2021, there has been a significant increase in the prescribing of GLP-1 agonists. Yeah, Victoza is currently a preferred product, and that is kind of why it captures most of the utilization. It looks like more than half of the clients using a GLP-1 agonists have used Victoza in 2023, and then for the nonpreferred products, Ozempic and Rybelsus saw the greatest increase. And with the caveat that Mounjaro is not shown just because we don't have that 2021 data from Mounjaro, since it wasn't out at that time. Okay, next slide. All right, so now this is some modeling we put together to kind of depict what would happen if we had one of the weekly GLP-1 products as a preferred. Status on our PDL. So when we look at the cost to the Y axis, it is labeled as Incremental Cost in Millions. So what does that means, what is that for a 90% switch? That means if 90% of the people using a GLP-1 agonist switched to Ozempic, for example, we would see an additional $10.9 million increase in expenses for 2023. So the costs that we spent in 2023 was about $30 million. That would mean if Ozempic became preferred -- we would have spent $40 million. And then along the X axis, we kind of show if 70% switched, 50%, and 30% switched. And then looking at which products might have the better rates, we included Trulicity as well. So I will keep this slide up for a little bit just to have the Committee be able to look at it and digest and see if there are any comments or questions.

Jon MacKay: Ryan, this is Jon MacKay. So I just had a comment. Given the massive demand for the GLP-1 class and growth and substantial costs, is there -- I don't know if there is any potential to kind of model a reimbursement similar to like hep C in terms of maybe a subscription model -- anything like that been thrown out there?

Ryan Taketomo: Hi. This is Ryan. I personally haven't heard of anything, but I will see if anyone else from HCA has anything to [cross-talk] with --

Donna Sullivan: [Cross-talk] Hi, Jon, this is Donna. You know, that is a great question. We have mulled over that in our minds as well. I can't say that we're in the process of doing that, but that is a great idea, especially when we look to consider the potential shift to covering the GLP-1s that are approved for weight loss, so yeah, stay tuned. And then also just a reminder that it depends on the willingness of the manufacturers to play in our sandbox [laugh] to play with us on that. So it will be interesting to see if we could arrive to some arrangement. That would be great.

Jon MacKay: Thank you.

Ryan Taketomo: All right. This is Ryan Taketomo. I think we can move on to the next slide. It might be the last one. Oh, no, second to last. All right, so on this slide, we're looking at the prior authorization determination rates, and this combines both fee-for-service and the managed care organizations. So the first column -- has the drug name, the second column has the total number of requests, and then we kind of break out those total requests by the number of requests that have been approved, their percentages, and then the number of requests that have been denied and their associated percentage. So I will leave this slide up again for just a little longer and then open it up for any questions or discussion.

Donna Sullivan: Ryan, I think it is important to point out that Victoza, Bydureon Bcise, the Bydureon Pen, and Byetta are actually not on prior authorization, so these requests are for most likely quantity limit exceptions, and that is why there is such a high rate of approval compared to the other medications.

Kavita Chawla: Do we -- have an understanding of the most common reason for denial? Especially for the approved medications or the -- yeah, the ones that don't require a PA.

Donna Sullivan: I didn't look at it specifically, Kavita, but my guess is that they haven't tried the preferred drugs, and that is why it was being denied.

Kavita Chawla: I see. So if I -- did I hear you correctly, then, that the Victoza does not require a PA, or it does require a PA?

Donna Sullivan: It does not.

Kavita Chawla: It does not. So then why would 84% be denied if it does not require a PA? So basically, is it a preferred drug then? I think I am conflating.

Donna Sullivan: It is preferred. And I am sorry, I probably was reading the wrong column when I said what I said. So most of the requests that you see for Victoza are likely for exceeding the quantity limits, and so the high rate of percent denied is likely because they are requesting a dose that is not FDA approved for treatment of diabetes.

Kavita Chawla: Ah, I see what you are saying. So they are trying to get to like a Saxenda-type dose.

Donna Sullivan: Potentially, yes.

Kavita Chawla: Yeah. I see what you are saying. Okay.

Peter Barkett: Donna, do any of these denials include lack of benefit or expiration of the patient's coverage, or are these all kind of medical necessity or quantity limit driven?

Donna Sullivan: These are all medical necessity reviews. If they have lost their eligibility, the claim rejects as no coverage, and they wouldn't even get to a prior authorization request.

Ryan Taketomo: All right. So this is Ryan Taketomo. We can move on to the last slide. And then I just have the net paid over time for the different products and the utilization by number of clients over time, and I wanted to use these two graphs and talk about just our GLP-1 agonist policy that went live February of 2022. So in that policy again we in order for a nonpreferred product to be authorized, they have to trial and fail a preferred GLP-1, a preferred SGLT2, and then metformin at maximum tolerated dose. And I think when we look at these slides just for GLP-1s, in general, with clients we have seen just an overall increase in general. but I think it is important to just to call the effectiveness of the policy and that when we look at kind of the net paid and the number of clients, the Victoza does provide a better value with cost per client, but we are still seeing patients being able to get their weekly GLP-1s once they meet those trial and failure requirements. So I think I will leave it at that, and then open it up for any last comments or questions before we

move on to the next agenda item. All right. So this is Ryan. Right. So hearing none and seeing no hands raised, I think we can conclude this part of the presentation, and we can move on. So thank you, everyone, for your participation. Appreciate it.

Kavita Chawla: Thank you, Ryan. Hey, so I think with that, well, I guess we'll keep you on Ryan. And Marissa, we're going to dive into our Cytokine and CAM Apple Health policies.

Marissa Tabile: This is Marissa. Yes. Let me pull them all up. It is quite a bit so [cross-talk] --

Kavita Chawla: How would you like us to -- is there a fair amount of overlap between the policies where we should look at all the policies together first and then discuss? Or do you think for every policy we should have a discussion, approve it, and then go to the next one?

Marissa Tabile: This is Marissa. So I am going to point out in the policies where there is overlap. I am not going to go through all of the 11, but instead I am going to take an approach of just going through all the indications because I do want to preface this. The criteria for all of the shared indications I am going to say are going to be very much largely the same, and that was by design as we were updating these policies just so that then it is uniform across all 11, so hopefully from what I have calculated out, I shouldn't have to go through all 11. There are about 35 indications. I can or can't go through them very quickly, very slowly, whatever you guys prefer, but I will point out at least all of the indications for them, any nuances to them, and then we'll just approve. We can go through if you are noticing -- if you do -- if any of the DUR Board Members do want to see a specific policy that I didn't go through indication by indication or whatnot, I can certainly pull up that particular policy for you all to look at, and then we can kind of make any changes. And even with any of the indications that I do go through, just know that any of the changes that you recommend will be applied to all of the policies once the DUR Meeting is over. So it is going to affect potentially all 11 or however many overlaps. So I know it is a lot. I appreciate your patience. I apologize, they don't have all of them pulled up yet but let me get them. There is quite a bit, so hold just one minute. And then -- isle 6 and then -- I am so sorry. This is quite a bit.

Kavita Chawla: Take your time. It is all right.

Marissa Tabile: Okay. Let me -- All right. Let me turn my camera, or I should be on already. Okay, perfect. So let me just share my screen. All right. So good morning, DUR Board. This is Marissa, and I will be going through with Ryan T. our Cytokine and CAM policies. So just to give you all some background on the strategy that we are taking, hence why we are presenting all of these policies to you all today. So currently what I have displayed on my screen is our current Cytokine and CAM policy that has been effective since about 2019. So this policy is inclusive, or we have tried to be very inclusive of all of the products that live in the Cytokine and CAM AHPDL drug class. So those are the Humira, the Enbrel, the Rinvoq, all of those products live in this one policy today. So we are finding that this particular policy is a very high touch policy, which is everchanging, sometimes every month, sometimes every couple of months, at least once a year these policies have to be updated whether that be new indications for products currently on the market and then new products that come to market. So this is a policy and then of course now with the Humira biosimilars, it is something that we're having to constantly update all the time. It is proving to be a little bit of a heavy load or at least something that, like I mentioned, is very high touch, just because of like the way that these products are changing in the market. So it has been a little bit hard to update and making sure that we're getting the indications current on here, the drugs current on here, and the overlapping of the indications is making it a little bit hard as far as trying to manage this particular policy. So we're taking a new approach moving into -- these policies you will see probably won't be implemented until 2025, but what we're looking to do is split this policy out -- the current policy into 11 different policies, and that is by mechanism of action for each of these drugs. So some of these products have the same mechanism of action, some of them are different, so that is why you will see them split up. We found that splitting them up into 11 was the best way for now that we would like to manage them. It is quite a bit of policies as far as even just 11 policies in general, but that is really what our strategy will be. We are considering also possibly splitting out the Cytokine and CAM AHPDL class into 11 different classes or subclasses based off of the mechanism of action, but that is still pending some internal discussion and what it is going to look like operationally once we implement these policies. So that is a little bit of background. I will say our current policy right now that you see displayed is missing some indications, so we have in these 11 policies added some of them that are missing. We have also included in the 11 policies -- and this is just a general rule of thumb that we do for all of our policies at HCA. We do include those non-FDA-approved but compendia-supported indications. There are particular strength of evidence and strength of

recommendation standards that we follow. So those ones are if the indication has a strength of evidence, which is category (a) and (b), and strength of recommendation class 1 or 2(a), then we do typically include those kinds of off-label indications in our policies. So you will see some of those scattered throughout, or you will see some of the drugs applied to some of those kinds of off-label indications. And Dr. Taylor, it looks like you have a question.

Zoe Taylor: Hey! When you split them up into different policies, does that also mean that you are creating new classes? Like, I am just trying to think about it as it would apply to the P&T Committee rather than the DUR Board. Does that mean that we're creating new classes, or they are all still going to be in the same class?

Marissa Tabile: This is Marissa. As of now, no, we wouldn't be creating new classes, but we are considering once these -- once this policy goes live or when we determine we want it to go live, if we do want to create those new classes. So that is something we're still kind of playing around with, but for now, everything will still be in one class. Everything will just have its own kind of separate policy for now.

Zoe Taylor: Okay, great. Thank you.

Marissa Tabile: Mm-hmm, no problem. So with that, I will go ahead and -- actually, okay. This might look a little confusing. This is a little visual that I created to show you all the overlap as far as all of the indications and all of the policies. So as I mentioned at the beginning, there are 35 indications spanned across all 11 of these policies. So as you can imagine, it is a little bit of a very loved labor of love policy. What I am going to do is I am going to start with the first one, which is our TNF inhibitors, and that is where you will see the Humira, the Enbrel, the Remicade products, or I am sorry -- yeah, those are going to be all in here. That is largely I will say where a lot of the products kind of branch off from and have the same indications, so a lot of the focus will be on the TNF inhibitor and policy. And the indications, like I said, span across all of the different ones. So I am not going to go through, for example, AD poly -- or plaque psoriasis because you will have seen the same -- we applied the same criteria to all 11 policies if it shared the same indications. So I am just going to call out the ones that maybe have special indications or like brand new things, and then Ryan will as well. So this is just if you see them the same color, so this green here, this means that this indication lives in this policy and so on and so forth. So it is kind of all over the place, kind of a rainbow of

sorts, but we'll get through it. So with that, I will go ahead and start with the first policy, like I mentioned, which is the TNF inhibitors, if I can get it pulled up. Okay. So this is our TNF policy, which, like I mentioned, it has -- it actually has more. There is Humira, Cimzia, Enbrel, Simponi, and Remicade, which all live in these policies, and then, of course, the Humira biosimilars and the infliximab biosimilars are in here as well. Some of these -- so I guess I will just get into it -- and feel free to -- if you want me to present it a different way, let me know. I know that 35 is a lot of indications, but I will try [audio cuts out] to go through them very quickly here. So for the first indication, I do want to mention for our PDL, Humira and Enbrel are -- our brand name Humira and Enbrel are our preferred Cytokine and CAM products at this time. So with that being said, we would typically -- and you know just by the way the PDL is designed, we would want patients to step through Humira Enbrel for whatever indication if it is appropriate for them before they can get a nonpreferred product, which is everything else. So I will try to call out the nonpreferred criteria for you all as it comes up. So for this first criterion, it is ankylosing spondylitis and nonradiographic axial spondyloarthritis. So this Criteria 1 through 8 applied to Humira and Enbrel, which I mentioned are the preferred. So for this we have an age indication 18 years or older, specialist indication, not used in combination with another Cytokine and CAM. And actually I do want to note a lot of these criteria you might see are the same. We did try to keep in mind any age differences, any weight requirements. But the specialist indication but not used in combination with another cytokine and CAM, those are going to be largely the same as well across all 11 policies. And some of the trial and failure are going to be the same as well. So if you see something like I am saying it multiple times or you see it. That is we did that by design just to create some uniformity across all of the policies. So 4.) is diagnosis of ankylosing spondylitis, or 5.) nonradiographic axial spondyloarthritis, 6.) is just we would want to see high disease activity either indicated by a BASDAI of at least 4 or ankylosing spondylitis disease ASDAS score of at least 2.1, 7.), treatment with at least two different NSAIDS has been ineffective, contraindicated, or it is not tolerated, and then 8.) other diseases manifested as either of the following: axial or peripheral arthritis, and they would need treatment with at least one non-cytokine and CAM DMARD. Those are like the methotrexate, sulfasalazine, leflunomide, those products. If they meet all 1 through 8, then that means that they could get approved for Humira Enbrel. If they are requesting a nonpreferred product, which is like the Cimzia, the Simponi, the Remicade, the adalimumab biosimilars, then they would also need to meet the criteria that is down here below. So they would need to meet 1 through 3,

which is above and 4 or 5, which is just 4 or 5, Criteria 6 through 8 is met, and then we just have this here, treatment with two preferred cytokine and CAM AHPDL medications have been ineffective, contraindicated, or not tolerated. So that is really essentially saying you have tried Humira and Enbrel in order to get the nonpreferred. And so for this indication if all -- I believe for most of them we have done 6-month authorizations for the initial, and then for the re-authorization we increase that to 12. And then for the re-authorization criteria, it is going to be largely the same across all of them as well. It is not used in combination with another cytokine and CAM, and then documentation is submitted demonstrating disease stability or positive clinical response, so decreases in BASDAI or ASDAS score. And Dr. Barkett, it looks like you have a question.

Peter Barkett: Here we go, coming off the mute. Thanks for sharing the re-auth criteria. That was initially going to be my question, but what about transition of care? Do you apply the initial authorization? Like if somebody comes on to Apple Health and they have been on a different biologic, would you apply the re-auth criteria or the initial auth criteria? It is not a protected drug class, right? So would you request people to change to a preferred, or would you grandfather their previous prescription if they are stable?

Marissa Tabile: I believe if they have been like on a nonpreferred product and they are transitioning over to Apple Health, there is continuation of therapy that we do allow, so we wouldn't require them to switch. We do have that in place, so they could use the re-auth criteria.

Peter Barkett: Thanks.

Marissa Tabile: Mm-hmm. Yeah, I believe all the nonpreferred have continuation. If I am wrong, let me know, but I believe that is the approach that we have for all of those. Dr. Taylor, it looks like you have a question.

Zoe Taylor: Yeah, hey. This is Dr. Taylor. So I have a patient who was kind of in this exact situation where rheumatology really felt strongly that he shouldn't have to try Enbrel also, given that Humira didn't work, given that he had already also tried like three or four other medications. So I think what happens is that if they haven't tried these two exact meds, but they have tried a bunch of other ones that are similar, it gets denied. And so I am wondering if for that last section the treatment with two preferred it would be possible to change that philosophy to like if they have tried something really similar to one of those,

and the specialist doesn't feel like they should have to try another thing that is very similar to something they have already tried that happened to not be preferred by Washington Apple Health, but maybe they had a different insurance before, or maybe the rules were different before. Is that making sense? I think what is unfortunately happening is then he's having to take a step back from the monoclonal antibody to the to the small molecule drug, even though we kind of know it is not going to work before he can move on to another monoclonal antibody, which just medically doesn't really make sense.

Marissa Tabile: Yeah, okay. This is Marissa. I see what you are saying. Um, we can consider adding language like that. I feel like with a case like that, that could fall under kind of our case-by-case basis language, and that could be -- oh, that is a little tough. I was going to say that could be up to the clinical reviewer and who reviews it. Because I see what you are saying for them to have to step back.

Zoe Taylor: Like, would it be possible if they have already tried Humira to be enough rather than having to try both Humira and Enbrel. I want to hear what maybe other doctors or pharmacists think about this.

Peter Barkett: So I have come across this in my other PNT work that I have done, and it does seem reasonable to require two agents in a class, and the only concern I would have about basically just crossing out that word Preferred. And you know if somebody tries two other agents in that class, like, does it really matter that you tried the particular agents? The only thing is the comparative efficacy, and some of the agents like Humira are very efficacious. If you don't if you don't respond to Humira typically, [cross-talk] there is not something stronger in that same class, but some of the agents in this class are going to be less efficacious, and so if somebody tries one of the less efficacious agents and it didn't work, is that good enough to go on to something more, or would you really want them to try the more efficacious one first. So I don't know. I [cross-talk] kind of throw up my hands [cross-talk] --

Zoe Taylor: [Cross-talk] So in this case he did try Humira. So I think if we know that Humira is really efficacious, what I am asking is, why do they also have to try Enbrel in order to move on? So in this case, he needed -- he wanted to move on to Stelara, and it has been like a year, and we still can't get him Stelara, and his psoriasis is terrible [cross-talk] --

Peter Barkett: [Cross-talk] So I think that [cross-talk] --

Zoe Taylor: And I think, like, why have to try Enbrel, basically, is the question.

Peter Barkett: Well, I think it is reasonable to try two agents. I think the question I am kind of wrestling with is, does it matter which two agents you try? The only situation where I think we have evidence where it says that if you try one agent and then trying the second one is unlikely to work is IBD -- and so in my other P&T role, like, we actually in IBD can switch after one agent. That was kind of the criteria we came up with, but that is because there was evidence. I think in this case for non-IBD indications, like, we don't have that evidence to say that if you tried one, you are definitely not going to respond to another one. I mean, I think adalimumab and etanercept are good agents. But do we need that word Preferred in there? I think that is where there might be some wiggle room, and I would be curious to hear what other people say. [cross-talk] --

Zoe Taylor: [Cross-talk] Well and I think the hard thing is because there are only two preferred agents, and only one of them is a monoclonal antibody, that also makes it hard, right? Like because you are forcing them to try these exact two, basically.

Marissa Tabile: So this is Marissa. I will note that we kept it broad with saying treatment with two preferred Cytokine and CAM because we do acknowledge that down the line as things change as this class changes, there might very much be a third or a fourth preferred Cytokine and CAM that we may change on the PDL. So without us having to go back and update all 11 potentially, we don't call out, like, specific medications in this language with the acknowledgement that there might -- we might add more Preferreds. We might take away Preferreds. We probably won't take away -- probably more so add, maybe. But we do that just so that then we won't have to constantly update it. If there are changes to the PDL where we add another preferred, then that kind of covers it. So I don't want to say, like, specifically. I mean right now it is Humira and Enbrel, like I mentioned, are the preferred products, but we wrote this language in a way that if it does change where there are more preferred products that get added, then they would fall underneath that umbrella, and then at that point, it wouldn't just be Humira and Enbrel that they would have to try. They could potentially have to try other products. And then it looks like Dr. Barkett and Dr. Weiland, you guys both have questions. I don't know who wants to go first.

Christy Weiland: [Cross-talk] I was just going to ask.

Peter Barkett: [Cross-talk] I usually take my hand down.

Christy Weiland: In the case where Zoey is describing, in the past when things haven't lined up, and it is kind of a scenario outside of the norm, I have requested peer-to-peer reviews, and that is been a scenario where those type of things can be taken into consideration. I am assuming there is an opportunity like that here as well. Is that true, Marissa? And so that would be kind of a situation that doesn't fall in line perfectly, but the peer-to-peer could resolve that.

Marissa Tabile: This is Marissa. Yes. I believe what we have is, I think we have called what is called the appeal process, so if you do have a request that does end up getting denied, then you -- then the patient can definitely appeal, and then it will get reviewed by somebody else. So there is -- we do have that process in place.

Zoe Taylor: Yeah. It is just really hard because we have rheumatologists that come once every two months to our Community Health Center and then don't look at their epic in between, so it is just logistically for rural areas where there are no rheumatologists. It is really hard to convince them to do a peer-to-peer, and I wouldn't be able to do it. It has to be the rheum -- so, anyway, I am just trying to share the actual real life struggles of trying to treat underserved patients in a rural area when we have all these hoops to jump through. But I understand why the rules are the rules. It is just I want you guys to understand that real life scenario.

Marissa Tabile: This is Marissa. Yeah, thank you, and thank you for providing that insight. Dr. Barkett, it looks like you might have a question or a comment. Or is your hand still up on accident? [laugh]

Peter Barkett: Nope. I tried to take it down [cross-talk] --

Marissa Tabile: Okay.

Peter Barkett: There we go.

Marissa Tabile: This is Marissa. I should also mention, I don't have pen forms to share with you all today just because for our operations team will be creating those kind of authorization forms after all of the policies, if they do get approved today after they get approved just because of the potential for these policies to

change, we didn't want to really create 11 different pen forms that we would all have to change, so we will have them ready probably once we decide to implement. When we implement these policies, we'll have pen forms to go with them. Any other questions? Okay. So I will just move through kind of briefly, I will point out maybe some differences as far as the diagnosis and maybe trials and failures amongst all the different indications. I think sitting here for all 35 might be a little much, so I will try to go through them pretty quick. The next indication we have on here is Behcet's disease, same age -- specialists are a little bit different, kind of same. The only thing that is different, of course, is going to be the diagnosis and then the trial and failure of particular products which are appropriate for that particular condition. So in this case, if you have Bechet's with oral ulcers, we would want you to try topical corticosteroids, sucralfate mouthwash, colchicine, and oral corticosteroids. Or if you have Behcet's that manifested as uveitis, we would want trial and failure of ophthalmic corticosteroids, and ophthalmic cyclopentolate, oral corticosteroids, and then at least one non-cytokine and CAM DMARD. And, of course, we do have language in that trial and failure. If it is not appropriate, so history of failure, if it is not appropriate for them, if they if it is contraindicated or not tolerated, then we do take that into consideration for approval or denial. Same thing [audio cuts out]. We do call out specifically just Humira because Humira does have -- it is off label or compendia supported, like I said, with the strength of evidence and strength of recommendation, so we would expect that they would try Humira before they get anything else. So we did add that here. Sorry, this is for the biosimilars. We want them to try brand before they can get the biosimilar. Same approval, six months. Same type of re-authorization language, just different types of clinical responses that we would be looking for. Next, is going to be Crohn's disease. We do have certain age indications just taking into account the different drugs. So you will see these are a little different. If you have a pediatric patient, I do want to point out we do want documentation of their current weight, just because it is weight-based dosing for this one, for Crohn's disease, moderate-to-severe. We do want to see a trial of a conventional therapy, so it will be oral corticosteroids and at least one immunomodulatory agent, so methotrexate, azathioprine, mercaptopurine, one of those. And then just documentation of their high risk disease. So these are the examples of what we would want to see in the documentation for this one. And it looks like Humira is the only one that has that indication. And then these just apply to the nonpreferred products, taking into account their age, indications, and any weight that we would be looking for, and then, of course, trial of the brand Humira before they could

get a nonpreferred product. Same re-auth criteria, just different kind of clinical things we would be looking for. This one has hidradenitis suppurativa. This one just has age, specialist. For this one they would just need that diagnosis of HS, presence of the nodules, staging of their disease if it is II or III. And then here, it is the history or failure -- history of failure, contraindication, or intolerance to at least one oral antibiotic, so that could be doxycycline, minocycline, tetracycline. We have the examples here for a minimum of three months. And then that would be for Humira. And then for the biosimilars, we just want to make sure that you have -- why does brand Humira -- have you tried brand Humira before you can get the biosimilar? Same read off that you have seen before. This one has Juvenile Psoriatic Arthritis, which applies to Enbrel. For this one, the treatment -- really the trial and failure that we're looking for is at least one non-Cytokine and CAM DMARD. So the methotrexate, sulfasalazine. We do want to see documentation, presence of active severe disease as indicated by the provider with at least one of these assessments. And then they will be authorized for six months. Same re-auth criteria. Next, we have Plaque Psoriasis, which is both Humira and Enbrel have that. For this one, there are age indications for the specific products. For this one, we would just want to see that they have at least 10% of their body surface area is affected or the disease affects the face, ears, hands, feet, or genitalia. Any baseline assessments are included in that and history of failure or contraindication or intolerance to either of the following: So if they have tried phototherapy for a minimum of 12 months -- 12 weeks or treatment with at least one non-Cytokine and CAM DMARD, so methotrexate, cyclosporine, those products there for a minimum of 12 weeks. And then for the nonpreferred, it is really the same as above, treatment with Humira and Enbrel, and you meet the above. Same re-auth. For this one, it is Polyarticular Juvenile Idiopathic Arthritis. Really the same. For this one, it is just the same treatment with at least one non-Cytokine and CAM DMARD, and then same thing for the nonpreferreds. This one is Psoriatic Arthritis. Pretty much the same as you can see. Treatment with at least one non-Cytokine CAM and DMARD, and then presence of active -- or presence of active severe disease as indicated by one of the following, and then same it looks like this is for Humira and Enbrel has both the indications, and for the nonpreferreds, they would just have to use at least treatment with at least those. Refractory Sarcoidosis. This is for Humira has the indication and infliximab. So for this one they need a diagnosis of pulmonary sarcoidosis, history of failure or contraindication to the following: oral glucocorticoids and immunosuppressive agents. And then we just want baseline assessments submitted. And then for nonpreferred,

just have you tried brand Humira? Does it work? Then for the re-auth, it is the same. For Rheumatoid Arthritis, it is both Humira and Enbrel have that indication. We are just looking for really baseline assessments and then treatment with at least one non-Cytokine and CAM DMARD. And then for nonpreferred, same step-through. Right now, our preferred is Humira and Enbrel, and then the same re-auth. We have Ulcerative Colitis on here that is just for Humira. Humira is the only one with that indication. So for this one, diagnosis, baseline assessments using the following, and then treatment with conventional therapies: so systemic steroids, azathioprine, mesalamine, sulfasalazine for a minimum of 12 weeks. And then if you are looking for the nonpreferred -- if your request is for nonpreferred, it is really just stepping through Humira since that is the only one out of the two that has the indication. This one is for Uveitis, Panuveitis, which applies only to Humira. So Enbrel does not have this indication. For this one, just a diagnosis of noninfectious intermediate posterior or panuveitis. This one treatment with at least one periocular injection implant, topical, or systemic -- corticosteroids. So the triamcinolone, dexamethasone, fluocinolone has been ineffective for at least one week, and then treatment with at least one non-corticosteroid systemic immunomodulatory therapy, so mycophenolate, tacrolimus, cyclosporine, those types of products, for a minimum trial of three months. And for nonpreferreds, have you stepped through Humira? And then re-auth there. And then these are all -- it was pretty extensive. These are all the quantity limits, which we are -- we do acknowledge. Some of them do need to be updated in this, so we are going to update those to reflect correct dosages that are available. That is it for this one. The next policy I will go through is the IL-4, which has our asthma indications. So let me -- there we go. So this one is the IL-4, IL-13 inhibitors, which is where Dupixent and Adbry live. In this policy, you will see the asthma, atopic dermatitis, chronic rhinosinusitis, eosinophilic esophagitis, and prurigo nodularis, which largely applies to Dupixent. Dupixent, as you all may have noticed, is getting more and more indications besides atopic dermatitis and asthma that are coming out. So we did find that this policy should be included in the 11 for these, just because of the nature of the indications and the drug. So we do have a Dupixent policy that is live on our website right now. Some of the criteria are largely the same in here. We did make a little bit of tweaks in here, but that is really the rationale. So for this one, the atopic dermatitis, we have Dupixent and Adbry. Dupixent is a preferred product right now on our PDL, and it is just PA to policy, so we did keep the criteria largely the same. There might be some small tweaks, which I can't really point out right, but that is kind of what we would require if you were requesting Adbry, for example, for atopic

derm. So age, specialist, not used in combination with another Cytokine and CAM, diagnosis of moderate-to-severe atopic dermatitis, documentation of the BSA that is involved or the disease severity they are experiencing, the patient is experiencing functional impairment, maybe due to some of the following: so it is affecting their activities of daily living, skin infections, sleep disturbances. This one is history of failure to find his inability to achieve or maintain remission to at least two of the following: so either a steroid, and Group 1 is topical corticosteroid of at least medium-to-moderate potency, so clobetasol, betamethasone, halobetasol, or topical calcineurin inhibitors of pimecrolimus, tacrolimus, or a topical PDE-4 inhibitor, which is crisaborole. So if they tried at least one -- two of those from different groups than we would -- that could make them eligible, and that is just for Dupixent. If they want Adbry, essentially what this is saying is you would meet all of the above 2 through 7 and that you have tried Dupixent, and Dupixent does not work for you, and that would be a minimum trial of 16 weeks. For this one, the re-auth criteria is a little bit different, kind of the same. We just want documentation demonstrating disease stability or positive clinical response, so showing that there has been a reduction in body surface area involved, achieved or maintained clear or minimal disease from baseline, experience or maintain a decrease in EASI score, or they have an improvement in functional impairment. And then we re-auth for 12 months for this one. Asthma, it only applies to Dupixent. For this one, they just need to have a diagnosis of moderate or severe asthma and moderate -- this is what is defined -- we define as moderate, which is really from the GINA Guidelines, so we have those there. Daily symptoms: Nighttime awakenings, limitation of normal activities, lung function exacerbations requiring oral systemic corticosteroids. And then for severe, it is just a little bit different as far as the number of nighttime awakenings, which we have defined here, difference in lung function, and then that looks like that is really the difference. Then we have different labs that we would be looking for. So the blood eosinophils, if they have had two or more exacerbations, and then that the patient is currently being treated with a medium-to-high dose inhaled corticosteroid and one additional asthma controller medication, or maximally-tolerated ICS and LABA combination product. So this one here is that they would be on an ICS and either a LABA or LAMA. This one is like the separate. Sometimes -- for the most cases, a lot of people are on combination, so we did just put here they are on the combination product for the ICS/LABA. And then they will continue to use their asthma controller medications. Same thing. Just here, we want to make sure in the re-auth that they are still using their controller medications. And then for this one, Chronic Rhinosinusitis with Nasal

Polyposis, this is really just for Dupixent. I believe this is new criteria, so I will kind of go through it quickly. For this one, not using in combination with another Cytokine and CAM. They need to have a diagnosis of chronic rhinosinusitis with nasal polyposis, diagnosis of bilateral sinonasal polyposis, as evidenced by an endoscopy or CT. The patient has an impaired health-related quality of life due to nasal congestion, blockage, or obstruction. Patient has at least one of the following symptoms: nasal discharge, facial pain or pressure, reduction of loss or smell, and they have a history of failure, contraindication, or intolerance to either of the following: so intranasal corticosteroids or oral systemic corticosteroids within the last 12 months. And their background intranasal corticosteroid, so the Rhinocort, Omnaris, Flonase, and Nasonex will be continued with the use of Dupixent unless those are contraindicated. For this one, we'll authorize the request for 12 months. And then for re-auth, it is pretty much the same as what you have seen. Just make sure that -- we just want to make sure that they are still going to use their intranasal corticosteroids, and then it will be re-authorized for 12 months. For this one, Eosinophilic Esophagitis (EOE), that is for Dupixent. For this one, what we're really looking for is diagnosis, weight, that they meet all the symptoms. They have symptoms consistent with eosinophilic esophagitis, so dysphagia, food impaction, vomiting, central chest and upper abdominal pain and eosinophil predominant inflammation consisting of a peak value of greater than 15 eosinophils per HPF as confirmed by endoscopic biopsy, and, c.) see the underlying cause of the condition is not considered by any other allergic conditions or any other forms of esophageal eosinophilia, and 7.) the patient has experienced persistent EOE symptoms during or following an adequate trial of dietary restriction, what is called the impaired elimination diet for a minimum of two months, and 8.) history of failure, contraindication, or intolerance to a PPI for a minimum trial of two months, and swallowed topical corticosteroids of fluticasone/budesonide for a minimum trial of 12 weeks. If they meet all of the criteria, it will be approved for 12 months. And then same re-auth criteria. That should actually be #2 there, so we will get that fixed, and then it will be re-authorized for 12 months. And I think the last indication on this one is prurigo nodularis, which is a newer indication for Dupixent for this one. We would want to see a diagnosis of moderate-to-severe prurigo nodularis. We would be looking for presence of greater than 20 nodules for at least three months, and a worst itch numeric reading scale of at least 7 or score of at least 7. The underlying cause of it is not caused by any drug-induced or any other medical conditions. They have tried at least one medium to very high potency topical corticosteroid for a minimum trial of at least four weeks, unless it is not

tolerated or contraindicated, and they have a failure or intolerance to one of the following: a topical calcineurin inhibitor, so the pimecrolimus or tacrolimus, for a minimum of three weeks, a topical vitamin D analog, so calcipotriene for three weeks, or they have tried phototherapy for one month, or they have tried systemic immunosuppressants, so methotrexate or cyclosporine, for a minimum trial of at least three weeks. For this one, we'll authorize the request for six months, and then the re-auth will be for 12 months. Any questions on this policy before I move on to the next one? I know I am going through them quickly. Yeah, Dr. MacKay, a question?

Jon MacKay: Yeah. Hi, Marissa. This is Jon. So on the Dupixent for the severe persistent asthma, we do quite a bit of Dupixent for asthma and for like eosinophilia with like the atopic disease. A lot of times people respond pretty well, and they can stop their ICS/LABA inhalers. So just on the re-authorization, is it always required? A lot of times we'll end up having to keep it on the active med list, even though it is maybe not clinically appropriate or not needed. So I just wonder if that is required if they stay on that inhaler for re-authorization. Just because sometimes it is so efficacious in terms of managing their asthma symptoms.

Marissa Tabile: Oh, okay. Um, yeah. We have that as one of them. We can definitely take that into consideration. I didn't see anything about patients, and I appreciate this insight that you are providing of them stopping their ICS/LABA because I would expect that they would still need that, so that is good insight. I can look into it and maybe consider if we want to take that off or not, but that was good feedback that I haven't heard of.

Jon MacKay: Okay.

Marissa Tabile: Yeah.

Jon MacKay: Yeah. A lot of times they do so well sometimes it is not necessary, and we will leave it on the active med list, even though they are not using it just so it can get re-authorized.

Marissa Tabile: Let me actually add a comment there. Okay. Thank you for that feedback. I appreciate that. Any other questions on this one? Okay, I am going to go ahead and move on to the next one, which is the IL-6 inhibitors. And that one is -- here we go. So this one is where the Kevzara, the Actemra, and the tocilizumab biosimilars live in this policy. For this one, the indications are a

little bit different, not something that we have seen before in the previous policies, so I will go through them pretty quickly. So for the first indication, we have Polymyalgia Rheumatica, and this is for Kevzara. For this one, we have the age indication, which is 50 years or older, prescribed by or in consultation with the rheumatologist. Same language, not used in combination with another Cytokine and CAM, diagnosis of polymyalgia rheumatica, and presence of all of the following: so bilateral shoulder or pelvic girdle pain lasting at least two weeks, and morning stiffness for greater than 45 minutes, and elevated C-reactive protein or erythrocyte sedimentation rate. And for this one we would be looking for a trial and failure of at least one glucocorticoid, and attempted dose reduction has been ineffective, so the prednisone, hydrocortisone. And then if they try to taper down and it hasn't been working, then we would be looking for that. That is a minimum trial of two months. If these criteria are met, we'll authorize it for six months. And then for the re-auth criteria, it is pretty much the same as what you have been seeing across all of them, authorized for 12 months. For this one, this is Giant Cell Arteritis, and this applies to tocilizumab and the biosimilars. So for this one, it is weight-based dosing, so we do want the weight there, the diagnosis of GCA, and then presence of at least three of the following: so the age of disease onset was at least 50 years old, or they have new onset headache at the time of diagnosis, or temporary artery abnormality, so tenderness to palpation, or decreased pulsation, or elevated ESSR, or abnormal artery biopsy. So if they have at least three of those, we would deem that -- we would check that off. And then for this one, it is a history of failure, contraindication, or intolerance to one glucocorticoid, which we have the examples listed there -- initially authorized for six months, and then if they meet the re-auth criteria, re-auth for 12 months. For this one, the Rheumatoid Arthritis, I won't go through this one just because I went through it in the TNF inhibitors, but the criteria are the same. The only difference that you will see with these -- I guess I will note the differences -- is just for tocilizumab. We just want the weight because it is weight-based dosing, and then we do have like that treatment with two preferred Cytokine and CAM there, which is the only difference. Well, it is still the same, but that kind of looks a little bit different. For this one, the Polyarticular Juvenile Idiopathic, I have gone through that. The Systemic Juvenile Idiopathic Arthritis, this one is for tocilizumab. This one, we would just be looking for the diagnosis and then, of course, we have age, weight, the presence of the -- or patient has severe active disease as indicated by one of the following: so suspected early macrophage activating syndrome or disabling polyarthritis or serositis. The history, failure, contraindication, or intolerance to one of the

following: so an NSAID for a minimum trial of one week or a glucocorticoid for a minimum trial of two weeks. And then for this one, treatment with at least one non-Cytokine and CAM disease DMARD, and then that would give them grounds for -- if they meet all the criteria, approval six-month initial authorization. Re-auth is 12 months. The next one is Systemic Sclerosis-Associated Interstitial Lung Disease. For this one, it won't be used in combination with Ofev or pirfenidone. They have the diagnosis. Their diagnosis is confirmed by a computed tomographic scan, and then they have treatment with at least -- they have used at least one immunomodulator, and that has been ineffective, contraindicated, or not tolerated. Humira and Enbrel don't have this particular, and even for the above, they don't have the indication for these, so that is why we don't specifically call them out. So if someone was requesting it, even though it is nonpreferred, we don't expect them to have to try. And this goes for all of them. If Humira and Enbrel don't share those indications, we wouldn't expect them to try them because it is not clinically appropriate if they are not indicated for those drugs. So in this example, if they meet 1 through 8 without having tried Humira and Enbrel, then that would be grounds for approval for a patient to get them. Hopefully, that makes sense. But that goes across all these kinds of different indications where they don't have them. And that is it for this policy. Any questions? Okay. I am hearing none. It looks like we'll go through the next policy, which is the IL-17 inhibitors. Um, that is not the right one. Here we go. And Ryan will be going through just one indication on this policy. Ryan, I will go ahead and hand it off to you really quick.

Ryan Taketomo: Hey. This is Ryan Taketomo. You can scroll down to the Enthesitis-Related Arthritis. This is the only new indication that we haven't discussed already. I didn't see that, or is that me? Okay, there we go. So I will walk through this indication. This one's just for Cosentyx in this policy. So Cosentyx or secukinumab may be approved when all of the following criteria are met. Criteria 1 is the patient is 4 to 17 years of age, and Criteria 2 it is prescribed by or in consultation with the rheumatologist, and Criteria 3, it is not used in combination with another Cytokine and CAM medication, and Criteria 4, they have a diagnosis of enthesitis-related arthritis, and Criteria 5, documentation of current weight is provided since dosing is weight-based, and Criteria 6, treatment with at least one non-Cytokine and CAM DMARD, for example, methotrexate, sulfasalazine, etc., have been ineffective, contraindicated, or not tolerated. And then you could scroll down. And I think we're missing an and after six with the period, and then for Criteria 7, [indistinct], and then also have to have treatment with two preferred Cytokine and CAM Apple

Health Preferred Drug List medications. And then once all those [cross-talk] --

Marissa Tabile: Hey, Ryan. Sorry, this is Marissa. Is this in here? I am just looking at it. Would this be -- do maybe we need to remove this because I don't believe Humira or Enbrel have this indication?

Ryan Taketomo: So for this one, [cross-talk] --

Marissa Tabile: [Cross-talk] Oh, I am sorry.

Ryan Taketomo: This indication is a subtype of the JIA or juvenile idiopathic arthritis. I think that is what it stood for. So that is where that Humira and Enbrel trial and failure criteria come from.

Marissa Tabile: This is Marissa. Oh, yeah. I forgot that we had discussed that. Apologies.

Ryan Taketomo: Yeah. Okay. So then once all the Criteria 1 through 7 are met, then it will be initially authorized for six months, and then for the re-authorization criteria just continued for criteria when not using combination with another Cytokine and CAM medication, and then Criteria 2, if there is documentation demonstrating disease stability or positive response. For example, improvement in joint pain and swelling, activities of daily living, and then once those are met, then the re-authorization will be for 12 months. So that will wrap up the criteria for this indication, I will open it up briefly for comments and feedback from the Committee before we move on to the next one. Okay. Hearing none. We can probably move on to the next one. I think that is on the next policy, Marissa.

Marissa Tabile: This is Marissa. Yep, you should be seeing the T-Lymphocyte Inhibitors, and I think it is just one indication on here.

Ryan Taketomo: Yeah. I think it is on the bottom for graph resource. Yeah. Okay, yeah. This is Ryan Taketomo. So for this particular drug, it is just Orencia. And the new indication we'll be discussing here is for graft versus host disease. Yep. Okay. This is Ryan Taketomo. For this particular drug, it is just Orencia, and the new indication we will be discussing here for graft versus host disease. This applies to the IV formulation only. And so in order to get this drug and formulation for the indication, it will be authorized when the following criteria are met: Criteria 1 is the patient is two years of age or older, and

Criteria 2, it is prescribed by or in consultation with an oncologist or hematologist, and Criteria 3, it is not used in combination with another Cytokine and CAM medication, and Criteria 4, documentation of current weight is provided, and Criteria 5, patient meets one of the following: 5(a), is patient has received a hematopoietic stem cell transplant, and it is used as additional therapy in combination with corticosteroids for chronic graft versus host disease, and the patient has no response. For example, steroid refractory disease to first-line therapy options, or Criteria 5(b), the patient is undergoing a hematopoietic stem cell transplant from a matched or one allele mismatched unrelated donor, and it is being used for prophylaxis of acute graft vs host disease, and it is used in combination with the calcineurin inhibitor and methotrexate. And the patient will receive antiviral prophylactic treatment for Epstein Barr virus reactivation and prophylaxis will continue for six months post transplantation. So once the criteria are met, it will be authorized for six months. And just to note, for the quantity limits and the FDA labeling, it should be for four total doses, but we allow six months to allow planning for the around the transplant. And then so for re-authorization, there is no re-authorization for this particular indication. Okay. And that should cover this indication. So I will open it up to the Committee for a brief moment for any questions, comments, or feedback. All right. Hearing none. I think we can move on to the next indication again on a different policy. All right, so with this indication, we'll be going over the use of baricitinib or Olumiant for the treatment of alopecia areata. And so baricitinib may be approved when all of the following documented criteria are met: Criteria 1 is the patient is 18 years of age or older, and Criteria 2 it is prescribed by or in consultation with a dermatologist, and Criteria 3, it is not used in combination with another Cytokine and CAM medication, and Criteria 4, the patient had a diagnosis of severe alopecia areata, and Criteria 5, the current episode of alopecia areata has been lasting more than six months, and Criteria 6, the patient has a greater than or equal to 50% of the scalp hair loss severity of alopecia tool SALT score greater than 50%, and Criteria 7, the patient has a history of [indistinct] one of the following options, unless all of them are contraindicated or not tolerated: 7(a) is high potency topical corticosteroids, or 7(b) intralesional corticosteroids, or 7(c) systemic therapy, which includes, for example, oral corticosteroids, methotrexate, cyclosporine. Once all the criteria are met, the initial authorization will be for six months, and then for the re-authorization, Criteria 1 is it will continue to not be used in combination with another Cytokine and CAM medication, and Criteria 2, -- there is documentation demonstrating a positive clinical response, and then once those are met, they will be re-authorized for 12

months. So can we give a brief moment for the Committee to go over it and provide any thoughts or comments, and we'll move on to the next one after. Okay. I am not seeing any hands raised, so I think we can move on to the next indication, Marissa. I think I hand it back to you.

Marissa Tabile: This is Marissa. Yep. Let me go ahead and display the next policy, which I think is -- let me pull it up. I don't have it pulled up. Let me -- IL-1 -- all right. So This is Marissa, again. I will be going through just the IL-1 inhibitor policy. In this policy are the products anakinra, Kineret, Ilaris, and Arcalyst. For these ones, their conditions are a little bit different than conditions that we have seen before. There is really only one indication in this policy that overlaps with the other ones, so some of these are -- pretty rare. So for this one, it is the -- the first one I will go through is cryopyrin-associated periodic syndromes (CAPS). It applies to all three products that I mentioned, and for this one we have just the age, indications, specialists, or rheumatologist, not used in combination with another Cytokine and CAM. They have a diagnosis of CAPS, which includes the following: Neonatal-onset multisystem inflammatory disease, or Familial cold autoinflammatory syndrome, or Muckles-Wells syndrome, and 5.) they have laboratory testing showing a genetic mutation in the CIAS1, also known as NLRP, and 6.), they have baseline assessments are included, so seeing like C-reactive protein serum amyloid A rash frequency. If they meet all of these criteria, the request will be approved for six months, and if they meet all the re-auth criteria, then it will be re-authorized for 12 months. For the next indication, we have Rheumatoid Arthritis, which I have already gone through before. That applies only to anakinra. For Systemic Juvenile Idiopathic Arthritis and Adult-Onset Still's disease, for this one we did kind of combine them. The only thing that is different is this is the adult-onset Still's disease, which is what SJIA kind of turns into. So we have included that here. The only difference that you will notice between the systemic juvenile idiopathic arthritis criteria and the adult-onset Still's is that we have just included the new diagnosis to either have juvenile SJIA, or they have adult-onset Still's disease there. Everything else from before is pretty much the same, and the product that it applies to is a Ilaris. And moving down to Tumor Necrosis Factor Receptor-Associated Periodic Syndrome (TRAPS). This applies to Ilaris. For this one we would be looking for the diagnosis of TRAPS and a documentation of a TNFRSF1A gene mutation. And 6.) the patient has chronic or recurrent fever flares defined by three or more flares a year and the following: so documentation of fever flares that last five days or more, and the fever flares are accompanied by at least one of the following symptoms: so if they are experiencing myalgia,

rash, eye symptoms, limb pain, abdominal lymphadenopathy, and chest pain. And 7.) the causes of the recurrent fever have been ruled out, so they are not having any recurrent bacterial or viral infections, cyclic neutropenia, or interferonopathies. If they meet all the criteria, it is authorized for six months, then the same re-auth duration is 12 months. The next indication is Familial Mediterranean Fever, and this is for Alaris. For this we're looking just for the diagnosis, they meet the age indications, then 5.) the patient has recurrent febrile episodes accompanied by at least one of the following: peritonitis or synovitis or pleuritis or erysipelas-like erythema, or they have a first-degree relative with familial Mediterranean fever, and 6.) causes of recurrent fever have been ruled out, and 7.) they have a history of failure, contraindication, or intolerance to colchicine for a minimum of three months. If they meet all the initial criteria, it would be a six-month initial approval, and then if they meet the re-auth, same re-auth criteria a 12-month re-authorization duration. For the next one, it is Hyperimmunoglobulin-D Syndrome/Mevalonate Kinase Deficiency (HIDS) or (MKD). For this one, we would just be looking for the diagnosis and then documentation of either of the following: so elevated immunoglobulin D levels or a documentation of the V3771 mutation in the mevalonate kinase gene, and 6.) documentation of the fever flares that last four days or more, and the fever flares are accompanied by at least one of the following symptoms: so chills, cervical lymphadenopathy, abdominal symptoms, and I think this is on here, lymphadenopathy that is a little different, and 8.) the causes of recurrent fever have been ruled out. For this one, six-month initial approval, a 12-month re-authorization approval if they meet it. For the next indication, we have Recurrent Pericarditis, and this applies to Arcalyst. For this we are looking for patient has a history of three or more episodes of pericarditis, and we're looking for the next criteria and baseline assessments are included: so white blood cell count, erythrocyte sedimentation rate, C-reactive protein, and history of failure to all of the following unless all are contraindicated or not tolerated. So a trial of NSAID or aspirin for a minimum trial of two weeks, a trial of colchicine for a minimum trial of 12 weeks, and trial of corticosteroids for a minimum trial of two weeks. If they meet all of the criteria, a six-month initial approval. Re-auth approval is for 12 months. As you can see, this policy has really like a hodgepodge of indications, depending on the drug, which I found was very interesting. For this one, the next indication is Gout Flare, and that is for Ilaris. For this we would be looking for the patient has experienced more than two gout flares within the previous 12 months, and they have a history of failure to all of the following unless it is contraindicated or not tolerated, NSAIDS for a minimum of two

weeks, colchicine for a minimum of 12 weeks, and then intra-articular or oral glucocorticoids for a minimum of one week. And if all of the criteria are met, the request will be authorized for three months. So this is a little bit different because it is gout flare. And then if they meet the re-authorization, it will be for another three months. The next indication is Deficiency of IL-1 Receptor Antagonist (DIRA). For this one, we're just looking for the diagnosis of deficiency of IL-1 receptor antagonist and the documentation of a mutation in the IL1RN gene. The baseline assessments are included looking for any of these following examples, and 7.) the patient experiences at least one of the following symptoms: a pustular psoriasis-like rash or sterile osteomyelitis or nail changes. And I think that is a typo right there. Apologies. A six-month initial authorization duration and then 12-month re-authorization. The last indication for this one is Schnitzler Syndrome, and it applies for Kineret. For this one, we're just really looking for a diagnosis of Schnitzler Syndrome. They have a documentation of monoclonal immunoglobulin gammopathy (IgM), and they have a presence of a chronic urticaria-like rash. If they meet all of those criteria, it will be authorized for six months, and re-auth is for 12 months. And that is it for this policy. We have one more policy to go. Any questions on this policy?

Kevin Flynn: Can I ask a quick question? I have seen anakinra used more for pericarditis and gout flares, [cross-talk] --

Marissa Tabile: [Cross-talk] Mm-hmm.

Kevin Flynn: -- but I am guessing that would just be like something where you would like need a peer-to-peer if you wanted to do something like that.

Marissa Tabile: Um, yes. And if -- it is used for that, it may not meet our standard of, like, the strength of evidence and strength of recommendation. That is probably why it is not included. But a provider can definitely if they feel it is appropriate and present the evidence, we will still take that into account if they want to use those products for that indication.

Kevin Flynn: There is data, I know, for both, it is just off label, so it is [cross-talk] --

Marissa Tabile: [Cross-talk] Mm-hmm.

Kevin Flynn: [Cross-talk] there is probably better clinical trial data at the other one -- for the other two. But anakinra is the first drug in this class, so it does for most of these other indications have off-label data for them.

Marissa Tabile: Yeah. So a doctor can definitely request it if they want. We do like to request that they send in if that -- if they do have the evidence like the journal article, so we can take that into account, and then we do look at that and then do either the approval or the denial for those.

Kevin Flynn: Okay. Thank you.

Marissa Tabile: Mm-hmm. Um, so hearing no questions or any other comments. Thank you, Dr. Flynn, for that. I will go ahead and move on to the last policy. We're almost done. And this one is the Integrin Receptor Antagonist policy. This one is a little bit -- the products are a little bit different in both. I do want to call it out in the integrin receptor antagonist and the S1P receptor modulators, I am not going to present the S1P just because of the indications we have already gone through. But these products are largely, or you may associate them mostly with Multiple Sclerosis, and that is where those products currently live on our AHPDL. So the Tysabri, the Entyvio, those are in Multiple Sclerosis, but they do have indications for Crohn's disease. That is why we have included it in the 11. I am not going to go through the Crohn's disease cause we have already gone through that. The only thing that I will go through is really just the multiple sclerosis indication. And for this one, it applies to Tysabri. And for this, we are just looking for the following: they meet the age indication, it is prescribed by or in consultation with a neurologist, and it is not used in combination with other disease-modifying therapies for multiple sclerosis, and have a diagnosis of one of the following: so RRMS, or active secondary progressive disease SPMS, or clinically-isolated syndrome, and 5.) the diagnosis is confirmed and documented by a laboratory report, so like an MRI, and 6.) documentation of baseline number of relapses per year or expanded disability status score, and 7.) treatment with two preferred multiple sclerosis Apple Health Preferred Drug List medications has been ineffective unless all are contraindicated or not tolerated. If they meet all the criteria, it will be authorized for 12 months, and then if they meet the re-auth criteria, which is pretty much the same as what you have seen before, we will re-authorize it for 12 months. So that is it as far as all of the indications, I think we have gone through all 35. If anyone has any questions on this particular policy, please let me know, and we can go through it. But if not, I will go ahead and open up the floor to any policies out

of the 11 that you may want to look at, any of the other ones. I know that there was a lot that I went through, so I will pause here. And Dr. Hudson, I [cross-talk] think you have a question?

Greg Hudson: Yeah. I have -- I guess I have more of a general question with regards to these 11 policies. I am curious in your view, Marissa, like, will this change -- I guess, will it make acknowledging that some of these disease states are quite -- I mean ranging from quite common to quite rare -- will it make or allow the drug utilization, like, will it allow more flexibility or like nimbleness to address some of these, like, kind of frequent changes? And -- or I guess I am wondering sort of like on this range between, like, efficiency and, like, more -- adding more work or more review?

Marissa Tabile: This is Marissa. I think as far as efficiency, which is kind of to be determined to be quite honest with you. I feel like just with the nature of, like, all of these medications, it just makes for any of these, whether we have it all in one policy or 11, I think it is just something that we're just going to have to like frequently update all the time. So we're still kind of working through that. Like, what is that going to -- like, what is the maintenance of this going to look like? Because we probably have to update it so often, I anticipate that we'll have to update it so often. So efficiency, I am not sure. It is kind of, yeah, I think we're just kind of taking this new approach just because having it all in one was just a little bit difficult, so splitting it out into the 11, where we can be specific with indications per drug, we thought was a little bit better, but we'll see if this does affect our efficiency or not once we go live with it or kind of what we decide. Hopefully, that answered your question. Dr. Flynn, I think you had another question.

Kevin Flynn: Yeah. Just pointing out I know [indistinct] everyone's anticipating that they will launch a biosimilar of natalizumab this year. Do we need to add that to this or --? I mean it is already technically FDA approved, it is just not on the market yet.

Marissa Tabile: This is Melissa. Yeah. So as you can imagine with, like, any of these drugs, like, this policy that you are looking at on 8/14 could be very well out-of-date tomorrow with the new biosimilars that come out, so we are going to be very mindful. Like, if you approve it today to add any new products that come out to the market from now until it gets implemented, and even when it does get implemented, we're just going to have to keep updating it with new products that come to market, so we will be sure to add those. I am sure there are

probably some indications that we're missing maybe from some of these, if they got a new indication yesterday or today, but we will need to add those as well.

Kevin Flynn: Perfect. Thank you.

Marissa Tabile: Yeah, no problem. Yeah. This is Marissa. As you can imagine, these policies are very much a labor of love as far as just how often we have to update them, and we fully acknowledge that it is going to require a lot of work. But I think, like I said, that is just kind of the nature of these drugs and all of kind of the spanned indications and just the nature of them as they have come out and continue to get expanded indications. Any other questions or feedback? I appreciate your patience going through all 35 indications with me. I know it was a lot, so.

Greg Hudson: Yeah. This is Greg Hudson. Marissa, I just wanted to reflect how much work went into this, and so I appreciate you taking the time to go through it with us.

Marissa Tabile: And thank you.

Kavita Chawla: It is really appreciated how the attention to detail and how laborious this whole process must have been of your team. Thank you. Um, I suppose a next step then would be to ratify these policies.

Nonye Connor: There is a comment in the Q&A if you want to review, please.

Kavita Chawla: Sure. Um, this is from the Teva Representative from Rochelle Yang, saying, "Hi, HCA team. I was signed up for public testimony, but I had a conflict come up and need to leave prior to the meeting. I would withdraw my request. However, I just had a comment that Simlandi, which is adalimumab-ryvk is not listed within the TNFI criteria. This Humira biosimilar was approved in February 2024 and launched in May 2024. Could HCA please add this drug? Thank you. Um, and so I assume that the response to this is similar to what you have said, and Donna has said before in terms of the preferred drug list. That really depends on a separate set of criteria. But is it currently included just in the drug list at all?

Marissa Tabile: This is Marissa. I am looking at it here, and it doesn't look like it is here, so we'll make sure that it gets added.

Kavita Chawla: For the biosimilars list.

Marissa Tabile: Yes. Yeah, it will get added to the biosimilar list.

Kavita Chawla: Thank you.

Marissa Tabile: Yeah. As you can imagine, there are so many biosimilars that have been coming out lately.

Kavita Chawla: Yeah.

Marissa Tabile: I am outdated already, so. I appreciate [cross-talk] --

Kavita Chawla: It is great for the patients and [cross-talk] provider we have these options. Other comments from -- or any other stakeholders I should first ask?

Nonye Connor: Hi, sorry. There are a couple of stakeholders that have their hands raised.

Kavita Chawla: Okay, great.

Nonye Connor: Okay. So the first one I have, Marissa, do you have the question?

Marissa Tabile: This is Marissa. Umm, hold on one minute. Let me pull up the questions and the timer. I don't have those ready yet.

Nonye Connor: Okay, perfect. Melinda, I will call on you. Just give us a quick second to just -- I will start with you because I saw your hands up first.

Marissa Tabile: Actually, I don't see it. Hold on. Let me find it in the folder. There we go. Apologies, it is still loading. Okay. There you go. It should be ready to go.

Nonye Connor: Okay. We'll start with Melinda. Melinda, can you hear us? Please feel free to unmute yourself when you are ready.

Melinda: I should be unmuted. Can you hear me?

Nonye Connor: Yes, we can hear you.

Melinda: Wonderful. So I had the opportunity to present in April, referring back to the TIMs for plaque psoriasis that was presented by Shannon Kugley, which showed that bimekizumab was more effective than adalimumab, ustekinumab, and secukinumab with a grade of moderate strength for all three. We are requesting preferred status, and I want to submit back the rest of my time. And I really appreciate you calling on me, so thank you so much.

Nonye Connor: Thank you. The next person that had their hands raised was Erin. [Cross-talk] --

Erin Nowak: Hi there. Can you hear me?

Nonye Connor: Yes, we can hear you.

Erin Nowak: Thank you. My name is Erin Nowak. I am speaking on behalf of AbbVie. I don't have any conflicts of interest to report beyond that. So, again, my name is Erin Nowak. I am a Medical Outcomes and Science Liaison at AbbVie. Thank you for allow me a few minutes. I plan to touch on Skyrizi as it is applicable to the IL-12/23 inhibitors policy. This is an IL-23 antagonist, and it is approved now for four indications; moderate-to-severe plaque psoriasis, active psoriatic arthritis, moderately-to-severely active Crohn's disease, and then the latest is ulcerative colitis. Now this is not a new therapy, but I would like to provide two updates in the inflammatory bowel disease space with the purpose of supporting two requests today. Number one to add Skyrizi to the policy for the ulcerative colitis indication and recognizing that this is a more recent indication approved in the last few months and that things are being updated, and then two, to consider reducing prerequisite requirements for Crohn's disease and ulcerative colitis. First, in the Phase III clinical trials, Skyrizi met both the primary endpoint of clinical remission in the key secondary endpoints of endoscopic improvement and remission after 12 weeks of induction and after 52 weeks of maintenance therapy. These are the [indistinct] recommended to target goals. The safety profile for Skyrizi remains consistent through this ulcerative colitis clinical program, and more information can always be found at rxabbvie.com for Prescribing Information. With this information, I respectfully request that Skyrizi be added to the policy for that ulcerative colitis indication as I mentioned. And then next, I will provide a brief overview of the American Gastroenterology Association of Clinical Practice Guidelines for moderate-to-severe Crohn's disease and ulcerative colitis. And as of 2021, the recommendation is for early use of biologics for moderate-to-severe disease. Specific to Crohn's

disease, the AG suggests early use of a biologic with or without an immunomodulator or IM or subcutaneous methotrexate for induction and maintenance of remission rather than delaying use until after [indistinct] I mean a salicylate and/or oral steroids as delaying appropriate [indistinct] by using a step-up policy might result in clinical harm from disease progression or inadequate treatment. Specific to ulcerative colitis, the AG suggests early use of biologic agents here as well, with or without immunomodulator therapy, rather than the gradual step-up approach after failure of [indistinct]. And again, that is delaying effective treatment may be harmful either due to ongoing untreated active disease or increasing risk of UC-related complications such as hospitalization, colectomy, and then the overall inferior quality of life. So in light of these guideline recommendations, I respectfully request the Committee to consider removing the oral conventional therapy steps for those patients with moderate-to-severe Crohn's disease and ulcerative colitis, providing timely access to these therapies that are proven to help patients achieve recommended treatment targets like those endoscopic outcomes as Skyrizi does, and reaching these endoscopic targets correlates with a reduction in expensive complications, which may be mutually beneficial to both patients and the state. So thank you for your time and consideration, and I am also available for any questions you might have.

Nonye Connor: Okay. Thank you, Erin. And the next person we have is Willis.

Willis Lonzer: Yes, I am present. Can you hear me?

Nonye Connor: Yes, we can hear you.

Willis Lonzer: I am presuming I am in the correct place for urea cycle disorders, or should I wait?

Marissa Tabile: This is Marissa. I don't believe this is the right section. It looks like the urea cycle is probably going to be later on this afternoon.

Willis Lonzer: Okay.

Marissa Tabile: We're going through Cytokine and CAM -- yeah -- policies.

Willis Lonzer: My apologies. [cross-talk]

Marissa Tabile: That's okay.

Willis Lonzer: I will -- I just want to make sure I did not misread. Okay. I will lower my hand and wait. Thank you.

Marissa Tabile: No problem. Thank you.

Nonye Connor: And right now that is all I have. No one else has their hands raised.

Kavita Chawla: Thank you, Nonye. All right, so it is Marissa, back. Yes, thank you for bringing up the motions. And so will we be [cross-talk] --

Marissa Tabile: This is Marissa. Yeah, it looks like there are going to be 11 different motions.

Kavita Chawla: Okay.

Marissa Tabile: This [cross-talk] be all look different policy titles. I am sorry.

Kavita Chawla: All right. Thank you for calling that out. All right, Committee, whenever you are ready. And, yes, I will also have the Committee members all come on camera, please.

Marissa Tabile: This is Marissa. I am sorry. I am going to update each of these because I just realized that the versions are not here, so let me actually -- I will be adding them in. You should be -- this should be good to go now.

Kavita Chawla: Okay. Thank you.

Kevin Flynn: This is Kevin Flynn. I move that the Apple Health Medicaid Program implements the clinical criteria listed on Policy 66.27.00.AA-4 as recommended.

Greg Hudson: This is Greg Hudson, I second.

Kavita Chawla: All in favor, please say aye.

Multiple Speakers: Aye. Aye. Aye.

Kavita Chawla: Any opposed or abstain? Thank you, and the motion carries. All right. This is Kavita Chawla. I move that the Apple Health Medicaid Program implements the clinical criteria listed on the policy 66.27.00.AB-4 as recommended.

Zoe Taylor: Second. Taylor.

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

Multiple Speakers: Aye. Aye. Aye.

Kavita Chawla: Any opposed or abstain? Okay. Thank you.

Zoe Taylor: I can do this one. Should we just kind of go around in a circle? Motion I move that the Apple Health Medicaid Program implements the clinical criteria listed on policy 66.27.00.AC-4 as recommended.

Kevin Flynn: I second.

Kavita Chawla: All in favor, please say aye.

Multiple Speakers: Aye. Aye. Aye.

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

Christy Weiland: This is Christy Weiland. I move that the Apple Health Medicaid program implemented the clinical criteria listed in policy 66.27.00.AD-4 as recommended.

Peter Barkett: Peter Barkett, I will second the motion.

Kavita Chawla: All in favor, please say aye.

Multiple Speakers: Aye. Aye. Aye.

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

Greg Hudson: I will take this one. This is Greg Hudson. I move that the Apple Health Medicaid Program implements the clinical criteria listed on policy 66.27.00.AE-4 as recommended.

Peter Barkett: Peter Barkett. I will second the motion.

Kavita Chawla: All in favor, please say aye.

Multiple Speakers: Aye. Any opposed or abstain? Okay. With that, the motion carries.

Jon MacKay: This is John McKay. I move that Apple Health Medicaid Program implement the clinical criteria listed in policy 66.27.00.AF-4 as recommended.

Greg Hudson: I will be second.

Kavita Chawla: All in favor, please say aye.

Multiple Speakers: Aye. Aye. Aye.

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

Peter Barkett: I can take this one. Peter Barkett, I move that the Apple Health Medicaid Program implements the clinical criteria listed in policy 66.27.00.A6-4 as recommended.

Jon MacKay: John McKay, I second.

Kavita Chawla: All in favor, please say aye.

Multiple Speakers: Aye. Aye. Aye.

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

Kevin Flynn: This is Kevin Flynn. I move that the Apple Health Medicaid Program implements the clinical criteria listed on policy 66.27.00.AH-4 as recommended.

Peter Barkett: Peter Barkett. I second the motion.

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

Multiple Speakers: Aye. Aye.

Kavita Chawla: Any opposed or abstained? And the motion carries. This is Kavita Chawla. I move that the Apple Health Medicaid Program implements the clinical criteria listed in the policy 66.27.00.AI-4 as recommended.

Christy Weiland: This is Christy Weiland. I second.

Kavita Chawla: All those in favor, please say Aye.

Multiple Speakers: Aye. Aye.

Kavita Chawla: Zoe, I am assuming you are saying "aye" in all of these.

Zoe Taylor: Sorry, I keep forgetting to unmute.

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

Jon MacKay: This is Jon MacKay. I move that the Apple Health Medicaid Program implements the clinical criteria listed in policy 66.27.AJ-4 as recommended.

Peter Barkett: Peter Barkett, I second the motion.

Kavita Chawla: All in favor, please say aye.

Multiple Speakers: Aye. Aye. Aye.

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

Greg Hudson: And this is Greg Hudson. I move that the Apple Health and Medicaid Program implements the clinical criteria listed on policy 66.27.00.AK-4 as recommended.

Zoe Taylor: Taylor, second.

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

Multiple Speakers: Aye. Aye. Aye.

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

Marissa Tabile: This is Marissa, and that is it.

Kavita Chawla: Oh, nice!

Marissa Tabile: [Cross-talk] all the motions [cross-talk] --

Kavita Chawla: [Cross-talk] Committee. Well done, Marissa.

Marissa Tabile: Thank you so much for being patient and sitting through all of that. I really appreciate it.

Kavita Chawla: No, thank you for all your hard work. And, Committee, I think that earns us a break. Let's see here. I think we're going to take a break, and then let's see, lunch was supposed to be at 11:55. How do we want to do this? Do we just want to take lunch now and then dive into the rest? Like combine the two? Or take a break now, do another hour's work, and then do lunch. How many for lunch now and just do a 30-minute break now. No. Okay, so 10 minutes now, we'll be back in 10 minutes, and then we'll do another hour's work. How's that?

Zoe Taylor: Sounds good.

Kavita Chawla: All right. See you back in 10.

[break]

Kavita Chawla: All right. It is 11:45, if we can have all our Committee members on camera so we know we have quorum. Great. Okay. And do we also have Marissa back? Hi, Marissa [cross-talk] --

Marissa Tabile: Yes, I am. I am back.

Kavita Chawla: Fantastic. All right. We're ready for Antiparasitics.

Marissa Tabile: All right. So let me go ahead and share my screen and pull up the slides here. I think that is it. Okay. All right. So let me -- there we go. Okay. So for these next couple agenda items, I guess for the rest of the meeting, -- this is Marissa by the way -- I will be going me then Nina. We will kind of be tag teaming some of our AHPDL drug class reviews. So I will go ahead and kick us off for the next remaining classes. So for this one, the Antiparasitics : Folic Acid Antagonists. I do want to caveat this by saying as of June 2024 -- well,

actually let me backtrack. So we did for fee-for-service we have just undergone a recent point of sale replacement, which went live in June of this year, so June 2024. With that point of sale replacement, we have had some reshuffling of some of the classes and products in classes on our AHPDL, so some of the drug class names have either changed. Some products have been moved from one class to another. There is potential for some products that have changed status on our AHPDL. And as you can imagine, like I think Ryan had mentioned in 2023, we had over 400 drug classes, and now I believe that number of AHPDL classes have increased. We may be somewhere near 500. So there has been some reshuffling, and this Antiparasitics : Folic Acid Antagonist class is one of the classes -- and the product that is in that class that has been affected by this change, so the one product it has been combined now with what is called our Antiparasitics : Antimalarials drug class, and for that, there is only one product that lived in that particular folic acid antagonist class, and that product is pyrimethamine or Daraprim, which is a 25 mg tablet. So it is just that one product that was affected. Like I said, it did get moved over to our Antimalarials drug class, but our antimalarial drug class is actually what we consider an archived drug class. So a couple of years ago, the DUR Board, we did go through our AHPDL, and we still continue to do this, it just hasn't been done recently. We have gone through a list of all of the drug classes on our AHPDL that we want to consider for archiving, and that was one of them. And what considers the drug to be archived is if there is not really any movement, any new products in the drug class, so it is like pretty old. It is like beta blockers, maybe some ACE inhibitors. They are really old drugs that have been on the market for a really long time that there haven't really been any new changes, like, guideline-wise, product-wise, so we consider those for archiving. So they are not drug classes that you will see typically reviewed every year just because there is not a lot of movement that happens in them. So for the Antimalarials class that was archived, the time that it was archived escapes me, which I believe was a couple of years ago -- I want to say within the last five years -- we will bring some of those archive drug classes back eventually just so that then if you agree with them still being archived, we'll bring them back. But for now, it is kind of tucked away in our back pocket and be re-reviewed when the time comes. So pyrimethamine is now in that class. Just to kind of give you an FYI, the products that are in that class, I don't believe they are on the publication that you all have received today, so I apologize that it is missing, but the products that are really in that class are like the hydroxychloroquine, the mefloquine, the atovaquone/proguanil and those that I mentioned are pretty much all of the preferred products probably without PA. I will have to verify that.

Pyrimethamine was nonpreferred, and I believe it continues to still be nonpreferred in that class, so that is more of like an FYI. So at this time, there is not really any motion or review needed for this drug class. So I am going to go ahead and skip it, but if you had any questions regarding that, just let me know, and feel free to stop me, but I am just going to go ahead and move straight into the Ophthalmic Agents : Ectoparasiticides if there are no questions for that, so I apologize for that oversight. We're still trying to kind of do a little bit of cleanup with some of the classes. I am still trying to identify which classes have changed or not. It is quite a quite a bit. So if you see some of that or if you saw a drug class in the past that you don't see anymore on our PDL, it could be very much that it changed name, but I just wanted to give kind of that caution to you all if you are seeing that it is just cause of our point of sale replacement that we have changed a little bit of things on our PDL. So Kevin, Dr. Flynn, it looks like you have a question.

Kevin Flynn: Oh, I just wasn't clear because there is a bunch of generics for it now. I know when it -- this was the weird guy. I already jacked the price up a lot, but I thought that [cross-talk] --

Marissa Tabile: Yeah.

Kevin Flynn: Since all the generics that come out, is it still nonpreferred?

Marissa Tabile: I believe it is. As far as what I saw this morning on our PDL, it is nonpreferred currently.

Kevin Flynn: Okay.

Marissa Tabile: All right. So I will go ahead and move on to the next class. Apologize for that oversight on our end, but I will give that FYI. So I will be going through the Ophthalmic Agents : Ectoparasiticides. This class I don't believe has been reviewed before, so this is brand new to you all. So just to kind of give some disease state overview and then getting into the drug specifics. For this one, blepharitis is a chronic ophthalmic condition which is characterized by inflammation of the eyelid margin associated with eye irritation. It can be either posterior or anterior. Posterior is the most common type, and that is usually when you have inflammation of the inner portion of the eyelid at the level of the meibomian glands. Anterior is when there is inflammation at the base of the eyelash. A common kind of complication that happens with blepharitis is dry eye disease, so that is you will see that in a lot of the

patients. Some symptoms of blepharitis are kind of what you would associate with irritated eyes of that sort, so you will see red, swollen, itchy eyes. The patients will experience a gritty or burning sensation, pink eyes, excessive tearing, crusting, or matting of the eyelashes in the morning. I believe that is the hallmark sighting of it. You have flaking or scaling of the eyelid skin, light sensitivity, and blurred vision. Management of blepharitis really depends on kind of the severity. So if you have mild to moderate symptoms, usually management is via warm compresses, lid massage, lid washing, the use of eye lubricants. If you have severe or it continues to kind of manifest. Even with those methodologies, typical management is topical oral antibiotic therapy plus, of course, the symptomatic measures that I have mentioned before. There is also topical ophthalmic antibiotic ointment, which actually is the preferred method, so using the bacitracin or erythromycin. There is the use of oral antibiotics that you could use, so the doxycycline, tetracycline, azithromycin. Topical glucocorticoids or topical cyclosporine. There is one specific type of blepharitis which is known as a demodex infestation. For that, the management of it I found was kind of interesting. There is topical tea tree oil that you can apply for about 6 weeks. That is one way. There is Lotilaner 0.25% ophthalmic solution which can be used, or the use of oral ivermectin. So the Guidelines from the American Academy of Ophthalmology Blepharitis Preferred Practice Pattern -- this was in 2023 -- they recommend that the eye be examined either by physical, slit lamp biomicroscopy, and then also measuring intraocular pressure. You can do microbiologic testing for those patients that keep having anterior blepharitis with that inflammation, especially if it is very severe, and if patients are just not responding well to therapy. They do recommend the management strategies that I mentioned before, such as the compress, the cleaning -- the eyelid cleaning, eyelid massage, various topical perfluorohexyloctane, and then the antibiotics both topical and systemic that you can use. And then also, like I mentioned, the artificial tears, so the eye lubricants that you can use. There is also other management as well. So there is antiparasitic medication, so metronidazole, ivermectin, lotilaner. Topical anti-inflammatory agent, the corticosteroids and the cyclosporin. And the there are in-office procedural treatments that are recommended, so something called vectored thermal pulsation, or microblepharoexfoliation. Not quite sure exactly what those are, but it looks like those are available for patients. So there is really only one product that lives in this particular drug class, and it is the lotilaner or Xdemvy is the brand name. It was recently approved by the FDA, so this was back in July of 2023. It is classified as an ectoparasiticide. It is indicated for the treatment of Demodex blepharitis, and the dosing for it is pretty straightforward. It is a

pretty straightforward drug. It is one drop in each eye twice daily. You want to space those about 12 hours apart. And the duration of it is about 6 weeks. The availability of it is an ophthalmic solution in 0.25%. And that is it as far as this drug class. It is pretty simple and straightforward. I can go through -- let me actually pull up our AHPDL so you can see exactly what is in there. Oh, there is actually -- that Xacduro is actually, that should not be in that class. We have identified that. And this is just kind of the result of us switching over from point of sale. So ignore that. Xacduro. The only product that is appropriate to be in that class is the Xdemvy, and as you can see, it is preferred, and we do not have PA on it. So I can take any questions from the Board.

Nonye Connor: Sorry, Melissa, we did not see the PDL. We are just seeing your slide right now.

Marissa Tabile: This is Marissa. Oh, my goodness. It is because I am not sharing the screen. [laughter] Thank you, Nonye.

Nonye Connor: No problem.

Marissa Tabile: There we go. Okay. Hopefully, you can all see it now that I am presenting correctly.

Nonye Connor: Yes.

Marissa Tabile: Okay. Thank you.

Nonye Connor: Uh-huh.

Marissa Tabile: As I was mentioning, this Xacduro here that you will see on line 4 is inappropriately placed in this class. We are working on getting that placed in the appropriate class, so Xdemvy is the only product, like I mentioned.

Nonye Connor: Okay.

Marissa Tabile: Yeah, I think there might -- I don't know if they are stakeholders. I will hand it off to you, Kavita.

Kavita Chawla: Nonye, I don't see any listed on the agenda. Well, actually, I guess for this section, we do have Dr. Jeff Reising from Tarsus Pharmaceuticals. Are you here?

Nonye Connor: Yes. Let me go ahead and --

Jeff Reising: Hello. Can you hear me?

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

Nonye Connor: [Cross-talk] Yes.

Jeff Reising: Okay. My name is Jeff Reising on behalf of Tarsus Pharmaceuticals. Are we ready to go?

Kavita Chawla: Yes, please.

Jeff Reising: Okay. Hi, there. My name is Dr. Jeff Reising. I am a Senior Medical Ambassador with Tarsus Pharmaceuticals, and I am also trained as an optometrist. I spent over 10 years in practice seeing primary care and ocular disease patients. Thanks for the opportunity to talk a little bit about Xdemvy and Demodex blepharitis. So keep in mind that a lot of the treatments options previously mentioned there were for blepharitis in general, and this is a condition with many etiologies. I am here today to focus just on Demodex blepharitis, which is a specific cause of the condition. So Demodex blepharitis is an ocular disease caused by infestation of Demodex mites. So Demodex are part of our normal human flora, but some individuals develop an overabundance of them, and this can lead to inflammation of the lid margin and ocular surface with symptoms such as dry eye, itchy, red eyes, irritated lids, and even recurrent [indistinct] styes, as mentioned. So this is a very simple condition for any optometrist or ophthalmologist to diagnose by simply looking for collarettes, which is the pathognomonic sign of Demodex, and these can be easily viewed during a microscope examination. So I know when I was practicing this was a very common condition that I saw, but managing these patients was really difficult due to the lack of safe and effective FDA-approved treatment options for use in the eyes. And we actually see about 7.2 million patients with Demodex blepharitis visiting eye care providers annually, and now Xdemvy is the first and only FDA-approved treatment indicated for this condition. So the Phase III SATURN pivotal trials were the largest Demodex blepharitis trial program ever, about 800 patients.

As mentioned, it is an eye drop. It was dosed one drop in both eyes b.i.d. for 6 weeks, so it is a defined course of treatment. And the 6 weeks is really important because it is two life cycles of the mites, so it is going to act on any active mites and then any eggs that may hatch during treatment as well. The primary endpoint looked at reduction of collarettes to two or less collarettes. And for frame of reference, the average number of collarettes patients had at the start of study was about 100, so pretty stringent guidelines from the FDA. Some secondary endpoints we also looked at were mite eradication, so this is proof that we're actually targeting and killing the mites themselves and really getting to the root of the problem in addition to just clearing the collarettes. And also, we looked at lid erythema cure, meaning that the patients had no eyelid redness at the end of the trial. And this is really important because patients are aware when their lids are red. This is something that bothers them, and they can appreciate improvement in. All the endpoints were met with statistically significant improvements, and as we look at safety, the most common adverse event was instillation site burning and stinging, which is about 10% of patients. Other adverse events in less than 2% were chalazion and hordeolum and punctate keratitis. And it is worth noting that no patients discontinued the trial due to any of these or any other treatment-related adverse events. So Demodex blepharitis is often overlooked and misdiagnosed, which can result in unresolved symptoms for patients and potentially wasted healthcare resources. So we respectfully request continued unrestricted access of Xdemvy for Washington State Medicaid patients diagnosed with Demodex blepharitis by an eye care provider through a slit-lamp exam. Thank you for your time. I am happy to answer any questions you may have.

Kavita Chawla: Go ahead [cross-talk] --

Peter Barkett: [Cross-talk] Dr. Reising, I have got a question. This is Peter Barkett. So you mentioned that blepharitis is extremely common, and that this particular medication really only is targeting Demodex blepharitis.

Jeff Reising: Right.

Peter Barkett: And is, what, is $2000 bucks for a course, right? So kind of an expensive treatment. So given the expense and that this is a subset of blepharitis, would you support having prior authorization on this medication either to confirm that it is Demodex blepharitis by the presence of a certain number of collarettes, or restricting the prescription to an eye care provider?

Jeff Reising: So I mean it is very easy to distinguish Demodex, because the collarettes are pathognomonic. If we see these signs of collarettes, we know with 100% certainty that the patient has Demodex blepharitis, so there is really no reason to differentiate any other way besides just by checking for the collarettes. We have also done studies that showed about 69% of all blepharitis patients do have Demodex, so it is a pretty common cause of blepharitis in general. At this point, it is really only going to be prescribed by eye care providers, so I think that is reasonable to restrict it to optometrists and ophthalmologists for prescribing this medication.

Kavita Chawla: Thank you, Dr. Reising. Other questions from the Committee? All right, great. Any other stakeholders, Nonye?

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

Kavita Chawla: Okay, great. So I guess if we can see -- review the motion. All right, and this is Kavita Chawla. I move that all products in the Ophthalmic Agents : Ectoparasiticides class are considered safe and efficacious for their medically accepted indications, and they are eligible for their preferred status and grandfathering at the discretion of HCA. Products in this class may require prior authorization to determine medical necessity. All nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Jon MacKay: This is Jon MacKay. I second.

Kavita Chawla: All in favor, please say aye.

Multiple Speakers: Aye. Aye. Aye. Aye.

Kavita Chawla: Any opposed or abstained? Great. With that, the motion carries. Thank you. And I think that takes us to Nina for your presentation on Antidepressants.

Nina Huynh: Yes. Thank you and hello, DUR Board. I am Nina Huynh Nina from Prime Therapeutics, also known as Magellan Health. And as Marissa mentioned earlier [cross-talk] --

Nonye Connor: [Cross-talk] I am sorry, but -- sorry, Nina.

Nina Huynh: Yes.

Nonye Connor: I didn't mean to interrupt you, but it looks like I have a hand raised from a stakeholder from Biogen. I didn't know if there was a question that they had or --

Daphne Ni: Oh, actually I was just going to speak on the Antidepressant : Other class.

Nonye Connor: Oh, okay. Okay. Sorry.

Daphne Ni: Sorry to steal away from [cross-talk] --

Nonye Connor: Sorry. Sorry, Nina.

Nina Huynh: No worries. Okay, so I will be presenting on a few of the AHPDL classes on today's agenda. Okay. For the agenda topics I will be going over, we will be going over the disease states, any new updates from the past 13 months, including Indications, Dosage, Formulations, and Guidelines. And as a reminder, the top in blue is the prime therapeutic drug classes, and below in black is the Apple Health drug classes. So the first Apple Health drug class that we will be going over is the Antidepressants : GABA Receptor Modulator - Neuroactive Steroid. Okay. First, we will be going over the disease state Perinatal Depression. For the treatment of perinatal depression, the American Congress of Obstetricians and Gynecologists recommends that SSRIs be used as first-line pharmacotherapy. If the patient has been successfully treated previously with an antidepressant from any class, this should be the agent of choice. They know that untreated depression during pregnancy is associated with disruptive health behaviors, relationship, parenting, and physiology. The group acknowledges that the risks and benefits of psychopharmacotherapy for perinatal mental health conditions be discussed with the patient when clinically indicated. Due to the date of publication, ACOG Clinical Practice Guidelines do not address the role of zuranolone (Zurzuvae) in the management of postpartum depression. Okay. So for this class there is only one update, and that is for Zurzuvae, zuranolone, which was FDA approved in August 2023. It is a neuroactive steroid GABA-A receptor positive modulator and is the first oral treatment indicated for postpartum depression in adults. Please note that Zurzuvae is a Schedule IV controlled substance. There is a Blackbox Warning for impaired ability to drive or engage in other potentially hazardous activities, and there

is also a Warning for suicidal thoughts and behaviors. So those who have worsening postpartum depression or who have experienced emergent suicidal thoughts and behavior should consider changing their therapeutic regimen, including discontinuation. Zurzuvae can also cause embryo fetal toxicity, so it is recommended for females of reproductive potential to use effective contraceptive during treatment and for one week after the final dose. Zurzuvae can be used alone or as adjunct to oral antidepressant treatment, and the recommended dose is 50 mg once daily in the evening with a fatty meal for 14 days. Dose may be reduced to 40 mg daily if CNS depressant effects occur, and dose reductions are required for patient with severe hepatic impairment and moderate-to-severe renal impairment. It is available in 20 mg, 25 mg, and 30 mg capsules. And that is it for the GABA receptor modulators and neuroactive steroid. I will pass it back to the Committee.

Kavita Chawla: Thank you, Nina. Yeah, Marissa. Go ahead. Okay. While Marissa pulls that up, any questions for Nina from the Committee? I suppose, Nina, one question I have is in these reviews you don't typically do like in efficacy evaluation, right? Like the trial data where it showed how much relative risk reduction or any of that data, just that it was FDA approved?

Nina Huynh: That is correct.

Marissa Tabile: And this is Marissa. So I should have the PDL pulled up this time. So looking at our GABA Receptor Modulator - Neuroactive Steroid drug class, if there is only one product in that class, which is like Nina mentioned, the Zurzuvae. And we do have it preferred. It looks like we do have PA on that product. And I can answer any questions from the Board about the PDL.

Kavita Chawla: So PA in this situation would because there is no other agent to try, what would the PA require.

Marissa Tabile: Typically, I don't believe this product because it is new there is not -- this is Marissa, I am sorry. Because it is new, we don't have a clinical policy created for it right now, so any requests that we get are reviewed for medical necessity per the labeling at this time.

Zoe Taylor: But in the future, it will probably be like they have to try two SSRIs or something like that. It is just that you don't have that yet.

Marissa Tabile: Yeah. This is Marissa. Yeah. Most likely, maybe. I don't want to say for sure [cross-talk] --

Zoe Taylor: No, no, that is fair. [Cross-talk] --

Marissa Tabile: [Cross-talk] Yeah. [Cross-talk] --

Zoe Taylor: [Cross-talk] I get that you can pick that. I would imagine that will be the policy later.

Marissa Tabile: Clinically, that makes total sense to me, yeah. But just at this time, we don't have that.

Kavita Chawla: Okay. Any questions for Marissa or Nina from the Committee? And if not, we'll go to our stakeholders. Okay. Nonye, I will hand it over to you to have our stakeholders speak.

Nonye Connor: Okay. And Daphne, is that -- I still have you -- have permission for you to speak. Is this the class you wanted to talk -- speak on?

Daphne Ni: Yes.

Nonye Connor: Okay, go ahead. Thank you.

Daphne Ni: Hi. My name is Daphne Ni. I am a Medical Liaison with Biogen, and other than that, I don't have any conflicts of interest to report. So I just wanted to provide the Committee a little bit more information on Zurzuvae. Like Nina said, Zurzuvae is the only oral product that is FDA approved for the treatment of postpartum depression. It has a mechanism of action addressing the drop in allopregnanolone levels seen in postpartum women that leads to depressive symptoms, so it is a more targeted mechanism of action for this population. Zurzuvae was studied in two Phase III studies, specifically in patients with PPD, and in both studies women in the Zurzuvae treatment arm experienced to see significant improvements in their depressive symptoms compared to placebo, and notably the symptom improvement was seen as early as three days after starting Zurzuvae. So this differs from traditional antidepressants like SSRIs that take on average four to six weeks to show symptom improvement. Dosing-wise, Zurzuvae is taken once daily in the evening for 14 days, so it is not a chronic therapy. And then on Safety, the most common Adverse Events for Zurzuvae include somnolence, dizziness,

diarrhea. And Nina did a great job with her slide outlining some of the Warnings, so I will refer you to that as well as the PI for the interest of time. One other thing I do want to address is regarding the ACOG Guidelines. So the ACOG Guidelines that was referenced earlier was published before Zurzuvae was approved. And once Zurzuvae got approval in August 2023, there was actually a release of a Practice Advisory by ACOG, and that practice advisory serves as an update to the ACOG guidelines. And in that practice advisory, they stated that ACOG recommends consideration of zuranolone in the postpartum period for depression that has onsets in the third trimester or within four weeks postpartum, and the postpartum period is defined as within 12 months postpartum. It also states that the decision to use zuranolone should balance the benefit with the risks and challenges. And then it goes on to list various considerations when using zuranolone, including dosing and various patient counseling points. So I am actually going to send a link to that practice advisory in the Q&A for the Committee to have. And then I will just end with taking a step back and say a mother suffering [audio cuts out] are at a higher risk of suicidal ideation, and we know that suicides are leading cause of death for new moms. And also knowing you have perinatal outcomes is an important priority for the state. So having equitable access to this treatment will align with the state's broader goals. So we actually would not advise having any sort of double step through SSRI, given that it is the only world product that is approved for PPD and with the with the rapid onset of simple improvement that we see in this product. So thank you. And I can take any questions.

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

Nonye Connor: No, I do not see any other stakeholder's hands raised.

Kavita Chawla: Okay, great. So we can review the motion then.

Zoe Taylor: I can make the motion. I move that all products in the Antidepressants : GABA Receptor Modulator and Neuroactive Steroid 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 nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Christy Weiland: Christy Weiland, I second.

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

Multiple Speakers: Aye. Aye. Aye. Aye.

Kavita Chawla: Any opposed or abstained? Okay. With that, the motion carries. And I think that takes us back to Nina on the Anti-Parkinson Agents.

Nina Huynh: Yes. So this is Nina. We will be going over Anti-Parkinson Agents with Apple Health Class Adenosine Receptor Antagonists, Dopaminergics, and MAOIs. So very brief updates for this class. In July 2023, FDA approved the first generic Xadago (safinamide) tablets by Aurobindo, and in August 2023, FDA reported discontinuation of Mirapex ER by Boehringer Ingelheim, but the generic formulation is still available. And that is all I have for that drug class. I will pass it back to the Committee.

Kavita Chawla: Thanks, Nina. Questions for Nina from the Committee. Okay. Over to Marissa.

Marissa Tabile: This is Marissa. So I have the three drug classes Anti-Parkinson Agents drug classes pulled up. So I will just go through them one by one. So the first one is the Adenosine Receptor Antagonist. There is only one product in that class, which is Nourianz brand name that is preferred. It looks like there is PA. For the Anti-Parkinson Agents : Dopaminergics. We have multiple products in this class. I will go ahead and just point out everything that is preferred. So we have generic amantadine. It looks like we have capsules and solutions. We have single carbidopa, but then we also have combination carbidopa/levodopa tablets. It looks like there are some ER formulations as well. We also have pramipexole tablets and ropinirole tablets and ER formulations of that as well as preferred. Those do not have PA. And then moving on to the MAOIs. The preferred product in this class is selegiline generic, both the capsule and the tablet. There is no PA on those. And then the nonpreferreds are everything else. But it looks like that is just a step-through. There is no PA for the nonpreferreds, so I can take any questions from the DUR Board?

Kavita Chawla: Okay. Hearing no questions. Any stakeholders, Nonye?

Nonye Connor: Looking at the list, I do not see any hand raised.

Kavita Chawla: Okay. All right, so no hands raised. We can look at the motion. We'll have our Committee members all on camera. Great.

Marissa Tabile: This is Marissa. I just wanted to note, I did make a change on here. This used to say Slide 5, but it looks like because I removed one of the motions for the Antiparasitics, it kind of shifted everything, so I just changed the number to 4. I am just verifying that all the product the drug classes are on Slide 4 here. so it is accurately reflected there.

Kavita Chawla: Thank you, Marissa.

Marissa Tabile: Mm-hmm.

Kevin Flynn: This is Kevin Flynn. I move that all products and 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 discussion of HCA. Products in these classes may require prior authorization to determine medical necessity. All nonpreferred products require a trial at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Jon MacKay: This is John McKay. I second.

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

Multiple Speakers: Aye. Aye. Aye. Aye.

Kavita Chawla: Any opposed or abstained? Okay. With that, the motion carries. And that gets us to lunch. How's everybody doing? Do we want to go and do lunch? Yeah! All right. All right. So back in 30 minutes, Nonye. I guess there is a question in here, Nonye, if you or Marissa can also answer the question.

Marissa Tabile: This is Marissa. Uh, sure. Let me go ahead and -- oh, it looks like there was the Aclog from the stakeholder that I think was posted.

Kavita Chawla: Yeah.

Marissa Tabile: So Nonye put that in the chat for you all.

Kavita Chawla: Yeah, but in the Q&A there is the [cross-talk] --

Marissa Tabile: Oh, I didn't [cross-talk] --

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

Marissa Tabile: It is hiding from me. Hold on one moment. Okay. This is Marissa. So it looks like there is someone that is asking about a particular product. I will have to look into that and see if it falls -- it is regarding the Vyvgart. I will have to see if it falls within any of these classes, and then I will provide an answer back to the stakeholder.

Kavita Chawla: Okay, great.

Marissa Tabile: I don't know off the top of my head where that class -- where that drug falls.

Kavita Chawla: Okay. Great. I think according to the original Agenda, 2:40 was when we were going to talk about Anti-Myasthenic Agents. But you are right, I don't know if in the PDL's classification it the same drug class is. Okay. For the Committee, we'll see you back in 30 minutes.

[break]

Kavita Chawla: Apologize for the delay. I think all of the Committee members are back on the line. Cool. All right. So we reconvened the Board, and we dive into our GI Agents. All right, back over to you, Nina.

Nina Huynh: Okay, this is Nina. And next, we'll be reviewing Gastrointestinal Agents : Ileal Bile Acid Transporter Inhibitors. So for this drug class, we will be reviewing the disease state pruritis associated with Alagille syndrome and progressive familial intrahepatic cholestasis. Alagille syndrome is an inherited condition that causes a buildup of the bile in the liver due to the lack of adequate numbers of bile ducts to drain the bile, which leads to liver damage. Signs and symptoms include severe itchy skin related to the presence of bilirubin as well as jaundice, delayed growth, xanthomas, heart murmurs, vascular changes, distinct facial features, kidney disease, and enlarged spleen. progressive familial intrahepatic cholestasis is characterized by an itch that is disabling and includes the eyes and ears. Agent approved for use in patients with pruritus is resulting from either Alagille syndrome or progressive familial intrahepatic cholestasis are maralixibat, which is

Livmarli, and odevixibat, which is Bylvay. So in March 2024, FDA approved Livmarli (maralixibat) for the treatment of cholestasis pruritus in patients greater than or equal to five years old with progressive familial intrahepatic cholestasis. For a limitation of use, it is not indicated in a subgroup of PFIC type 2 patients with specific ABCB11 variants resulting in a non-functional or complete absence of bile salt export protein. There is a new indication for prior or active hepatic decompensation event including variceal hemorrhage, ascites, and hepatic encephalopathy. The recommended dose for this new indication PFIC is 285 microgram/kilogram orally once daily in the morning, titrating as tolerated to a recommended maintenance dose of 570 micrograms/kilogram twice daily, taken 30 minutes before a meal. The maximum daily dose for PFIC is 38 mg, and there are no changes in the availability. And that is all that I have for the bile salts. I will pass it back to the Committee.

Kavita Chawla: Thank you, Nina. Questions from the Committee for Nina? Okay. Go ahead, Marissa.

Marissa Tabile: This is Marissa. So I am displaying the Gastrointestinal Agents : Ileal Bile Acid Transporter Inhibitors drug class. And like Nina mentioned, there are really two products, which are brand name Bylvay and brand name Livmarli, which we do have in this class. And it does look like they are preferred with PA, most likely to the label. And I can answer any questions from the Board.

Kavita Chawla: Thank you, Marissa. Questions? And if not, Nonye, are there any stakeholders?

Nonye Connor: I see one hand raised, and that is for April.

April LaRow: Hello, everyone. Can you hear me?

Nonye Connor: [Cross-talk] Yes.

Kavita Chawla: [Cross-talk] Hi, April.

April LaRow: Hello. Thank you so much for this opportunity. I am a Medical Science Liaison with Mirum Pharmaceuticals, and I have no other disclosures to report. I just wanted to provide some updates from the slide the Nina just showed. Just late last month we received an update in our Indication specific to progressive familial intrahepatic cholestasis. So I wanted to share that

update with you, which is that Livmarli is now FDA-approved for ages 12 months and older, with cholestatic pruritis associated with PFIC, which I will use that acronym instead of saying the full disease. And there are now two different strengths. So on your slide you had the 9.5 strength with the most recent update from last month. There are two strengths available now, which is 9.5 mg/kg for Alagille patients, and for PFIC patients there is now a strength of 19 mg per -- I am sorry, I said mg/kg. It is mg/mL. I apologize for that -- so two different strengths, 9.5 mg/mL with Alagille and 19 mg/mL for the PFIC patients. I also just wanted to share a quick overview because these patients -- these diseases are rare, and this community is -- I like to raise awareness about these -- both of these communities, the Alagille and PFIC communities. They are rare diseases. PFIC is about 1/50,000 to 1/100,000 live births, so you are going to see a lot less of it than your Alagille, which is about 1/30,000 to 1/50,000 live births. The similarity between the two of them is this extremely debilitating cholestatic pruritis that doesn't just take over the patient's life but the whole family. It is extremely disruptive. These kids are suffering in every area of their life. So think of this beyond like atopic dermatitis and beyond. It is something that completely inhibits them from functioning and the family from functioning because the child is not sleeping. I wanted to talk a little bit about our approval in PFIC. And we, of course, had a pruritis reduction statistically significant and serum bile acid reductions that are statistically significant. But in both Alagille and PFIC, we have additional endpoints such as quality of life that we have seen, and over the long-term for both of these and growth, we see these patients growing. And if you think about it, it makes a lot of sense because the growth hormones are excreted while these patients are sleeping, and now they are sleeping better, so under quality of life, we see drastic improvements in sleep. We also have a Natural History Cohort Comparison that showed a reduction in events for Alagille patients against a natural history cohort, 70% reduction in events, including liver transplant, portal hypertension, and death. So just to conclude, I want to thank you, and maralixibat is the only indicated drug for ages three months [indistinct] in Alagille and is now indicated in 12 months and up in people. Thank you so much.

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

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

Kavita Chawla: Okay. All right. Thank you for pulling up the motion. Okay. Kavita Chawla here. I move that all products in the Gastrointestinal Agents : Ileal Bile Acid Transporter Inhibitors 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 nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Kevin Flynn: This is Kevin Flynn. I second.

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

Multiple Speakers: Aye. Aye. Aye. Aye.

Kavita Chawla: Any opposed or abstained? Okay. With that, the motion carries. And back to Nina for Glaucoma Agents.

Nina Huynh: Thank you. So this is Nina. Next, we have Glaucoma Agents with Apple Health Classes - Adrenergic Agents, Adrenergic Agents Combinations, Beta Blockers, Beta Blocker Combinations, Carbonic Anhydrase Inhibitors, Kinase Inhibitors, Miotics, and Prostaglandins. The next disease state we will be going over is Glaucoma. So approximately 3 million people in the United States suffer from glaucoma, and it is the second most common cause of permanent blindness in the United States. It is the leading cause of blindness among Hispanics and the second most common cause of blindness among African Americans. Increased intraocular pressure is common in glaucoma and is believed to contribute to the damage to the optic nerve, which can lead to loss of visual sensitivity and field. Some patients with glaucoma have normal IOP, and many patients with elevated IOP do not develop glaucoma. IOP alone is no longer considered a diagnostic criterion for glaucoma. There are two major types of glaucoma, open-angle and closed-angle. Open-angle glaucoma has reduced flow through the trabecular meshwork and accounts for the majority of glaucoma cases. In closed-angle glaucoma, the iris is pushed forward against the trabecular meshwork, blocking fluid from escaping. Presbyopia is an age-related gradual loss of near-focusing ability of the eye due to the loss of the elasticity of the lens. Here I provided the 2020 AAO Guidelines. Since this is well over one year, I have just included it for completeness' sake and for your Committee's review at your leisure. Okay.

The first medication we have is Qlosi. So in October 2023, FDA approved Qlosi (pilocarpine) a cholinergic agonist indicated for the treatment of presbyopia in adults. Qlosi may cause blurred vision, risk of retinal detachment, and iritis. The recommended dose is one drop in each eye. It can be repeated a second time after two to three hours for an effect up to 8 hours. Qlosi can be used on a daily basis or as needed up to twice each day. It is available as a 0.4% 4 mg/mL ophthalmic solution in a single patient use vial. Next, we have iDose TR travoprost intracameral implant, which was FDA-approved in December 2023. IDose TR is a prostaglandin analog indicated for the reduction of IOP in patients with ocular hypertension or open-angle glaucoma. It is recommended to use iDose TR with caution in patient with narrow-angles or other angle abnormalities as it can cause iridocorneal angles. It is recommended to monitor patient routinely to confirm the location of the iDose TR as device dislocation may occur. The iDose TR may also cause permanent iris pigmentation. The iDose TR is a travoprost delivery system consisting of a 75 microgram travoprost-releasing implant preloaded in a single sterile dose inserter. It is administered intracamerally by a healthcare professional under standard aseptic conditions, and it should be administered -- it should not be readministered to an eye that received a prior dose of TR. And that is all for glaucoma agents. I will pass it back to the Committee.

Kavita Chawla: Thank you, Nina. Questions from the Committee for Nina? Okay. And, yes, Marissa, go ahead with the review.

Marissa Tabile: And this is Marissa. So I pulled up all of the Glaucoma Agents and the subclasses, so we'll go through it one by one. So the first one is the Adrenergic Agents, and our preferred products in this class look like brand name Alphagan P, and we have generic brimonidine tartrate drops. It doesn't look like there is any PA on those. For Adrenergic Agents : Combinations. The preferred products are both the brand name Simbrinza and the generic brimonidine dorzolamide drops. Again, no PA on those. For the Beta Blockers, our preferred products are the levobunolol and the timolol maleate drops. It looks like there is a solution. And then we have Timoptic Ocudose. It looks like it is a dropperette that is preferred without PA. For the Beta Blockers Combinations, it is easier if I actually say what is nonpreferred. So what is nonpreferred in that class is it looks like it is the Cosopt PF and, uh, maybe that was not easier. [Laugh] Cosopt and Cosopt PF. Everything else is preferred without PA. The next class is the Carbonic Anhydrase Inhibitors. For this class, it looks like what is not preferred is the Azopt. Everything else

is preferred without PA. In the Kinase Inhibitors, we have Rhopressa and Rocklatan. Those are preferred without PA. For the Miotics, the preferred product in this class looks like the pilocarpine drops. It looks like that is generic. There is no PA on that. And then for the Prostaglandins, the preferred products are -- it looks like brand name Iyuzeh and generic latanoprost drops. And I can answer any questions from the Board.

Kavita Chawla: Thank you, Marissa. Hearing no questions. Any stakeholders, Nonye?

Nonye Connor: No. I do not see any hands raised.

Kavita Chawla: Okay, great. So we can then review the motion.

Marissa Tabile: And this is Marissa. I am just going to go ahead and update the number. So I am just verifying that all the drug classes are listed here on Slide 7, and then I will be updating this slide to reflect the correct slide.

Kavita Chawla: Perfect. Thank you. Okay, Committee, whenever you are ready.

Christy Weiland: This is Christy Weiland. I move that all products in the drug classes 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 [audio cuts out] HCA. Products in these classes may require prior authorization to determine medical necessity. All nonpreferred products require a trial of at least two preferred products with the same indications before a nonpreferred 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: Thank you. All in favor, please say aye.

Multiple Speakers: Aye. Aye. Aye. Aye.

Kavita Chawla: Any opposed or abstained? Okay. With that, the motion carries. Back to Nina for the Hematologic Agents.

Nina Huynh: Thank you, This is Nina. So next we have Hematologic Agent : Miscellaneous, Complement Inhibitors, and Injectables. So first we will be going over Neuromyelitis Optica Spectrum Disorder (NMOSD), also known as Devic's

disease. NMOSD is a rare autoimmune inflammatory CNS syndrome involving the optic nerve, spinal cord, and brain stem, with an estimated prevalence of 0.37 to 10 cases per 100,000 persons. NMOSD is more common in men -- women than in men, and it is proposed to primarily be mediated by B cells and aquaporin-4 immunoglobulin G antibodies, which are likely involved in the pathogenesis of NMOSD because they bind to the astrocytes in the CNS. This binding can trigger attacks such as loss of vision, paralysis, nerve pain, and respiratory failure. There are currently no clinical practice guidelines for the treatment of NMOSD in the US, and in practice, the standard treatment for acute attacks involves steroids such as high-dose IV methylprednisolone or plasma exchange for patients with severe symptoms. The chances of relapse and permanent disability are approximately 90% in these patients. So in March 2024, FDA approved Ultomiris (ravulizumab-cwvz) for the treatment of adults with NMOSD who are anti-aquaporin 4 antibody positive. The recommended dose for this new indication is based on patient's body weight, and there are no additional changes on the Warning and Availability. The next disease state we will be going over is CD55-Deficient Protein-Losing Enteropathy. This is also known as complement hyperactivation angiopathic thrombosis and protein-losing enteropathy (CHAPLE) disease. So CHAPLE disease is a rare genetic disorder caused by a mutation in the gene encoding for complement decaying accelerating factor CD55 combined with immunodeficiency. Mutations in the CD55 gene leads to the inability to control complement activity, a cascade of proteins that provide host events resulting in an overactive complement system that causes damage to the blood and lymph vessels in the digestive tract. Patients have chronic abdominal and cardiovascular symptoms and can also experience severe recurrent infections as well as potential fatal thrombosis. Veopoz is the first FDA-approved treatment for CHAPLE disease. So in August 2024, FDA approved Veopoz (pozelimab-bbfg) a complement immune -- inhibitor, as the first treatment for adults and pediatric patients greater and equal to one years old for CHAPLE disease. There is a Blackbox Warning for life-threatening meningococcal infections and sepsis, which may become rapidly life threatening or fatal if not recognized and treated early. Veopoz can also cause other bacterial infections and systematic hypersensitivity reactions. The recommended dose is 30 mg/kg IV loading dose on day one, then 10 mg/kg subcutaneous once weekly starting on day 8 and thereafter. Maintenance dose may be increased to 12 mg/kg subcutaneous once weekly. If there is inadequate clinical response after at least three weekly doses, and the maximum weekly dose is 800 mg. And all doses must be administered by a healthcare professional. Veopoz is available as 400 mg/2 mL single-dose

vial. Okay, and the last disease state for this class we will be going over is Myasthenia Gravis, which is a relatively uncommon disorder but is the most common disorder of neuromuscular transmission and is caused by an antibody-mediated attack of the proteins in the postsynaptic membrane of the neuromuscular junction. The cardinal feature of MG is fluctuating skeletal muscle weakness often with true muscle fatigue. The fatigue is manifested by worsening contractual force of the muscle. There are two clinical forms of MG; ocular and generalized. In ocular MG, weakness is limited to the eyelids and extraocular muscles, and in generalize disease, weakness may also commonly affect the ocular muscle, but it also involves a variable combination of bulbar, limb, and respiratory muscles. There are four classes of therapies used to treat MG: symptomatic, chronic immunomodulating, rapid but transient immunomodulating and surgical treatment. For symptomatic treatment, we have anticholinesterase agents. For chronic immunomodulating treatment, we use glucocorticoids and nonsteroid immunomodulating agents. For rapid but transient immunomodulating treatment, we use plasmapheresis and IVIG. For surgical treatment there is thymectomy. Here I have included the 2021 American Academy of Neurology Guidance for the maintenance of MG. As this is well over one year, I have added here for your review at your leisure. Okay. And the last drug that we will be going over for this drug class is Zilbrysq. So in October 2023, FDA approved Zilbrysq (zilucoplan) a complement inhibitor indicated for treatment of generalized MG in adults with -- who are anti-acetylcholine receptor antibody positive. Zilbrysq also contains a Blackbox Warning for serious meningococcal infections. Other Warnings include pancreatitis and pancreatic cysts. The recommended Dose is based on patient's body weight, ranging from 16.6 mg to 32.4 mg subcutaneously once daily, and it is available as a 16.6 mg/0.416 mL, 23 mg/0.574 mL, or 32.4 mg/0.81 mL in a single-dose prefilled syringe, and that is all for the Complement Inhibitors : Injectables. I will pass it back to the Committee.

Kavita Chawla: Thank you, Nina. Questions for Nina from the Committee? All right. Go ahead, Marissa.

Marissa Tabile: This is Marissa. So this is our Hematological Agents : Complement Inhibitors - Injectable drug class. And as you can see, we have a wide range of different products here, some of which Nina mentioned. As you can see, they are pretty much all preferred. They all have PA. I believe these are relatively costly drugs. So we have Empaveli, Enjaymo, Soliris, Ultomiris, Veopoz, and

Zilbrysq all in this class. So it is pretty. Straightforward and I can answer any questions from the Board.

Kevin Flynn: Almost all of these are like infused in a physician's office, so I guess it applies the same across on the medical and pharmacy side?

Marissa Tabile: This is Marissa. Yeah, we do. I believe we do a lot of these through medical. They are included on our AHPDL because they are what we call carveouts from the MCOs. So just to give them kind of direction on those, that is why we include them. And then we do have some statuses like preferred with PA on them. We are finding that some -- we are getting requests from, I believe it is like infusion pharmacies where they would need to use a point of sale system. So that is why you may see that we do have statuses on them because we do allow them through a point of sale system just due to that kind of billing and administration that we're finding is happening.

Kevin Flynn: That makes sense.

Marissa Tabile: Yep.

Kevin Flynn: Thank you.

Kavita Chawla: Any other questions for Marissa? Okay. Nonye, any stakeholders for this section? [Cross-talk]

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

Kavita Chawla: [Cross-talk] And Marissa [cross-talk] -- yeah, sorry. Go ahead, please.

Nonye Connor: Okay. Yeah. I see two hands raised. The first hand that I see here is David. Let me go ahead and give you permission to speak. So David, whenever you have a chance, go ahead and unmute yourself.

David Armstrong: David Armstrong, US Medical Affairs with Alexion Pharmaceuticals. Thank you for the opportunity to speak on behalf of Ultomiris and Soliris and Alexion. I would make one comment that in PNH, you have myasthenia gravis and NMOSD listed under that category. They are actually three separate and distinct disease therapies, only one of which is Hematological Agents. That being said, we support the recommendations of the Board, and I will yield back the remainder of my time.

Kavita Chawla: Thank you, David. Questions for David from the Committee? Okay, go ahead, Nonye.

Nonye Connor: I have one more person, and I am so sorry.

Lisa Carman: Yep, hi. This is Lisa Carman. Can you hear me?

Nonye Connor: Yes.

Lisa Carman: Hi. Just really quickly, again, Lisa Carman. I am speaking on behalf of Genentech. I don't have any other conflict of interest other than my employment. I just wanted to mention we had a recent approval a few months ago for a drug called Piasky, which is crovalimab. I just mention it because it is at this time only indicated for PNH, which I know isn't one of these. It is a complement inhibitor, but not one of the disease states that Nina went into but given the list that you just showed and the other drugs, that they also -- some of them are also indicated for PNH. I just wanted to put that on your radar. And without any questions, I will yield the rest of my time back.

Kavita Chawla: Thank you. Okay, I don't hear any questions from the Committee. Any other stakeholders, Nonye? Okay. Should we review the motion then?

Kevin Flynn: This is Kevin Flynn. I move that all products in the Hematological Agents : Miscellaneous Complement Inhibitors - Injectable 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 nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Christy Weiland: This is Christy Weiland. I second.

Kavita Chawla: All in favor, please say aye.

Multiple Speakers: Aye. Aye. Aye. Aye.

Kavita Chawla: Thank you. Any opposed for abstained? Okay. With that, the motion carries. And then back to you, Nina.

Nina Huynh: Okay, thank you. This is Nina, and this is my last topic for today, and it is the Oncology Agents : Antineoplastic - Miscellaneous Combinations - Oral. 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 the United States. In 2023, the NCCN Guidelines indicated Stivarga and/or Lonsurf with or without bevacizumab as treatment options for patients who have progressed through all other standard regimens. Although the FDA approved dose of Stivarga is 160 mg daily for 21 days of a 28-day cycle, the NCCN Guidelines note that is common practice to start at a lower dose for the first cycle, giving 80 mg for the first seven days, followed by 120 mg daily on days 8 through 14 and then 160 mg daily on days 15 through 21. And this is the last drug which is Lonsurf (trifluridine/tipiracil combination). In August 2023, FDA approved the use in combination with bevacizumab for adults with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy and anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy. Lonsurf was previously approved as monotherapy for this indication. The Warning, Dosage, and Availability for Lonsurf remains the same for this expanded indication. And that concludes my slide deck for Oncology.

Kavita Chawla: Great job today, Nina. Thank you.

Nina Huynh: [Cross-talk] Thank you, appreciate it.

Kavita Chawla: Questions for Nina from the Committee? Okay. Take it away, Marissa.

Marissa Tabile: This is Marissa. So I am displaying the Oncology Agents : Antineoplastic Combinations - Oral drug class. This is pretty straightforward. There are only three products in this class, which are the Inqovi, Kisqali, [audio cuts out] and Lonsurf. They are all preferred with PA. And we don't have a policy for it, so it would just be PA per labeling. And I can answer any questions from the Board.

Kavita Chawla: Okay, I don't hear any questions. Okay, Nonye, any stakeholders?

Nonye Connor: I do not have any hand raised here.

Kavita Chawla: Great. Okay, Marissa, I will have you pull up the motion. Great. Thank you.

Zoe Taylor: This is Zoe Taylor. I move that all products in Oncology Agents : A Antineoplastics Combinations - Oral 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 nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Greg Hudson: This is Greg Hudson, I second.

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

Multiple Speakers: Aye. Aye. Aye. Aye.

Kavita Chawla: Any opposed or abstained? Okay. With that, the motion carries. And I think, Marissa, you get to stay on and take us into the Other GI Agents.

Marissa Tabile: This is Marissa. Yes, you have the rest of the meeting to hear my voice.

Kavita Chawla: It is a marathon for you today.

Marissa Tabile: Yeah, I know. [Laugh] So I will go ahead and show my video here and then go ahead and get started. All right. So the first class that I will be presenting on is the Gastrointestinal Agents : Short Bowel Syndrome drug class. I believe we have reviewed this before, so I will probably go rather quickly and just give a little background on it and do light drug overviews if there is anything worth mentioning for it. So short bowel syndrome (SBS) is a malabsorptive condition which is often caused by massive resection of the small intestine. Usually surgical resection is for Crohn's disease, malignancy, trauma, radiation, or vascular insufficiency. It is the most common cause of chronic intestinal failure, and it affects about 3 out of 1,000,000 people per year. The main symptom of SBS is diarrhea, but a patient can have other signs and symptoms such as bloating, cramping, fatigue, foul-smelling stool, vomiting, and weakness. So there are different management strategies depending on the phase that a patient is in. So there is what is called management of the acute phase, and that is usually characterized by high intestinal fluid losses and metabolic derangements. Management of the acute phase you want to

start immediately after resection, and it is usually during the initial three to four weeks after resection. So really what you are wanting to do for these patients is to stabilize their large fluid and electrolyte losses, and then also maintain their fluid and acid/base balances, so you would see IV replacement with NS, potassium, and magnesium. You would see acid suppression with a PPI or an H2RA. There is parenteral nutrition, and then you would also see some possible enteral feedings. So moving into what is called the adaptation phase, the management of this is really characterized by structural and functional changes to the remaining small bowel and the colon in order to increase absorption and slow gastrointestinal transit. This usually lasts for patients about one to two years. So patients in this phase are usually transitioned from oral feedings over which spans over weeks to months, and then it is usually done in a stepwise approach, so pretty slowly. One of the main goals here is still fluid management. The goal is to maintain urine output for patients of at least one liter per day. You can use which you would see pharmacologically for some of these patients are antibiotic treatments for possible small intestinal overgrowths and then the use of octreotide. If a patient enters intestinal failure, what you would see is a reduction in their GI function below the minimum necessary for absorption of micronutrients, water, and electrolytes. This type of intestinal figure can be transient or potentially permanent for patients, so SVS-associated failure reverses completely in about 50% of adults within the first two years. For this, you would see the use of GLP-2 analogs for patients that are unable to be weaned from their parenteral nutrition. So I have included here the American Gastroenterological Association management for short bowel syndrome guidance. This was published in 2022. I did not see any current updates within the last year and a half, so I included this just for completeness' sake, if you wanted to take a look at it, but I won't go too in depth into it just because it is -- I don't want to say completely outdated, but it is not really relevant within at least like the last year. So nothing's really changed. Getting into the drugs. So the one product I believe that is really only in this class is what is Gattex (teduglutide). So a little bit of the drug overview in case it has been a while since you have seen this drug. It was approved a while ago, so in 2012. It is a GLP-2 analog, different from GLP-1s that we typically see. It is indicated for adults and pediatric patients one year of age and older with SBS, who are dependent on parental support. There really haven't been any changes to any of the dosing, any of the availability of which it is in the market, so everything is largely still the same. There are not really any updates for this product. And so I can actually just pivot over to -- that's the end of that presentation. I will pivot over to what is happening on our PDL

for this class, and it does look like Gattex is the only product in that class. It is preferred with PA. We do not have a policy for it, but it would be reviewed per labeling. So I can take any questions either on the presentation or the PDL.

Kavita Chawla: Thank you, Marissa. Questions from the Committee? And any stakeholders, Nonye?

Nonye Connor: I do not see any hands raised.

Kavita Chawla: Okay, thank you.

Jon MacKay: This is Jon MacKay. I move that all products in the Gastrointestinal Agents : Short Bowel Syndrome 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 preferred -- all nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Greg Hudson: This is Greg Hudson, I second.

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

Multiple Speakers: Aye. Aye. Aye. Aye.

Kavita Chawla: Any opposed or abstained? Okay, thank you. With that, the motion carries. And back to Marissa to review the Hematologic Agents. [Cross-talk] --

Marissa Tabile: [Cross-talk] All right.

Kavita Chawla: [Cross-talk] Marissa, are we reviewing both of the sections together?

Marissa Tabile: Oh, actually there are -- I could. It might actually -- maybe I will do that just so that then it will have to be two separate motions, but these will probably go relatively quickly, so I will just go through both.

Kavita Chawla: Okay.

Marissa Tabile: Okay.

Kavita Chawla: Yeah. And was there a question before you get started? I thought I heard somebody else's voice. Okay, never mind. Okay, thank you, Marissa.

Marissa Tabile: No problem. So the first class that I will go through is the Hematologic Agents: Aminolevulinate Synthase 1-Directed SiRNA drug class. Boy, that's a mouthful. And there really, to be quite honest, there are really no guideline updates that I did see. So if you do see any, they are just there for completeness' sake, but there are some kind of drug updates that I will go through that I have seen. But just to kind of give you all the brief disease state overview, so Acute Hepatic Porphyria (AHP) is a family of rare genetic diseases that are characterized by potentially life-threatening attacks with chronic manifestations that negatively impact quality of life and daily functioning, so they do manifest. There are really four different types that fall under this umbrella. There is acute intermittent porphyria (AIP), hereditary coproporphyria (HCP), variegate porphyria, or (VP), and ALA dehydratase-deficiency porphyria (ADP). It is usually caused by altered activities of enzymes with the heme biosynthetic pathway, and usually these cause neurovisceral manifestations. So patients will usually experience things such as abdominal pain, motor and sensory peripheral neuropathy. They can have neuropsychiatric type of manifestations, or they can have cutaneous photosensitivity, so things like chronic blistering or acute blistering. The most common way that this presents is by neuropathic abdominal pain and acute intermittent porphyria is the most common out of all the porphyria that I mentioned. The management of this particular condition is really to help with management of an acute attack as soon as possible, and then, of course, provide symptomatic and supportive treatment until the attack subsides. So usually prevention of attacks is really managed by avoiding the exacerbating factors. So some examples of those are there are medications that can cause it, smoking and alcohol, a patient's diet, treatment of infections or trying to prevent infections, attention to iron stones -- iron stores and suppression of menstrual-style related attacks. Like I said, these are just guidelines that have been there. It was January of 2023, so not completely outdated, but I just won't really mention -- haven't seen any real updates for this. And then getting into really the pharmacological therapies, which I believe there might just be one. A lot of these classes I think might only have one product in them. But this one is for Givlaari (givosiran). Hopefully, I am pronouncing that correctly. For this one, the drug has largely stayed the same. There are no really big updates besides the Warning and Precautions,

which now this drug has a Warning and a precaution of a risk of acute pancreatitis. The Dosing and everything else and Availability is still largely the same for this product, so pretty straightforward. And then I will jump straight into the Hematologic Agents : Pyruvate Kinase Activators drug class. So for this one, it is really dealing with pyruvate kinase deficiency, which is a rare disorder that is characterized by the premature destruction of red blood cells, which is otherwise called hemolytic anemia. It is caused by mutations in the PLKR gene, which leads to deficiency of the enzyme pyruvate kinase. And just to kind of throw you back to bio chem, pyruvate kinase helps cells turn glucose into ATP via glycolysis. That is a very high level biochemist refresher for you, if you will. Management of PK deficiency. It really just depends on the age and when the disorder becomes present in a patient's life. So if it is before birth, the baby may require intrauterine transfusion. If it is during the neonatal period, you can use phototherapy or exchange transfusion. And then if it manifests from infancy through adulthood, there are red blood cell transfusions, folic acid, and some of these are pharmacological therapies that you might see, mitapivat, splenectomy, iron chelation. There are gene therapies, and then there is also hematopoietic stem cell transplant that is available as well. For these patients, they should be monitored during routine medical care for symptoms of anemia and, of course, use the supportive treatments that are available if it does if patients do experience that. So the transfusions, the mitapivat, and folic acid, and then splenectomy is reserved for more severe cases. The main goal and one of the treatment goals is prevention or treatment of iron overload in these patients. So the one drug that I keep mentioning and mispronouncing is mitapivat or Pyrukynd. It was approved by the FDA in 2022. There haven't really been any updates to this drug, so the dosing and the availability are still the same. So I will go ahead and stop there, and then I can go ahead and show our PDL for these two classes. So we have Hematological. Here, I believe these -- I am going to make a bet there is one product per class, which I am correct. So they are the products that I mentioned. So for the first class, the SiRNA, is Givlaari. This one is, I believe, a carve out, so we do allow it on the medical side. We haven't assigned it any kind of preferred or nonpreferred status just because we haven't really been seeing any claims come through these infusion pharmacies for this particular product. So that is why you see the X, but we do still have it on our AHPDL just on the medical benefit. And then for this one for pyruvate kinase activators, we have Pyrukynd, and this one is preferred with PA. We do not have a policy for it yet, so it would just be reviewed per the labeling. So I can answer any questions from the Board regarding these two classes.

Kavita Chawla: Thank you, Marissa. Questions from the Board? Okay. And Nonye, any stakeholders?

Nonye Connor: I do not see anyone's hands raised.

Kavita Chawla: Okay, thank you. Okay. Thank you, Marissa. For the motion.

Zoe Taylor: I can do it. Zoe Taylor. I move that all products in the Hematological Agents : Miscellaneous : Aminolevulinate Synthase 1-Directed SiRNA 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 nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only when product is preferred.

Christy Weiland: Christy Weiland. I second.

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

Multiple Speakers: Aye. Aye. Aye. Aye.

Kavita Chawla: Any opposed or abstained? Thank you. With that, the motion carries. The schedule is telling me that we are scheduled for a 10-minute break right now.

Marissa Tabile: Oh, Kavita, sorry. This is Marissa. I have one more [cross-talk] for the pyruvate kinase activators class.

Kavita Chawla: Oh, yes, that motion and then. My mistake. Thank you. Okay, this is Kavita Chawla. I move that all products in the Hematologic Agents : Pyruvate Kinase Activators 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 nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Peter Barkett: Peter Barkett. I second.

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

Multiple Speakers: Aye. Aye. Aye.

Kavita Chawla: Any opposed or abstained? Thank you. With that, the motion carries. Okay. How about now, Marissa?

Marissa Tabile: This is Marissa. You are good. So next is the break if you all want to take it or not.

Kavita Chawla: How is the team feeling? Yes? Okay. I see thumbs up. All right, we'll be back in 10 minutes.

[break]

Kavita Chawla: All right. Ready to resume? We'll just make sure all our Committee members are back. Also I apologize for the kind of raspy, weird voice you might be hearing all day. My kids have COVID, so I am pretty sure I have it, too, at this point. So just oh joy.

Greg Hudson: Oh, I hope you feel better soon.

Kavita Chawla: Thank you, Greg.

Greg Hudson: And your kids.

Kavita Chawla: Yeah. Okay, I think we have quorum. Marissa, if you are ready to proceed.

Marissa Tabile: Yeah. Let me share my screen again.

Kavita Chawla: Thank you.

Marissa Tabile: All right. I think we're in the home stretch of all the other classes after this. I don't think there are any more breaks, so we'll see how long this goes. All right. So this is Marissa. I will be -- well, not really -- going through the Hematologic Agents : Other. I did find that we did actually just make a change for this particular drug class. So I believe previously we did include this class and the products in this class on our PDL, but I believe ever since our new

point of sale when we switched over with the AHPDL changes, we did change this class to be not included on our PDL. And that makes sense and is probably by -- and is by design. Just because of the nature of the drugs that fall within this class. So with that being said, there is no real clinical review that I will be doing. I know that I have included slides, but this was an oversight on my end, so I apologize. Because it is not a PDL class, it is not a class that you all need to review, make a motion for, but just for completeness' sake, I will show you what is in that class, even though it is not PDL. We still do classify our non-PDL items into drug classes, so it is really the drugs that you would see for the more emergent conditions, which makes sense why we wouldn't include them on our PDL. But we do cover them through medical, so it is the alteplases, the protein C, the Panhematin, protamine sulfate, Reteplase, and Tenecteplase. We do allow those through medical, so they still have coverage, but they are just not included on our PDL. So with that, I will go ahead and skip to the next agenda item, which is the Neuromuscular Agents : Antimyasthenic Cholinergic Agents. So I apologize for that oversight on our end. It is just changes that we have made to our PDL. So with that, next is the Neuromuscular Agents : Antimyasthenic Cholinergic Agents drug class. And for this, the conditions that I will mostly be talking about -- or condition -- is myasthenia gravis (MG). So just a brief overview on this. It is an autoimmune, and I believe Nina went through this earlier, actually, so I am just kind of piggybacking off what she presented earlier. It is the autoimmune neuromuscular disorder that causes weakness in the muscles. It is usually due to antibody-mediated immunologic attack directed at protein in the postsynaptic membrane of the neuromuscular junction. It is the most common disorder of neuromuscular transmission. It manifests from mild to severe with, their can or can't be respiratory failure in others. There are two clinical forms of myasthenia gravis, so there is ocular, which is really the weakness is limited to the eyelids and extraocular muscles. And then you have generalized myasthenia gravis, which involves a variable combination of ocular, bulbar, limb, and respiratory muscles. The treatments for myasthenia gravis. There is very -- there are many different ones. So there is symptomatic treatment or different management strategies, I should say, symptomatic treatment where you would want to increase the acetylcholine available at the neuromuscular junction. There are chronic immunotherapies which target the underlying immune dysregulation, so things -- glucocorticoids and non-steroidal immunosuppressive and immunomodulatory agents. There is rapid immunomodulating treatments, and then there is the possibility of surgical treatment, which would be a thymectomy. The goals of therapy are to help patients really manage their

symptoms so that then that they are not really experiencing the side effects from the medications, so that is really the goal. The next one is kind of in this realm, which is similar is Lambert-Eaton myasthenic syndrome (LEMS). It is a rare autoimmune disorder of the neuromuscular junction. It is caused by a miscommunication between the nerve cell and the muscles leading to muscle weakness. There are two different classes of LEMS. There is LEMS associated with small lung cancer, and then there is LEMS without cancer. It is characterized kind of similar to myasthenia gravis, where you have weakness and fatigue of the muscles, especially in the legs and the arms. It really -- the known cases are pretty small. It is only about 400 in the United States. And it can get mixed with myasthenia gravis, and it often gets misdiagnosed. But the key differences between LEMS and myasthenia gravis is that the eye muscle weakness is mild, and it is not the only symptom that patients experience. They have -- the severe respiratory muscle weakness is very rare in these patients, and the autonomic symptoms that affect LEMS patients are not present in myasthenia gravis. So the treatment really depends on whether or not a patient has cancer on the presence of associated cancer or not. So the treatments are usually aimed at trying to improve the quality of life in a patient and then also symptomatic treatment for patients. This is the American Academy of Neurology Management of Myasthenia Gravis. It has been a while since it has been updated, so I won't go through it too in depth, but it is just there as a reference. And getting into the drugs, the one drug is Firdapse or amifampridine. What I have highlighted yellow is the new updates to this drug. So this drug is indicated particularly for the treatment of LEMS in adults and pediatric patients six years of age and older. The Dosing has changed a little bit from what you have last seen. So for patients that are six years or older that weigh less than 45 kilograms, you would do 5 mg to 15 mg per day by mouth in three or five divided doses, and the max dose is now 50 mg per day. For patients that are six years of age or older that weigh 45 kilograms or greater, or if you are an adult patient the dosage is still 15 mg to 30 mg a day by mouth. And now this has been updated in three or five divided doses with the maximum dosage now to be 100 mg per day. The Availability and the Precautions are still the same for this drug, so the real only update is what I have highlighted yellow. And with that, I will go ahead and go through the PDL for this particular drug class. And I do want to point out that for this particular drug class, you will see that we do have Vyvgart listed here at the bottom. However, that is an error on what is reflecting on our PDL, so we are in the process of actually separating that product into a different drug class because we do consider that a carve out. So everything from line 4 to line 18 we do not carve out, but Vyvgart is, so we have to treat

it a little bit special and separate it from this class. So it will not be reviewed. You are not reviewing that drug, so just ignore that product at the bottom, but everything else is included in the class. And what we have preferred in this class are [cross-talk] --

Zoe Taylor: [Cross-talk] I don't think you are sharing the [cross-talk] --

Marissa Tabile: [Cross-talk] Oh, I am sorry.

Zoe Taylor: No, no, you are good.

Marissa Tabile: Thanks. There we go. Can you see it now?

Kavita Chawla: Yes, we can.

Marissa Tabile: Okay, thank you. The zoom gets confusing if you only share the document, and I forgot. So what I was saying was just to reference you all back, the Vyvgart that I have here at the bottom is an error on our part, so we are fixing that. But everything else that you see here in line 4 through 18 is included in this class. So what we have preferred in this class, even though I didn't mention them, are we have neostigmine and pyridostigmine preferred in this class. Some of them have PA, and some of them do not. So I can take any questions from the Board. I apologize for not sharing the PDL initially.

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

Nonye Connor: No, there are no stakeholders' hands raised at this time.

Kavita Chawla: Okay. So we can review the motion then.

Jon MacKay: This is Jon MacKay. I move that all products in the Neuromuscular Agents ; Antimyasthenic Cholinergic Agent class 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 this class may require prior authorization to determine medical necessity. All nonpreferred products required a trial of at least two preferred products for the same indication before nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Kevin Flynn: This is Kevin Flynn. I second.

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

Multiple Speakers: Aye. Aye.

Kavita Chawla: Any opposed or abstained? Okay. Thank you. With that, the motion carries. And back to you, Marissa, for the Ophthalmic Agents.

Marissa Tabile: All right. This is Marissa. So I will be going through the Ophthalmic Agents : Nerve Growth Factors. So for this class, the condition that I will be referencing is the Neurotrophic Keratitis (NK), so this particular disease or NK is a corneal degenerative disease, which is characterized by a reduction or an absence of corneal sensitivity. Usually what happens is corneal innervation by the trigeminal nerve is impaired in patients. The prevalence is really only about 50 out of 100,000 people. The management of this particular disease state is to promote corneal healing and avoiding complications. So the management of it also depends on the disease stage for patients, so there are three different disease stages. There is Stage I, II, and III. For Stage I, the main management goal is to help improve quality and transparency of the epithelium and to avoid epithelial breakdown. For Stage II, the management is to promote persistent epithelial defect healing and prevent development of a corneal ulcer, and then for Stage III, it is really for ulcer healing and prevention of corneal perforation. For this, the guidelines were pretty old from what I could find. I didn't find any real updates or anything. This is from 2014. I think we have gone through these before, so I won't go too in depth, but that is just there for your reference. And the drug that this really is referencing or the drug in the class is Oxervate or cenegermin-bkbj. It was approved a while ago in 2018. It is used for the treatment of neurotrophic keratitis. There really haven't been any updates to this product. There are no changes in Dosing or Availability, so everything is still relatively the same as the last time that you reviewed it. And for this, pretty straightforward. These are pretty small if not any. No updates to some of these. And for this class I can show you -- I believe it is only going to be the one product. Yes. So for this one, it is just the one product in this class, which is Oxervate. It is preferred on our PDL with PA. I do believe we have a policy for it, which is live on our website. So if you were curious to what is in those criteria, it is listed there. I can take any questions from the Board.

Kavita Chawla: Thank you, Marissa. Questions from the Board? Okay. And if not, any stakeholders, Nonye?

Nonye Connor: No hands raised.

Kavita Chawla: Okay. Thank you. Then let's review the motion, please.

Greg Hudson: This is Greg Hudson, and I can do the motion. I move that all products in the Ophthalmic Agents : Nerve Growth Factors class 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 this class may require prior authorization to determine medical necessity. All nonpreferred products require a trial of at least two preferred products with the same indication before a nonpreferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Christy Weiland: Christy Weiland [audio cuts out].

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

Multiple Speakers: Aye. Aye. Aye. Aye.

Kavita Chawla: All right. Any opposed or abstained? Okay. Thank you. And on to Vasopressors with Marissa.

Nonye Connor: Oh, quick -- sorry, quick question. Marissa. Did you need the Hematological Agents : Other to be -- for the motion to go through?

Marissa Tabile: This is Marissa. No, we don't.

Nonye Connor: Okay, thank you.

Marissa Tabile: It is not included on the PDL. Yeah.

Nonye Connor: Okay, thank you. Sorry.

Marissa Tabile: No problem. All right. So I believe that this particular class, the Vasopressors, there really are no updates to this class. So it looks like we're actually moving in the next section. These are all the drug classes that have no updates. So I think I will just lump it at least in this review altogether. You will still do the

motion on this one but then review everything else. This particular class is really a hodgepodge of different drugs which treat different types of conditions here, so I will just go ahead and show you what the PDL looks like for this particular class. And then, actually, I will just get straight into the no update classes. and then we can do all the motions at the end. So let me go through these one by one. And moving forward, this class -- and the classes before with no updates will probably get shifted to a no update class, just in the interest of time. So in the Vasopressors : Miscellaneous - Oral -- and, of course, feel free to stop me if you have any questions because now, we're just getting into no update classes -- for this class, the products in this are droxidopa, midodrine, and Northera, and in this class what we have preferred is midodrine tablets and is preferred without PA. So that is what that class is looking like. For the rest of the classes I will just click through what I am seeing. So the next one with no updates is the Allergy : Allergenic Extracts - Biologicals - Oral, and in this class, it is a mix of different oral, I guess, allergenic products. So in this one we have Grastek, Odactra, Oralair, Palforzia, and Ragwitek, which all treat different types of allergic conditions, whether that be grass pollen, peanut, weeds, dust mites, they are all in that one class. And as you can see, we do have them all preferred with PA. We don't have policies for them right now, so they would just be reviewed per labeling. Getting into, I will just click through all of our asthma classes. So for this one, our anticholinergics asthma products. These are we have Atrovent, Combivent, Cromolyn, and ipratropium, which it does look like all of them are preferred without PA. For our Inhaled Corticosteroid Combinations, the preferred products in this class we have brand name Advair Diskus. We have Breyna, which is a budesonide formoterol. We have generic budesonide formoterol. motor. We have brand name Dulera, and then we have the generic fluticasone salmeterol, which is the Advair. We have some of the generics preferred, and then we have Symbicort preferred in that class. Then just getting into the regular Single Inhaled Corticosteroid Agents. For this, we have budesonide. We have Flovent Diskus and HFA. We have generic fluticasone. And we have looks like Pulmicort Flexhaler preferred. Moving into the Long-acting LAMA/LABA drug class, so Long-acting Muscarinic, long-acting beta agonist class. For this our preferred products are Anoro Ellipta, and we have Stiolto Respimat. For long-acting muscarinic agents just single agents, we have the -- kind of hard to tell here -- uh, let me highlight it. We have Spiriva Handihaler, and we have generic tiotropium bromide. For the phosphodiesterase-4 inhibitors, the one preferred product in this class is roflumilast. And that has PA. I do want to make note the preferred inhalers that I did run through pretty quickly, which I apologize, those are preferred

without PA on our PDL. For the next, I will go through the Atopic Dermatitis. So for this, it is the Immunosuppressive Topical Combinations drug class. There is only one product in this class right now, which is Oxianujo. It is a tacrolimus niacinamide and hyaluronate niacin cream and ointment. We do have those actually non-covered because they are not technically FDA approved, so they are non covered on our PDL. Getting into our Endocrine and Metabolic Agents. For our GAA Deficiency Agents, and actually this just popped up in my mind. The classes that I am going through right now, I believe, are a mix of carryover from the June meeting that we didn't get to, so I did carry some of these over into this section, and then there is a mix of new products as well that just needs to be reviewed that don't have updates. So our GA Deficiency Agents, these are, I believe for the most part, like, the first -- this class is what we consider a carve out, so you will see the preferred statuses as X, but we do include them on our PDL similar to how we included the other carve out products. You will see it is the Lumizyme, Nexviazyme and Pombiliti. We do allow those through medical, so there is coverage for them, just not through POS at this moment. For Growth Hormone Releasing Hormone, we have Egrifta SV that is preferred with PA. That is the only product in that class. For the Mucopolysaccharidosis Agents, those are carve outs as well, so you will notice that the preferred status has that designation X treated really the same as the other carve outs that I have gone through before. So we have Aldurazyme, Elaprase, Mepsevii, Naglazyme, and Vimizim still through medical, just not through point of sale. For this one, we have the Somatostatic Agents, and in this class our preferred products are the lanreotide acetate, Mycapssa capsules, octreotide injectables of different kind of Dosages and Formulations. We have Sandostatin, which is octreotide, and then we have Signifor, which is pasireotide. Those are preferred and they have PA. For the Urea Cycle Disorder Agents, these are -- the preferred products in this class are Buphenyl, which is sodium phenylbutyrate. We have the powder and the tablet, and then we do have the generic powder and tablet preferred as well. Both of those have PA. For the Vasopressin Receptor Antagonists, there are three products in this class, and the two preferred products are Jynarque, which is a tolvaptan. There is a tablet, and then there is generic tolvaptan which is preferred. Getting into our Hematopoietic classes, which here is the Erythroid Maturation Agents. So we have one product, which is a carve out, Reblozyl (luspatercept). It is a carve out, so that is why it has that status X there, but it is included. For the Erythropoiesis-Stimulating Agents (ESAS), we have a couple of products preferred here. So we have Aranesp and Retacrit. We do have PA on those products, and we do have a policy, which you will find on the website if you are curious on what

those criteria are. And then for the Hypoxia-Inducible Factor Prolyl Hydroxylase Inhibitor, there is one product in that class, which is Jesduvroq, and that product is preferred with PA. We don't have any clinical policies yet for that, so it would be reviewed per labeling. Next, is our Neuromuscular Agents : Systemic Lupus Erythematosus Agents. So in this class we have what is preferred as Benlysta, and we do have a policy for that, which is posted online, but there are other products. Lupkynis and Saphnelo, but Benlysta is the preferred. Getting into our Oncology Agents, I am going to try to not put one that we have reviewed. So starting with our Androgen Biosynthesis Inhibitors and, actually, just in general with our Oncology products, we typically do have them preferred with PA either to a policy that we have created, or some of them if we don't have a policy created, it is the same PA for medical necessity per labeling. So for the most part, you will see a lot of these oncology products are preferred. The only way that you might see something nonpreferred is if there is if it is a brand with a generic product, which there are some examples in here, that is when you will see a nonpreferred. But for the most part, we have a lot of things preferred and, really, for the most part, a lot of them have PA on them. So I think it is easier for me to maybe call out things that are not preferred because there is probably less of those than there are preferred. So for this one, we have this particular, it looks like generic abiraterone, and Yonsa and Zytiga. Uh, we do have Casodex and Eulexin and Nilandron. Those are brand products, like I have mentioned. I think pretty much everything that is nonpreferred is a brand name product, with the exception it looks like with the toremifene, but everything else is just branded products that have generics on the market. And then getting into the Respiratory Agents : Pulmonary Fibrosing Agents. For this one, our preferred products in this class are Ofev and pirfenidone generic. We do have a policy for that, so there is PA. And that policy is posted on our website. And the next class -- and I think this is the last class -- is the Smoking Deterrence : Miscellaneous - Other. So in this class, our preferred products do not have PA. So it is the bupropion hydrochloride SR, which is the ER tablet. And then we have varenicline tartrate tablets preferred without PA. And it looks like brand name Chantix is nonpreferred because there is generic available. So with that, I went through a lot. I will go ahead and stop here. If any of the DUR Board has any questions about any of the classes that I went through on our PDL, we can go through any of them.

Kavita Chawla: Amazing, Marissa.

Marissa Tabile: I know, I went through [cross-talk] a lot today, so I have been throwing a lot of information, so please feel free to ask me any questions.

Kavita Chawla: Thank you. Yes, Committee, any questions for Marissa? And Marissa, I will also direct your attention to a question from, I think, a stakeholder.

Marissa Tabile: This is Marissa. So it looks like we got a question if this particular stakeholder is allowed to give testimony in the Urea Cycle Disorder. So to answer your question, yes. If the Committee doesn't have any questions, they will solicit if any stakeholders have questions, so just be sure to raise your hand, and then Nonye will be sure to unmute you, and then you will have your three minutes to provide your testimony.

Nonye Connor: So for this, I don't know how we want to proceed. I know there are four pre-registered stakeholders. Kavita, how do you want to proceed with that?

Marissa Tabile: This is Marissa. So Nonye, I would recommend -- and Kavita -- I would recommend just doing all of the stakeholders all at once because with the exceptions of the Vasopressors : Miscellaneous - Oral, all of the no update classes are going to be on one motion just to encompass everything instead of you having to do like 10 different motions.

Kavita Chawla: [Cross-talk] Yeah.

Marissa Tabile: So yeah, you can just do all the stakeholders all at once, and then we'll do really like the two different motions at the very end once everyone has provided their testimony.

Kavita Chawla: Okay. All right, Committee, if no questions for Marissa, then we can go into our stakeholders. And Nonye, I will turn it over to you to go through our list.

Nonye Connor: Okay. Hello, again. And I am so sorry if I mispronounce anyone's name. Um, the first person I have on the stakeholder for the pre-registered stakeholders is Rafik Marouf. And if I can go ahead. I see you here. I -- oops, oops. Uh, sorry. You moved from where I saw you but let me find you again. Okay, there we go. Okay. Rafik, you can meet yourself whenever you are ready.

Rafik Marouf: Hi, I am Rafik Marouf, the Medical Director of Medical Affairs at Medunik. I am speaking today on Pheburane and urea cycle disorder. Urea cycle disorders are inherited deficiencies in various enzymes involved in

ureagenesis, the process to clear the blood from a toxic component, ammonia resulting from protein metabolism and hyperammonemia, which corresponds to an increased plasma level of ammonia. It is the main consequence of the broken urea cycle seen in all UCD patients who are not under metabolic control, and it is a life threatening condition if not treated. Ammonia is toxic to neurons and other brain cells. Severe, prolonged, and/or repeated episodes of hyperammonemic coma can lead to brain damage, impairment of intellectual function, and ultimately, death. Sodium phenylbutyrate, a nitrogen scavenger drug, established decades ago as the gold standard adjunctive therapy to the standard of care which includes dietary management, has changed the prognosis of this condition by saving the patient's life and improving drastically their outcomes. Sodium phenylbutyrate noncoated formulation has been used since 1987. It was approved as Buphenyl in the United States in 1996; however, the bad taste or taste aversion are amongst the most frequent adverse events reported with commercial noncoated formulations. They are extremely bitter and may cause taste disturbance and vomiting at intake. The intolerable taste makes their chronic use very difficult to the extent that compliance to the treatment can be jeopardized and thus trigger serious and life-threatening hyperammonemia crisis, especially in children. Since commercial noncoated formulation of sodium phenylbutyrate does have an offensive taste, an improved tasteless pellet formulation of sodium phenylbutyrate Pheburane was developed whereby coating of individual pellets results in a formulation which has no immediate taste when swallowing the drug. This product was approved for marketing in Europe in 2013, in Canada in 2015, and in several other countries. Data from the French Compassionate Program cohort in comparison with the noncoated formulation used before entering [indistinct] showed high acceptability, no vomiting, and ease of administration without any reconstitution and improved control of ammonia plasma levels, with no hyperammonemia crisis up to 30 months of treatment with Pheburane. Medunik dedicated to improving the management of orphan diseases offers an accessible option. Pheburane, the first palatable FDA-approved sodium phenylbutyrate for UCD patients in order to help them to improve their compliance, thus, their outcomes. Therefore, we respectfully request you to include Pheburane as preferred in your products list. Thank you. I am here for any question.

Nonye Connor: Any questions? Okay. The next person I have is Nicole. Let me look for you. There you go. Okay, Nicole, whenever you have a chance, you are free to unmute yourself.

Nicole Tran: My name is Nicole. I am with Recordati Rare Diseases. So we would like to submit this request in support of patients with urea cycle disorders. And as Rafik Marouf already [audio cuts out] mentioned some of these details [audio cuts out] I will give you back some of your time. So we're asking that the availability of ammonia-lowering medication is essential to patients who suffer from UCD. We are seeking Carbaglu tablets for oral suspension remain preferred over generic for glutamic acid for three indications: the adjunctive treatment of acute hyperammonemia due to propionic acidemia, known as PA, or methylmalonic acidemia, known as MMA. And the second indication is for the adjunctive treatment of hyperammonemia due to NAGS deficiency. The third one is the maintenance of NAGS deficiency. And we make this request for Carbaglu to remain preferred, since this is currently approved for use in three noted indications, while the carglumic acid is only approved for individuals with NAGS deficiency. Individuals with NAGS deficiency, PA, and MMA do not break down nitrogen correctly, as already mentioned, and according to Baby's First Test website, Washington State has newborn screening for PA and MA but not NAGS deficiency. Therefore, checking the ammonia level of newborn is one of the key ways to define these rare genetic conditions. Those with born errors of metabolism must balance dietary needs for growth and development and while simultaneously managing ammonia levels that result from normal catabolism, which are elevated due to stress. Since 2010, the standard of care including Carbaglu tablets for those with NAGS deficiency, and in 2021 the FDA approved the use of acute hyperammonemia with PA and MMA. In an NIH study by Dr. Tuckman, which is also the same study referenced in RPI, Carbaglu safely enhances ammonia lowering along with the standard of care. The most common adverse reactions with Carbaglu are vomiting, abdominal pain, pyrexia, tonsillitis, anemia, diarrhea, ear infection, nasopharyngitis, hemoglobin decrease, and headache. Please refer to our complete Prescribing Information for Carbaglu, as the only carglumic acid approved for NAGS deficiency and also for acute crisis stemming from hyperammonemia due to PA and MMA. We request that Carbaglu remain preferred given the key differences in the indication. Thank you, and happy to take questions.

Nonye Connor: Any questions for Nicole? Okay, thank you. Next, I have on the list is Alexandria. Let me find you. There you are. Whenever you are ready, Alexandra, you can unmute yourself. Alexandria? Okay. We can come back to you, Alexandra. The next person I have on the list is Andrea. And there you are. Andrea, you can unmute yourself. Okay, there you go.

Andrea Atherton: Willis Lonzer is going to be presenting if you [cross-talk] could unmute him.

Nonye Connor: Will?

Andrea Atherton: Willis.

Nonye Connor: Willis? Okay.

Willis Lonzer: Yes. Can you hear me?

Nonye Connor: Yes, I can hear you.

Willis Lonzer: Excellent. Hello, my name is Willis Lonzer from US Medical Affairs for Amgen. Thank you for the opportunity to present and share important information about a life-threatening rare disease, urea cycle disorders, and the essential treatment Amgen provides, Ravicti. Urea cycle disorders are devastating inherited diseases that interrupt the removal of excess nitrogen from the body and exhibit a broad spectrum of serious clinical manifestations ranging from impaired cognition to permanent brain damage, coma, and death. In healthy individuals, protein is metabolized to amino acids and subsequently ammonia, a neurotoxin, which is then converted to urea and excreted. In the urine, however, those living with UCD's are not able to convert ammonia to urea, and they require individualized treatment plans, including protein restriction and medication called nitrogen scavengers, which remove ammonia. The robust clinical trial for Ravicti was championed by the patient community. Ravicti is nearly odorless and nearly tasteless, with no time limitation placed on ingestion of the medication, whereas the taste-masked versions of sodium phenylbutyrate have a time frame during which taste is actually masked. In addition, Ravicti can be administered via G-tube, while the tasted-masked versions cannot. Ravicti is the only medicine approved for all subtypes of UCDs, except for NAGS. Taste-masked versions are only approved for three UCD subtypes. In addition, taste-masked sodium phenylbutyrate products were approved via bioequivalent studies. Washington Medicaid has five UCD patients who take Ravicti. The clinical manifestations that have been shown to be significantly reduced by Ravicti are most devastating for newborns and pediatric patients. Notably, two of the patients who take Ravicti in Washington are pediatric patients, a three-year old, and an infant. The adult patients on Ravicti have been on therapy for an average of seven years. Due to the grave risks involved with switching stable

UCD patients to a new therapy, we ask that the Board strongly consider allowing existing stable Ravicti patients to maintain access to their current therapy. I appreciate your time and consideration of the significant negative impact that interrupting therapy will have on patients, and I am available for any questions if there are any.

Nonye Connor: Thank you. Any questions? Okay. And I wanted to try Alexandra Harrold one more time. If you can unmute yourself. Okay. Um, I see another community -- another stakeholder has their hand raised, and this is Brent. Brent, you can unmute yourself.

Brent: Can you hear me okay?

Nonye Connor: Yes, we can hear you.

Brent: Thank you. Again, my name is Brent with UCB. I heard you call for Alexandria. Do you have her down to speak on behalf of Rystiggo? I don't think she's on and wanted to make a mention. Sorry.

Nonye Connor: I do have her down here to speak. That's why I was calling upon her.

Brent: Yes. Okay. Thank you. Appreciate it. I am a teammate of hers. Sorry.

Nonye Connor: Okay. And Kavita, at this time I do not have any other stakeholder with your hand raised.

Kavita Chawla: Thank you, Nonye. So I suppose in that case, unless there are questions from the Committee for any of the stakeholders, Marissa, should we pull up the motion?

Marissa Tabile: This is Marissa. Yep. I will go ahead and pull up the motions. And just to remind the DUR Board, we will do the Vasopressors : Miscellaneous - Oral separate, and then all of the no update classes will just be one motion. So let me pull up this first one, and then whenever you all are ready.

Kevin Flynn: This is Kevin Flynn. I move that all products to the Vasopressors : Miscellaneous - Oral 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 nonpreferred

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

Jon MacKay: This is John McKay, I second.

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

Multiple Speakers: Aye. Aye. Aye.

Kavita Chawla: Any opposed or abstained? Okay. With that, the motion carries.

Marissa Tabile: And this is Marissa. I believe I am going to have to shift some of the numbering for these no update classes. So just so you all can verify it is listed on Slides 18, 19, 20, and 21. So let me update that here, and I am going to abbreviate for [indistinct].

Kavita Chawla: That looks good.

Marissa Tabile: Succinct [indistinct], and it is all ready for you.

Kavita Chawla: This is Kavita Chawla. I move that all products in the drug classes listed on Slides 18 to 21 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 necessities. All nonpreferred products require a trial of at least two preferred products within the same indication before a nonpreferred 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.

Kavita Chawla: Any opposed or abstained? Thank you. With that, the motion carries. All right, Marissa and team, where to next?

Marissa Tabile: This is Marissa. It looks like we are actually at the end of our agenda. I am actually very surprised that we are done [cross-talk] we got through everything.

Kavita Chawla: All right.

Marissa Tabile: So I have everything that I need. Thank you, DUR Board, for going through all of the information that we have thrown at you today with the utilization, the Cytokine and CAMs and getting through all the drug classes. Thank you, Nina, for going through the drug class review. But I don't have anything else, so I will go ahead and turn it over to you to end the meeting. Unless Nonye, sorry, Nonye, if there is anything that we missed for logistics, I apologize.

Nonye Connor: No. I think we have everything. Thank you.

Kavita Chawla: An amazing job, Nina, Marissa, and Nonye. It was a marathon for all of you. And thank you, DUR Board. If nothing else, we adjourn the Board today.

Marissa Tabile: Thank you so much.

Kavita Chawla: Thank you.

Nonye Connor: Thank you.

Greg Hudson: Thanks everybody.

Jon MacKay: [Cross-talk] great day.

Nonye Connor: Bye.

Christy Weiland: Bye.

[end of audio]