Washington State Pharmacy and Therapeutics Committee
Drug Utilization Review Board
Meeting Transcription
December 16, 2020

Ginni Buccola: Good morning, everybody. I'm Virginia Buccola and I'm the P&T committee drug utilization review chair and we're going to go ahead and convene the drug utilization review portion of the meeting. I'm going to read off the names of the participating attendees and after I call your name, if you could just say here, starting with the P&T committee members, Alex Park.

Alex Park: Present. Good morning.

Ginni Buccola: Diane Schwilke?

Diane Schwilke: Here.

Ginni Buccola: And Jordan Storhaug?

Jordan Storhaug: Here.

Ginni Buccola: Nancy Lee?

Nancy Lee: Here.

Ginni Buccola: Leah Marcotte?

Leah Marcotte: Here.

Ginni Buccola: Connie Huynh?

Constance Huynh: Here.

Ginni Buccola: Susan Flatebo?

Susan Flatebo: Here.

Ginni Buccola: Catherine Brown?

Catherine Brown: Here.

Ginni Buccola: And moving to the Health Care Authority members. Leta Evaskus?

Leta Evaskus: Here.

Ginni Buccola: Donna Sullivan?

Donna Sullivan: I'm here.

Ginni Buccola: Ryan Pistoresi?

Ryan Pistoresi: Here.

Ginni Buccola: Luke Dearden?

Luke Dearden: Here.

Ginni Buccola: Amy Irwin? Going to Joey Zarate. Next is Ryan Taketomo? Marissa Tabile?

Marissa Tabile: Here.

Ginni Buccola: Dr. Chris Chen? And Dr. Charissa Fochinos. We also have our Magellan Medicaid administration member Umang Patel.

Umang Patel: Here.

Ginni Buccola: And our DERP presenter will be Brittany Lazur.

Brittany Lazur: Good morning.

Ginni Buccola: And our Managed Care Organization representatives, Greg Simas with Molina Healthcare. Heidi Goodrich with Molina Healthcare. Petra Eichelsdoerfer with United Healthcare. And Catherine Vu of Community Health Plan of Washington. So I'll hand it back to Leta to go over meeting logistics.

Leta Evaskus: Thank you, Ginni. Okay, so the committee and presenters and the managed care organization representatives have all been added as organizers so you can mute and unmute yourselves. Please mute yourself when you're not speaking to limit the background noise. When the presenters are speaking, please share your webcam and then when the P&T committee and chair are [indistinct] if everybody can mute their mic. Thank you. Please share your webcam when you're presenting or when the committee is speaking and discussing the motions. If you're not presenting, you can turn off the webcam. For stakeholder participation, the chair will first read the list of stakeholders who preregistered to speak. I'll unmute you after your name is called. You'll have three minutes. Afterwards, the chair will ask if there are any other stakeholders. Please use the raise hand

function. I'll call on you and unmute you. You can also use the question box and your questions will be addressed during the stakeholder time. And just a reminder that the meeting is being recorded so please state your name every time you speak. Alright and I will turn it over. Let me show my screen here first and then we can start with Brittany.

Ginni Buccola: And this is Ginni. Just confirming that we're starting with Brittany with DERP to give us an updated report on HIV.

Brittany Lazur: Great, thank you so much. As mentioned, my name is Brittany Lazur. I'm a research associate at the Center for Evidence Based Policy in Portland, Oregon and I'm very pleased to present to you today the findings of the update reports on initial anti-retroviral therapies for treatment-naïve individuals with HIV-1. And of course, as mentioned, this is a drug effectiveness review project report. Next slide please. Great. So this presentation will follow a similar format to which I believe you're familiar with. And so I'll start a little bit with the topic history and background, go into the methods which include the PICO inclusion criteria, key questions, and of course methods, and then spend most of our time here on findings and then wrap up with conclusions. Next slide please. So, I want to take a moment to highlight some of the commonly used abbreviations that you'll see throughout this presentation and, of course, in the report itself. You may be familiar with some of these, however, I'd like to note three abbreviations that are topic specific. So INSTI, NRTI, and NNRTI that you see here on the screen. And these refer to the mechanism of action of the component therapies in our regimens that we'll be covering today. Next slide please. So as mentioned earlier in this presentation, this is an update to a prior DERP report that was completed in 2017. Based on our participant feedback, we've modified the scope to be more targeted and I'll go into greater detail about the changes we made to scope in subsequent slides. Next slide please. So as you well know, HIV is a serious and persistent health concern as there are approximately 1.2 million HIV-infected adults and adolescents in the US. And there are two types of HIV: HIV-1, which is more common and which is the focus on this report, and HIV-2, which is much rarer and less infectious. Briefly, the HIV virus attacks the body's immune system, specifically reducing the number of CD4 cells in the body. And over time, this makes a person more likely to acquire other infections or develop

infection-related cancers. And if left unchecked, HIV can ultimately transition to Acquired Immunodeficiency Syndrome, or AIDS. So due to advances in treatment and care, HIV has transformed from an acute life-threatening infection to a more manageable chronic health condition. In this combination, ART therapies have dramatically reduced HIV associated morbidity and mortality with general life expectancy approaching that of the general population. Given that there are a plethora of options to choose from, this report was commissioned to evaluate the comparative efficacy and harms of guideline recommended regimens for the initial treatment of HIV-infected individuals. Next slide. As a general rule, guideline organizations recommend ART therapies utilizing this schema that you see on the slide. So guidelines recommend administering what's called a backbone of therapy - so in this case an NRTI - in combination with one or two add-on therapies, so INSTIs or NNRTIs, commonly with a protease inhibitor or booster. And we'll go into more detail about the specific components in the next few slides. Next slide please. So in terms of the inclusion criteria for this report, we focused on evidence in treatment-naïve adults and adolescents with HIV-1 infection. And as I illuded to earlier, we focused on interventions that were recommended as initial regimens, so first-line therapies, for most people with HIV according to recent guidelines from the International Antiviral Society, USA Panel, the Department of Health and Human Services Panel on Antiretroviral Guidelines for Adults and Adolescents, the European AIDS Clinical Society, and interim guidelines from the World Health Organization. And I want to mention that slide seven through eleven will list the interventions specifically. We focused on evidence of head-to-head comparisons, so one recommended regimen versus another. And we also included studies that evaluated recommended regimens in fixed dose combination products compared to a regimen that administered as separate tablets. Next slide. So as mentioned earlier, recommended ART regimen consist of a backbone and add-on therapies. Based on the guidelines that were used to shape the scope of this report, we're focusing on the component medications that are listed on this slide. So in terms of backbone and RTIs, we're focusing on Abacavir, Lamivudine, Tenofovir alafenamide, Tenofovir disoproxil fumarate, and Emtricitabine. For add-ons, we're focusing on INSTIs such as Bictegravir, Dolutegravir, and Raltegravir; NNRTIs including Doravirine, Efavirenz, and Rilpivirine; and then protease

inhibitors including Darunavir. Next slide please. And as previously mentioned, we focused solely on regimens that were recommended as initial or first line regimens for most people with HIV that were recommended by the four guideline organizations mentioned previously. And this slide shows the recommended three-drug regimens consisting of an INSTI and two NRTIs. Next slide. And this is a continuation of the table on the previous slide showing the included three-drug regimens consisting of an NNRTI and two NRTIs. Next slide. And continuing the table from the previous slide, this slide shows the included three-drug regimens consisted of a protease inhibitor co-formulated with [indistinct] booster and two NRTIs. Next slide. So finally, this slide shows the recommended two-drug regimen consisting of an INSTI, so dolutegravir and an NRTI, Lamivudine. I'd like to refer you to table two in the report that provides greater detail about which regimens are recommended by each specific guideline organization. Next slide. So, in terms of outcomes, we focused on the viral suppression, so as defined as HIV RNA less than 50 copies per milliliter, also virologic failure and AIDS defining illness. We also looked at adherence, persistence and drug resistance. And we also looked at serious adverse events, withdrawals due to adverse events, and then specific adverse events such as kidney injury, hepatotoxicity, cardiovascular events, and bone marrow suppression. And we also looked at drug-drug interactions. In terms of study designs, we only include randomized control trials for this report. Next slide. So this report consisted of five key questions. The first is dealing with the effectiveness of backbone medications and followed by the second key question of harms of backbone medications. Key questions three and four, look at the effectiveness and harms of add-on medications. And key question five looks at the benefits and harms and subgroups, so those co-infected with hepatitis B, C, or tuberculosis. Next slide. So briefly, we used standard DERP methods for conducting this report. We conducted searches of Ovid MEDLINE and the Cochrane Library from March 2017 to June 2020. And we carried forward studies from the last DERP report that met inclusion criteria for this update. We conducted risk of bias assessments for each study in which one independent researcher conducted the initial assessment and one senior researcher validated the assessment. Similarly, we conducted grade quality of evidence assessments to evaluate the quality of the body of evidence for selected outcomes. And these outcomes include

viral suppression, drug resistance, adherence, serious adverse events and kidney injury. Next slide. So briefly, DERP risk of bias ratings consist of three categories that you might by now be familiar with. So they range from low to high, low being that there is clear reporting of methods and mitigation of potential biases and conflicts of interest, and all the way to high, which includes clear flaws that might introduce serious bias. Next slide. And of course, grade quality of evidence ratings consists of four categories. So ranging from high in which we are very confident that the estimate of effect of the intervention on the outcome lays close to the true effect, and then all the way down to a rating of very low in which we have no confidence in the estimate of effect of the intervention on the outcome. Next slide. So let's delve into the findings of this report. Next slide. But before we do, I want to make a note about noninferiority studies, as many of the included studies in this review took this approach. By design, a noninferiority study tests whether an experimental treatment is no less efficacious than an active control treatment. And this is in the context of a predetermined equivalence margin. However, these studies do not evaluate whether one treatment is superior to another in terms of efficacy. They want to flag this because this is important to keep in mind as you see that noninferiority will be mentioned throughout this presentation. Next slide. In this update, we ultimately included 21 studies in 36 publications, including 11 studies in 22 publications that we carried forward from the last DERP report. Studies were rated as having moderate or high risk of bias, largely due to issues of generalizability of the study populations, concerns with funding, and conflicts of interest, and other issues such as unbalanced population characteristics at baseline, large or differential loss to follow up, and unclear accounting of randomization, allocation concealment, or blinding. So in terms of studies for key questions one and two of backbone therapies, you found two randomized controlled trials of two drug versus three drug combinations and six randomized controlled trials comparing three drug to other three drug combinations. For key questions three and four of add-on therapies, we found 13 randomized controlled trials comparing three drug to three drug combinations. And then also, we found one publication that was specific to key questions five in subgroups. Next slide. So let's first look at the findings for key question one and two. This is the comparative effectiveness and harms of backbone therapies.

Next slide. So I want to first start with some high level findings, because it can get pretty granular in this presentation. So the key findings for key questions one and two were that backbone therapies were largely not inferior to each other. We found that three drug regimens including abacavir and lamivudine were noninferior and statistically significantly more effective in achieving viral suppression compared to three drug regimens, including tenofovir disoproxil fumarate and emtricitabine. We also found that there was high adherence across treatment groups with largely no differences between treatment groups. And of course, there were fewer occurrences of drug resistance, serious adverse events, specific adverse events, and withdrawals due to adverse events with largely no differences between groups. Next slide. So when comparing regimens including the backbone therapies of lamivudine compared to tenofovir disoproxil fumarate and emtricitabine, we found that the two drug regimen including dolutegravir with lamivudine was noninferior to the three drug regimen including dolutegravir and the combination of disoproxil fumarate and emtricitabine. And this was in terms of viral suppression. However, there was no significant difference between groups. There were no occurrences of resistance mutations in either group through week 48 and no differences between groups in terms of serious adverse events. Finally, participants in the two drug group experienced significantly smaller increases in serum creatinine, which is a marker for kidney injury, compared to those participants in the three drug group. And the grade quality of evidence was rated as low for all outcomes. Next slide. When comparing the backbone combination of tenofovir alafenamide with emtricitabine compared to tenofovir disoproxil fumarate and emtricitabine, we found that tenofovir alafenamide was considered noninferior to tenofovir disoproxil fumarate in terms of viral suppression. However, there was no significant difference between groups. Few participants in each treatment group developed drug resistance with no differences between groups. Both treatment groups were highly adherent to their study regimens with greater than 88% of participants reported as greater than or equal to 95% adherent to their study medications. However, there were no differences between treatment groups for this outcome as well. Few participants experienced serious adverse events, and there was no difference between treatment groups. And finally, there were significantly greater increases in serum creatinine

in the tenofovir disoproxil fumarate group compared to the tenofovir alafenamide group. However, as you can see, the difference between the groups was quite small and the grade quality of evidence was rated low for all outcomes. Next slide. So for the comparison of tenofovir alafenamide and emtricitabine to abacavir and lamivudine, we found that tenofovir alafenamide and emtricitabine was noninferior to abacavir and lamivudine in terms of viral suppression, although there was no statistically significant difference between groups. Also, there was no participants in either group that developed resistance to study drugs. Furthermore, the occurrence of serious adverse events was generally low with no significant differences between groups. And there was no difference in serum creatinine between groups. And finally, the grade quality of evidence was rated as moderate for all outcomes. Next slide. For the comparison of abacavir and lamivudine to tenofovir disoproxil fumarate and emtricitabine, we found that abacavir and lamivudine was noninferior and led to a significantly greater percentage of participants achieving viral suppression than the combination of tenofovir disoproxil fumarate and emtricitabine. And this was at week 48. This trend was consistent also at weeks 96 and 144. In terms of drug resistance, we found no resistance in participants in the abacavir and lamivudine group and there was few occurrences of resistance in the group receiving tenofovir disoproxil fumarate and emtricitabine. This was consistent at weeks 48 and 144. There were no differences between groups and serious adverse events at weeks 48, 96 and 144. And serum creatinine was stable through week 144 for the abacavir and lamivudine group, but this was not reported for the tenofovir emtricitabine group. Finally, grade quality of evidence was rated as moderate for all outcomes. Next slide. For the comparison of tenofovir disoproxil fumarate to lamivudine, to tenofovir disoproxil fumarate and emtricitabine, we found that tenofovir disoproxil fumarate and lamivudine was noninferior to tenofovir disoproxil fumarate emtricitabine. Although there was no significant difference between treatment groups. Fewer participants in the tenofovir disoproxil fumarate lamivudine group developed resistance mutations than those in the tenofovir disoproxil fumarate emtricitabine group, although resistance was low in general. Finally, there are no differences between groups in serious adverse events and serum creatinine levels as a marker of kidney injury. Finally, grade quality of evidence was rated as low for all outcomes. Next

slide. So let's move on to the findings for key questions three and four. And this was the comparative effectiveness of harms and add-on medications. Next slide. So again, starting with some high level key findings. So the key findings that we found for key questions three and four were again that add-on therapies were largely noninferior to each other. Raltegravir was found to be noninferior to efavirenz and statistically significantly more effective in achieving viral suppression at long term follow-up. This was considered weeks 192 and 240. We found that there was high adherence across treatment groups with largely no differences seen between treatment groups. And there were few occurrences of drug resistance, serious adverse events, specific adverse events, and withdrawals due to adverse events, with largely no differences between groups. Next slide please. So on comparing regimens including bictegravir and dolutegravir, we found that bictegravir was not inferior to dolutegravir in terms of viral suppression. However, there were no significant differences between groups. Similarly, there was no difference in treatment resistance between groups and adherence to study medications was high in both groups. And again, there was no significant difference between groups. The greater percentage of participants in the bictegravir group experienced serious adverse events compared to those in the dolutegravir group, but this was only seen that week 96. And finally, there was no difference in serum creatinine level between groups. The grade quality of evidence for these outcomes was rated as low and very low across outcomes. Next slide. So what comparing dolutegravir to raltegravir, we found that dolutegravir was noninferior to raltegravir in terms of viral suppression. And again, there was no significant difference between groups. Few participants develop resistance to the study drugs at week 48 and all were participants in the raltegravir group. The study for the specific comparison reported no serious adverse events in either group at weeks 48 and 96. And finally, there was a greater increase in serum creatinine in the dolutegravir group compared to the raltegravir group at both weeks 48 and 96. And the grade quality of evidence for these outcomes was rated low across these outcomes. Next slide. When comparing darunavir and ritonavir to doravirine, we found that doravirine was noninferior to darunavir and ritonavir in terms of viral suppression, although there was no significant difference between groups. Resistance was generally rare but more doravirine

participants developed resistance then darunavir and ritonavir participants at both weeks 48 and 96. And there were no differences between groups in serious adverse events and serum creatinine levels. And the grade quality of evidence was rated as low for all outcomes. Next slide. When comparing darunavir and ritonavir to raltegravir, significantly fewer participants achieved viral suppression in the darunavir ritonavir group compared to participants in the raltegravir group. However, fewer participants developed a drug resistance in the darunavir ritonavir group compared to those in the raltegravir group. There was no difference in serum creatine between groups. The grade quality of evidence was rated as low across these outcomes. Next slide. When comparing dolutegravir to efavirenz, we found that dolutegravir was also noninferior to efavirenz in terms of viral suppression. Again, there were no significant differences between groups. Few participants developed resistance to study drugs and there were no significant differences between these treatment groups. As seen in other drug comparisons, adherence to study medications was high and there were no differences between groups. There were also no differences between groups in terms of serious adverse events. In terms of kidney injury, studies were mixed in the effect of dolutegravir and efavirenz with studies finding both increases and decreases in serum creatinine over time. And the grade quality of evidence ranged from very low to low across outcomes. Next slide. When comparing raltegravir to efavirenz, we found that raltegravir was noninferior to efavirenz in terms of viral suppression, and this was over 156 weeks. However, there are no significant differences between treatment groups. Alternatively, there were significantly more participants in the raltegravir group that achieved viral suppression at weeks 192 and 240 compared to those in the efavirenz group. There were no significant differences between groups in terms of drug resistance. And as seen in other comparisons, adherence to study medications was high in both groups with no differences seen between groups. Finally, there were no differences between groups in serious adverse events through weeks 240 and no differences between groups in terms of kidney injury. And the grade quality of evidence ranged from very low to low across outcomes. Next slide, please. In the comparison of rilpivirine to efavirenz, we found that rilpivirine was noninferior to efavirenz in terms of viral suppression at week 48. However, again,

there were no significant differences between groups. We found that a greater percentage of participants in the rilpivirine group developed drug resistance at week 48 compared to those in the efavirenz group. Again, adherence to study drugs was high in both groups with no significant differences between groups. And there was no differences in serious adverse events between groups. Finally, participants in the rilpivirine group experienced a small mean increase in serum creatinine over time. However, there was no change over time seen in the efavirenz group. And the grade quality of evidence was rated as low for all outcomes. Next slide. Let's move on to slide 36. So moving on to the findings for key questions five. So this is benefits and harms and subgroups. Next slide. So we identified two publications that were eligible for this key question. The first publication evaluated the benefit and harms of raltegravir compared to efavirenz in patients with HIV and tuberculosis co-infection. And this publication found greater viral suppression in participants treated with raltegravir compared to efavirenz at week 24 but not at week 48. And there were no differences between treatment groups in terms of adherence, drug resistance, serious adverse events, and kidney injury. The second publication evaluated the benefit and harms of rilpivirine to efavirenz in patients with HIV and hepatitis B or C co-infection. This publication found that participants without co-infection experienced greater rates of viral suppression than those with co-infection. And you can see that this finding was significant for the ropivacaine group but not for the efavirenz treated participants. And this publication also found that there was a greater occurrence of hepatic adverse events in the coinfected group compared to those in the non-coinfected group. Next slide. So let's wrap up with a summary of what we've discussed today. Next slide. But before we do so, it's important to note the limitations of this body of evidence. So all included studies were rated as having moderate or high risk of bias due to a number of reasons. And these include lack of generalizability. This was largely due to studies including mostly white males despite higher prevalence of HIV in black males, and HIV risk factors for participants were largely not reported. The second reason pertained to concerns with sources of study findings and conflicts of interest of the authors. And finally, there were concerns with unbalanced participant characteristics at baseline, high or differential loss of follow-up, unclear randomization or allocation concealment

methods, or blinding. And again, as we mentioned earlier in this presentation, the evidence was also limited in that the included studies were largely designed to test for noninferiority. Next slide. Finally, in summary, there were six main findings that we'd like to leave you with. So treatments were generally noninferior to the drug to which they're being compared. The three drug regimens that included abacavir and lamivudine were noninferior and statistically significantly more effective in achieving viral suppression compared to three drug regimens that included tenofovir disoproxil fumarate and emtricitabine. Raltegravir was considered noninferior to efavirenz and was statistically significantly more effective in achieving viral suppression at long term follow-up at weeks 192 and 240. We found that there was high adherence and persistence to study medications across treatment groups. And there were few occurrences of drug resistance, serious adverse events, specific adverse events, and withdrawals due to adverse events, again, with largely no differences between groups. And finally, the grade quality of evidence was very low to moderate across outcomes, with the majority being very low or low. Next slide. So thank you, I'd be happy to answer any questions at this time.

Ginni Buccola: Thanks, Brittany, that was a really thorough review. I have one question and then of course, I want to open it to all the committee members. Again, if I didn't say, this is Ginni Buccola. And this may be asking a pretty obvious question but I just want to go back noninferiority studies. Can we just kind of maybe state that out loud again, comparing that to a study that's looking for statistically significant findings?

Brittany Lazur: Absolutely. So a noninferiority study is specifically designed to test whether one experimental treatment is no less efficacious than another treatment. And in order to do these, they have to come up with a predetermined equivalence margin. So basically, you're saying that one treatment is no less effective than another. However, these studies do not evaluate whether one treatment is superior to another in terms of efficacy.

Ginni Buccola: And the margin -- I'm sorry, what term did you use? The difference margin? Is that determined by the developers of the study? Or is there any sort of predetermined sort of standard of practice in research?

Brittany Lazur: That's a great question. So typically, the authors will look in the literature if there's some sort of agreed upon standard equivalents margin. If not, they will determine something that is applicable.

Ginni Buccola: Thank you very much. Do any of my committee members, any other questions for Brittany?

Nancy Lee: Hi, Brittany, this is Nancy. I had a question more about the harms, in terms of when you went over the limitations. What would you say would be some of the limitations in terms of the harms that were reported in these studies? For instance, I guess what I'm trying to get at is, for like, the renal issues, they just measured, serum creatinine. And my understanding is that serum creatinine is a surrogate or intermediate marker that does not necessarily equate to actual chronic kidney disease or things of that -- more significantly patient relevant harms. And I don't know if you can maybe touch on that a little bit.

Brittany Lazur: Absolutely. I think you're absolutely right. And it's unfortunate sometimes in the literature when we're only able to have surrogate markers for some of these outcomes. And I agree, sometimes it's insufficient to really compare or to show what we're looking for in terms of real hard outcomes for kidney injury. So I think that is one of the limitations is that sometimes in the literature, we're only able to have these surrogate markers. And I think at times you need to determine whether or not that's good enough for your decision making.

Nancy Lee: Great. Thank you.

Alex Park: It's Alex park here. Can I ask a question? Just getting back to or tailing off of Ginni's question about noninferiority. I think in the report, you said that the ABC 3TC regimens were generally not inferior to those other backbone therapies that included TDF FTC. But did you also say, though, that maybe C3TC was also statistically more significant to result in viral suppression?

Brittany Lazur: Yes, that's a good point. So in terms of these findings, it actually can be statistically significant if they did look for that. Just noting that

noninferiority really does only show one side of the spectrum really, of showing that one drug is no less efficacious. However, they can, if statistically significant, find that one drug was actually superior to another. It's just knowing that not all of these comparisons reach that level of evidence, and not all these studies are able to come to that conclusion.

Alex Park: I see. Were there other parts of the analysis that found not only no less efficacious, but also some evidence of statistically significant variances in effectiveness besides those two backbone examples?

Brittany Lazur: So looking at slide 40, you mentioned those two backbone examples. I'd also mentioned in terms of add-ons, so raltegravir and efavirenz. So raltegravir was not inferior, but also statistically significantly more effective for viral suppression. And this was seen at long term follow up. So actually pretty interesting to have that long term.

Alex Park: Thank you. And then as a follow on, can I also ask, would it be fair to say that not all of the studies were adequately powered or designed to answer the comparative question across the board in the analysis? So it would be difficult to draw hard conclusions on that topic in this analysis.

Brittany Lazur: Yes, you're absolutely right.

Alex Park: Okay, thank you.

Ginni Buccola: Any more questions for Brittany? Okay. Brittany, thanks very much. That was a really detailed report. I appreciate it. Next we have Donna Sullivan with Medicaid HIV utilization review.

Donna Sullivan: Hi. So good morning. I'm Donna Sullivan. I'm the chief pharmacy officer with the Health Care Authority. You can go to the next slide, Leta. So today we're going to talk about why the Health Care Authority changed its HIV policy. And first, I wanted to give some background about the Health Care Authority and what our mission and really what our job is. So the Health Care Authority's mission is to provide high quality health care through innovative health policies and purchasing strategies. And our vision is to create a healthier Washington. Next slide. And the Health Care Authority is the state's largest health care

purchaser. We purchase health insurance for one in three non-Medicare Washington residents. It's over two million Washington residents that include the Apple Health Medicaid program, our public employees benefits board program, and the school employees benefit program. Next slide. Our approach to health care purchasing is transforming care. We want to provide better health care at lower cost. We believe in whole person care, which is why we've integrated physical and behavioral health services and we use data to inform our decision making decisions and purchasing decisions. So we want to get away from paying for volume, which is fee for service the old way and start paying for a value. Next slide. The agency budget for the Health Care Authority is almost $30 billion per biennium ,with the Medicaid program exceeding $17 billion. And of that $17 billion, the Apple Health program spends about $1 billion on prescription drugs. Next slide. Some of the benefits for the Apple Health program are major medical coverage. So they include the items that are listed here on the slide such as doctor and health care professional, professional services, emergency care. We provide the maternity care for newborns, mental health services, substance use disorder treatment. We have limited services that are optional, including dental and vision care. And also of note, the prescription drug program within the Medicaid is actually an optional service as well. And I'm just not going to read the other services that are listed there. So next slide. So I wanted to point out some of the Medicaid regulations that we also must follow. So the Health Care Authority is the designated single state Medicaid agency and we are required by federal law to be the sole decision maker in administering the program. We do also partner with Department of Health and the Department of Social and Health Services to help consult with administering some of these programs on our behalf. But the HCA is the single state Medicaid agency. Also federal dollars can only be used to pay for care that has been deemed medically necessary. And we usually manage this through utilization review programs, including prior authorization and our program integrity functions. The Health Care Authority has also come up with a medically necessary definition, which is a term for describing requested services which is reasonably calculated to prevent, diagnose, correct cure, alleviate, or prevent worsening of conditions in the client that endanger life or cause suffering or pain or result in an illness or infirmity or threatened to cause or aggravate and handicap or cause physical deformity or malfunction. Also part of that definition

is the qualification that there is no other equally effective, more conservative, or substantially less costly course of treatment available or suitable for the client that is requesting the services. And for purposes of this course of treatment may also include mere observation where appropriate or no medical treatment at all. Next slide. Other services that the Health Care Authority has been directed by our legislature to do is to control the cost of drugs. So RCW 70.14.050 actually directs state agencies to cooperate with each other to take any necessary actions to control costs without reducing the quality of care when reimbursing for prescription drugs. Agencies may establish an evidence based prescription drug program, which is what the pharmacy and therapeutics committee and drug utilization and review board assist us with doing. The statute also says in developing the evidence based prescription drug program, agencies shall prohibit paying for drugs that are determined to be ineffective by the US Food and Drug Administration. We are also to ensure less expensive generic drugs will be substituted for brand name drugs when appropriate. And we may take other necessary measures to control costs of drugs without reducing the quality of care. And this is where we're looking at prior authorization on certain drugs or drug classes. Next slide. [unrelated discussion] This slide here, I had actually changed it. Washington State has quite a bit of experience managing a preferred drug list. In 2003, the Washington State Legislature directed the Health Care Authority to create the evidence based prescription drug program that I had just mentioned with that statute. Within that statute, they also established the pharmacy and therapeutics committee. And since 2003, the Health Care Authority has been managing a preferred drug list that has many drug classes on it for serious chronic conditions including antidepressants, antipsychotics, multiple sclerosis medications, as well as other drug classes to treat autoimmune disorders. In 2018, the legislature directed the Health Care Authority to implement a single preferred drug list for the Apple Health Program. And within this program, we included the HIV drug class on the PDL. And now the Health Care Authority really is just treating HIV as if it was any other serious chronic condition. We can go to the next slide. And that was the slide I was just looking for Sorry about that. So I just kind of spoke to this slide. So again, HCA has 15 years managing preferred drug lists. We have successfully managed these drug classes without any harm to patients. So we can go to the next slide. So going into now, why do we

apply prior authorization. So the Health Care Authority is obligated to be good stewards of resources that are entrusted to us. We receive a significant amount of the state budget as I mentioned earlier and we're required to provide health care benefits to, again, one third of the Washington State non Medicare residents. So with this charge, we need to use limited state dollars wisely, especially when there's an economic downturn like we are currently. Previously, during the recession, you might remember that adult dental services were cut because of the budget shortfalls that we were experiencing within the Washington State. So prior authorization is a resource intensive for both plans and providers, however, not having the prior authorization leads to increased expenses. Prior authorization also allows us to review these services and prescriptions and make sure that what's being prescribed is safe for the patient to take, that it does not interact with any of the other medications that they're taking, and also to prevent unneeded medications from being prescribed. Next slide. So with our prior authorization requirements, they're developed to assure that only safe and effective treatments are provided. Medical intervention really starts with what is accepted to be equally effective and less costly. Every payer has their own unique payment structure. The least costly alternatives might be different for each payer. So when you might hear questions being asked, the Medicaid program is being treated differently from commercial payers. Oftentimes, that's because the Medicaid price for our drugs are different than the prices that the commercial payers pay. And then generally, after the failure of less costly treatment alternatives, patients receive other and often more costly treatments. In general, the less costly alternatives work for most patients and they do not require prior authorization. We make exceptions on a case by case basis. There's always exceptions to the clinical policy. Not every policy can account for every condition that might be or circumstance that a patient might have. And this approach is really to benefit the patient, the employer, or in our case, the Medicaid program, and all other covered lives. Next slide. So the Health Care Authority, we apply prior authorization when there's variability in the practice community, there's clear evidence of superior efficacy or increased harms of therapies for certain conditions or sub populations, when there's equally effective, less costly alternatives available. And we also work with providers to determine what information we need in order to consider the request. So when we're working to develop these clinical policies, we do

consult with providers within our agency as well as providers within the community and our local experts in the field. Next slide. So specifically regarding HCA's clinical policy, it supports access to, I'll say, most of the recommended initial HIV treatment regimens. There are seven treatment regimens that are recommended first line treatments, and four of them are available without prior authorization. HCA provides access to all HIV treatments through the prior authorization process. HCA's policy does not require patients established on HIV regimens to change their regimens. And in the absence of certain clinical conditions, we do require patients to begin treatment with equally effective less costly alternatives prior to starting the more costly HIV drugs. And again, our policy provides exceptions on a case by case basis to allow access to the nonpreferred drugs when clinically appropriate. Next slide. So I want to give you background on the HIV class. When it was implemented on the preferred drug list, it was implemented in 2018. And we've had really steady utilization of HIV medications, approximately 6000 patients per year. However, our costs have steadily increased over time. And what we have seen is these newer HIV medications, the single tablet regimens, and the newer TIF containing medications are more expensive. And as we've seen increased utilization in these particular products, we've seen our costs go up. So this has indicated that there's been a shift in prescribing to more significantly costly alternatives. Next slide. So I also wanted to provide the prior authorization data. Since our policy went live in August, we have had 433 requests for authorization. Those are unique cases for request for authorization. And as I mentioned before, our intention is not to deny continuation of therapy. So you'll see here highlighted in red, we had seven cases that were inappropriately denied for continuation of treatment. And when those denials were identified, they were quickly overturned and either the Health Care Authority or the managed care plan notified the pharmacy and requested them to reprocess the claim, and then we contacted the member to make sure that they were aware that they had a prescription available to pick up. Because of this, Apple Health has implemented an expedited authorization code that will allow pharmacists to process claims for individuals continuing on treatment if their claim gets rejected at the point of care. This generally happens when a member is new to the Medicaid program or they might change from one of the managed care plans to another. This expedited authorization process went effective December 1 for the fee for

service program and is going to be implemented January 1 for the managed care plans. And as you can see, in general, we have a pretty high approval rate for these medications once they have been reviewed and an overall 82% approval rate. So this is another just look at the utilization. You can see when Biktarvy was released in early 2017 or 18, it's the blue on the bottom, you can see the utilization is increasing slowly over time. The next bar up is the green bar, which is the Descovy, which is the TAF product, which is similar to Truvada which is in the purple, which has the TDF component in it. So you can see that the Descovy has increased over time as well. And I'm looking on the left hand side of the slide. On the right hand side of the slide it shows the costs for these drugs. So if you compare the proportion of the colors on the left hand side to the proportion on the right hand side, you can see Truvada has a pretty high utilization rate, but the cost is quite low compared to its utilization. With all of these other drugs, their cost is a higher proportion than their utilization. You can go the next slide Lita. I also wanted to point out, I looked at our top ten drug classes by net paid. HCA, our number two class and our number ten class are out HIV medications. When we add these together, HCA spends more on HIV medications than any other drug class. So we spend over $40 million a year to treat those roughly 6,000 unique individuals with HIV medications. So that's more than anti-psychotics, ADHD meds, the drugs for autoimmune disorders, and so on. Next slide. We also looked at our top drugs themselves. So in 2019, six of the top 25 drugs by net expenditure were HIV medications. And I've circled them here. About 25% of the top 25 drugs are HIV meds. And there were 5195 individuals taking one of these medications and they totaled more than $32 million in 2019. Next slide. So we just had a review of the evidence looking at some of these HIV medications and some of them that were the single tablet regimen. So are they better? We talked about an inferiority trial and really, Biktarvy was found to be no worse than Tivicay plus Descovy. So the study that was in the OSHU report is the one that I have here. And the authors found that the co-formulated component, component, the Biktarvy is a once a day potent, un-boosted regimen that is expected to be virologically similar to the other two tablet regimen. So the authors of the study that was sponsored by Gilead are saying that the drug is similar to the two tablet regimen. They're not saying that it's better. And we'll hear probably stakeholders say that these medications are better than others. And the next slide please. So we also question, is TAF safer

than the TDF. The studies that were in the OHSU presentation were looking at head to head trials only. However, there is a meta-analysis that looked at all published randomized control trials. And what they have found is that - we have an op-ed here as well - that after over ten years on the on the market, Truvada, which is the TDF, has been used for prep and for treating HIV patients. And it's been used in thousands of patients. And there have been no real world toxicities that have been reported. And there's really no difference in the renal or bone harms when they compared all of the study's together. And we can go to the next slide. And so the study that the op-ed was actually quoting or citing was the one found here. And the authors in this particular study looked at 13 randomized controlled trials. There were only 12 cases of a grade three serum creatinine elevation. And a grade three is 1.9 times the upper limit. And what they found is that there was no significant difference between the numbers of events in the treatment versus the control groups when they looked across all of the randomized controlled trials and pulled that data together. Because of the low number of grade three cases, they looked at all cases of elevated creatinine, and they found a total of 514 creatinine elevations occurring. And 97% of those were in grades one and two, so 1.1 to 1.8 times the upper limit. And then with the meta-analysis, there was only a borderline statistically significant overall risk difference between the numbers in the treatment group versus the control arm. And the next slide, please. So with that, the Health Care Authority is really left with some tough decisions. Most patients can successfully achieve and maintain viral suppression with the preferred once daily multi-pill regimens that are listed on the Apple Health preferred drug list. The FDA has approved some drugs that offer convenience through once daily single tablet regimens but are no more effective and potentially no more safe than the existing medications, but they cost much, much more. In addition, critically needed state supported optional Medicaid programs such the adult dental program have been defunded in the past during economic downturns. So we need to consider that as a risk when we're looking at our coverage options. I want to remind that HCA is responsible for the stewardship of scarce resources and protecting essential services for the entire safety net and the entire Medicaid population. Again, that's two million Medicaid lives. So the questions that we grapple with: are the higher price single tablet regimens that are no better than the multi tablet regimens, or the TAF containing products that also have serious side effects, are they worth

the additional cost? And I believe that's the last slide. So any questions from the committee?

Ginni Buccola: This is Ginni. I don't have any questions, Donna, but I do want to make sure we leave it open for enough time if any of the committee members are pondering things. Okay. Donna, do you have any last comments for us before we go to break?

Connie Huynh: Hi, Donna, this is Connie. Sorry, just trying to finagle my way. I'm not as easy to navigate the buttons. I just have a quick question and I think you discussed this a little bit and I want to just ask a little bit more specifically. So when it comes to the algorithm - and thank you so much for laying that out in terms of what is determined for prior authorization and the justification for it was very, very helpful. Can you just remind me again what the four HIV medications are that do not require prior authorization? I thought I wrote those down. I just wanted to make sure.

Donna Sullivan: Sure there's actually more than four medications that don't require prior authorization. Really, the workhorse that we have for our medications are Truvada, which is primarily used in combination with Isentress or Tivicay and occasionally Evotaz. And I believe all of those do not require prior authorization. There are many others that do not require prior authorization as well but they're less commonly used.

Connie Huynh: Right. And I did see that on the PDL. So okay. And then just a general kind of question from a historical standpoint. And I saw your graph. How often do you find that when it comes to so-called parity of prescribing medications for, say, something like HIV, is that something that can be considered? Or is it something that has been done in the past to authorize or give status of parity for a particular type of treatment plan?

Donna Sullivan: And when you say parity, we're treating HIV like it is a chronic disease, which it really has become a chronic disease. I'm going to give an old example, which would be some diabetes medications. You know, 15 years ago, when we first started this program, diabetes drugs and blood pressure medications were what were really pressuring our budget. And what we would see is, like, Metformin came out and then we'd have newer diabetes medications, oral

products that would come out. And then they would start creating combination products. So you would find medications, the DPT4 inhibitors, plus a Metformin product as well in a combination product. And so what we would do is we would look at the total cost of that combined drug. And if the two components were cheaper than the combined product, we would put the combination product on prior authorization and we would require the patients to take the two separate pills. And so essentially, that's what's happening with the HIV products. Many of these single tablet regimens have two or three components in them. Sometimes the individual components are all available generically or there might be a less costly combination product. So Truvada is a combination product of emtricitabine plus the TDF product. And then Deskovy is emtricitabine plus the TAF. But there's a significant cost difference between the two. And then when we look at other combination products, they might include both of those or one of those products and then a third drug that may or may not be available individually. So again, we're just looking at the total cost of the equally effective regimens, whether they're one pill or two pills, and then we're making those that are the least costly, equally effective alternatives available without authorization. And then we do have clinical criteria that Marissa is going to present when we're finished here that shows when patients are able to receive the non-preferred regimens without having to first try the preferred drugs. So, for example, we heard that the TDF product has concerns over increased renal complications. So patients that have renal disease, they're going to be excluded. They'll be allowed to go to the non-preferred regimens. Or if there's other combinations of conditions that might put a person at risk for developing renal disease in the future, those people will be able to receive the non-preferred drug, however, they still have to go through the prior authorization process.

Connie Huynh: Okay. I'm glad you brought the example of the diabetes medication because what I'm trying to think about is what contingencies do we have in place for say, when we have a meta analyses of populations that don't necessarily represent marginalized groups or, just as Brittany was talking about how she mentioned there were some limitations in terms of African American representation in some of the studies. And how does that then represent in our policy when that particular marginalized group may not necessarily fall into that particular paradigm? I guess you mentioned it a little bit. But I think

diabetes is similar in terms of access of the medication to the newer formulations and compliance, as well as ease of use.

Donna Sullivan: Yeah, and actually, in the OHSU study, I don't know if how prominently it was pointed out, but the study that I showed that had the Biktarvy plus the two drug regimen, they actually looked at adherence and the adherence was no different between the one pill regiment or the two pill regimen. So, we're talking about taking one pill once a day versus two pills once a day. And it might behoove us to just move to the policy discussion. But part of the kidney risk factors, one of them is being an African American. We also have added considerations for people that have an altered mental status, where they need assistance with the activities of daily living or they're just unable to manage their own life. And so, you'll see when we go through the policy that we have added some of those considerations. Although we didn't make being unhoused or homeless a criteria in itself but again, you have to have some sort of ability to actually manage your life.

Connie Huynh: Okay. I greatly appreciate it. Thank you so much for the report.

Ginni Buccola: This is Ginni again. Just checking in with everyone to see if there's any other questions for Donna. So Donna, I don't hear anything from the committee. Do you have any last comments for us?

Donna Sullivan: No. Thank you.

Ginni Buccola: Yeah, thank you. We are at 10:09. We were scheduled for a break at 10:40. And I want to maybe check in with Leta to see if we want to stick to the break now or --

Leta Evaskus: Yeah, this is Leta. I think it would be good to take a ten minute break now and then come back, because we're going to have all the stakeholders after Marissa's presentation. So it's 10:10, so let's come back at 10:20 and I'll put up a sign.

[break]

Ginni Buccola: This is Ginni. I hope everybody had a nice little break. Up next we're going to hear from Marissa Tabile with HCA to talk about Apple Health HIV policies. Marissa, are you ready?

Marissa Tabile: Hi, Ginni. This is Marissa. I am ready. I have to unmute myself. Alright, so good morning, everybody. Good morning committee. I will be presenting on the HIV combination policy this morning. Well, actually, we have two HIV policies. So we have the HIV combination policies and then we have an HIV Descovy policy, which I will be going through this morning. So just to give you an update, we do have current HIV policies posted online on our website. However, these policies that I'll be presenting this morning are actually updates. It's gone through several revisions since we've posted them August 1 of 2020, which was the date that these two policies were implemented. And just to give you some background on these policies - I know Donna had spoken a little bit about them this morning - it is a collaborative effort that we have created these policies. So we have had some internal review and feedback from both our clinical staff, which is our pharmacists and our medical directors. here at HCA. We worked together with the MCO pharmacy directors and received feedback from them, as well as work very closely with the Department of Health HIV Clinical Advisory Committee in creating these policies. So we have worked all together amongst that group of people, even including these revisions. So you'll see those included here. And just to give you some background, the agents that are listed, I have the policy displayed here. In this box in the medical necessity box with the drug listed, those are actually our nonpreferred HIV combination agents. But the policy does have references within the policy saying which products regimens are our preferred product on the HPDL. So just to go through the policy, we've already gone through the background things due to Brittany going through the DERP report. So just to go through the policy, we have added and changed some of the language in the policy. So we have now included this criteria here where if all criteria are not met but there are documented medically necessary or situational circumstances based on the professional judgment of the clinical reviewer, request may be reviewed on a case by case basis up to the initial authorization duration. So that statement has now been added to the criteria. It's not currently added on the posted criteria on the website but we are making that change to this policy. And then, like Donna had said before, if there are clients or patients that are new to Apple Health or new to an MCO who are requesting for continuation of therapy, those requests should be reviewed following the reauthorization criteria, which are listed below. And I'll go

through that a little bit later. So to get into the policy, we have divided some of the products into they have their own criteria. Each product kind of has different nuances to them, so whether that be renal consideration, contraindications, or drug interactions. So those that's why they're separated. So the first criteria that I'm going to go through is the Dovato and the Juluca. And I would say across the board, most of the criteria is essentially the same with the different nuances like I've mentioned before. So you'll probably see differences in that but it might seem a little bit repetitive. So just to go through the criteria for these two products, the patient must have a confirmed diagnosis of HIV-1 and the patient is either HIV-1 treatment naive, and that's for Dovato only, or the patient is virologically suppressed with the HIV-1 RNA less than 50 copies per mil, or they've been adherent to an ART regimen for at least six months with no history of treatment failure, no known substitutions associated with resistance to the individual components of Juluca. So those are specific to both Dovato and Juluca. And you can also see as well on the side, we do have the preferred alternatives listed on the side here just for some reference if you're curious as to what products are preferred on the PDL. So just to go back to the criteria, they have to have an absence of severe hepatic impairment, creatinine clearance greater than or equal to 50 mils per minute, and like Donna was mentioning before, we have included these kind of limitations here. So if the patient has documentation of significant drug interaction or an allergy to maybe some inactive ingredients contained in the commercially separate agents, active psychosis that is poorly managed, severe substance disorder, diagnosed swallowing disorder, or cognitive impairment requiring assistance with activities of daily living. And then of course, Dovato and Juluca will not be co-administered with other ART products. So this is the criteria specific for Dovato and Juluca. And I just want to make it clear that these criteria are really for new starts. so patients that are requesting new starts to these medications. If it's a continuation of therapy, we do have the expedited authorization that Donna had mentioned before and that is listed in this policy, which I'll go through later on when we get to that portion. So just to go down, next is the Temixys. And you can see the preferred alternatives here that we have on the HPDL. Of course, the criteria is largely the same with the exception of the bodyweight. So we have for Temixys that the body weight is greater than or equal to 35 kilograms. And then we have the renal, the creatinine clearance criteria here as well with also

these documentation of these other limitations as well. So that's listed here. And for Biktarvy, this criteria is a little bit different than the two that I previously discussed. And that's because of the tenofovir alafenamide component in that medication, that we have included some renal and bone criteria in this criteria. So we have here the confirmed diagnosis of HIV-1, body weight is greater than or equal to 25 kilograms, and the patient is treatment naive or virologically suppressed. We have documentation that the patient is not a candidate for tenofovir disoproxil based regimen due to contra indication or intolerance defined as any one of the following. So if the patient requires renal hemodialysis or they have a stabilized creatinine clearance less than 60 mils per minute, but greater than or equal to 30 mil per minute within the prior three months, or if the patient has a stabilized creatinine clearance between 60 to 89 mils per minute and the patient has hypertension plus one of the following. So if they had diabetes, hepatitis C, or are African American descent with a family history of kidney disease, or they have a stabilized creatinine clearance greater than 60 mils per minute and a high risk for bone complications as determined by a history of one of the following. So they've had a vertebral compression fracture, they've had an arm or hip fracture with minimal trauma, their T-score is less than negative 2.0 at the femoral neck or spine, or they're currently taking glucocorticosteroids for more than two months. And the documentation must be included for that. And that is if they have a diagnosis requiring chronic glucocorticoid regimen, taking a current glucocorticoid regimen, or the expected duration of therapy. And then we also have stabilized creatinine clearance between 60 to 89 mils per minute. And the patient has chronic kidney disease with protein urea, low phosphate, or is a grade three or worse. So that's a little bit different than the criteria that was listed above. And this criteria that I just explained or went through pretty much applies to all of the tenofovir alafenamide regimens or products. So you'll see that probably be listed in the other products as well as the criteria. Criteria is still the same like listed above. And that's really the only difference with the Biktarvy compared to the other products. So now moving on to the Delstrigo. And the Delstrigo is essentially the same as the other criteria, not exactly the same as the Biktarvy because Delstrigo has tenofovir disoproxil. But now with the Delstrigo, there is the co-contraindications of these drugs listed in the criteria. So as long as it’s not co-administered with Carbamazepine, Oxcarbazepine,

Phenobarbital -- I'm not going to go through the whole list. You can see it there. And that's really the only difference with Delstrigo's criteria. And then moving on, we have Symfi and Symfi Lo. And this criteria is essentially the same as the others except for the body weight is a little bit different and Symfi and Symfi Lo have different nuances to their body weight. So for Symfi it would be a body weight greater than or equal to 40 kilograms. And for Symfi Lo the body weight is 35 kilograms. And the creatinine clearance is listed here, greater than or equal to 50 mils per minute, absence of severe hepatic impairment, and that these products, the [indistinct] will not be administered with efavirenz, lamivudine, tenofovir disoproxil, or Zepatier. And then criteria seven is the same as the criteria that I've discussed above. So then moving on to Symtuza. Symtuza does have the alafenamide component inside of it as well. So you will see here in criteria number six, it's essentially exactly the same criteria that I went through for the Biktarvy. So of course, that's listed here in their criteria. And moving right along Symtuza also does have some drug-drug interactions, which are listed here. So as long as it's not co-administered with those following products, so Alfuzosin, Carbamazepine, Cisapride, Colchicine , there's a whole gambit of products listed. I won't go through all of them but you can see them listed here. And we get to the reauthorization criteria. So for fixed dose combination ART therapy, it may be reauthorized if the patient shows a previous history of medication use within the last six months. So as long as the patient doesn't have more than a six month gap in their therapy, the medication can be reauthorized and will be approved. And just to kind of reiterate a little bit more about the expedited authorization, we do have the expedited authorization that did go live for fee for service December 1 and is anticipated to go live no later than January 1 with the MCOs. But that expedited authorization is here. So the pharmacy can use this expedited authorization code if they see that it's a continuation of antiviral treatment. So they can enter this code that's listed here so that then the claim can process and be approved. And just to give you some background on the expedited authorization, it does give overrides for the PA requirements if it's, like I said, the continuation of therapy. So then the pharmacist can make that claim go through. And I think these are the dosage and the quantity limits for those products. And I think that's it for the policy. I'll pause if the committee members have any feedback or want to discuss the policy before I move on to the form.

Ginni: This is Ginni. Just making sure we're feeling comfortable as a committee that we've had our questions answered and had time to ask those.

Alex Park: Marissa, it's Alex park here. Can I ask you something about the Biktarvy policy?

Marissa Tabile: Hi, Dr. Park. Sure. Let me go ahead and scroll down to that. Alright, I have it displayed. Go ahead.

Alex Park: Thank you. I thought you and the team did a great job looking at the [indistinct] manifestations that can happen as people switch from disoproxil to alafenamide. And it's a long policy. So there may have been something like this. So I apologize if that's the case. But one thing I was thinking about is sometimes you have people who have a GFR decline on the traditional tenofovir but the decline may not necessarily meet the creatinine clearance targets. And I think the IDSA talks about if you have a 25%, decline in GFR then you might want to think about switching to the alafenamide. So I'm just wondering if that's something that we should think about adding to the criteria as far as the renal options go. Thank you.

Marissa Tabile: Hi, Dr. Park. Thank you. This is Marissa. I don't think, like you said, we do address that or anything about the decline in renal function, but I can definitely take that back and figure out how we would want to add that into the criteria. I think that's a very good point. So thank you. I will go ahead and make a note.

Alex Park: Thanks. Yeah, I'm just thinking of a patient who maybe doesn't have, let's say, someone starts off with a creatinine clearance of 89. But they don't have any of the risk factors that you very appropriately mentioned, the diabetes, the hep, C, etc. But if it drops 25%, they might be someone who wants to think about an alafenamide option. So thank you.

Marissa Tabile: No, thank you so much, Dr. Park.

Donna Sullivan: Hi, Marisa, this is Donna. We'll go ahead and add that as a criteria for all of these that have the TDF versus TAF. But when you're making your motion, just to remember, we will make that inclusion.

Alex Park: Thanks, Donna.

Donna Sullivan: You're welcome.

Ginni Buccola: This is Ginni again. Committee, what other questions do you have for Marissa? Okay, I think we're going to go ahead and then move on. Thank you, Marissa, for presenting this.

Marissa Tabile: No problem. Ginni, this is Marissa. We have a Descovy policy in the form so I'll just go ahead and go through those. Okay. So here is the antivirals HIV combinations form, which is the form that a provider would fill out if the medication finds that it needs a prior authorization or if they're requesting for this medication. So this is a form that a provider would fill out. And it pretty much follows the same format up above is our other forms that we typically present with our policies. The criteria or the content is just a little bit different and more specific to these HIV policies. So we do have the expedited authorization listed in the form as well for their reference. So if the provider finds that this patient has used this medication within the last six months, the provider can call the patient's pharmacy and let them know to submit that claim with the expedited authorization and the claim should process through and be approved. So I won't go through all of it. It's pretty lengthy. But of course if the medications are being used for HIV-1 treatment, is the patient treatment naïve, are they virologically suppressed? It mirrors the same questions that were in the policy just kind of in a checkbox format. The patient's weight, do they have hepatic impairment? The patient's creatinine clearance, of course, we want that as well. Are they taking any of these following medications? Of course, the list is very extensive. So I won't go through all of that. And do they have documentation or is it listed in the clinic, no, or the doctor finds that they have these kind of social barriers or other medical barriers that might warrant them getting this medication. And then of course, we have room for any other comments that the provider might want to write in number nine, so any other additional circumstances that we might want to take into consideration. And then we have a little bit more specific criteria for

the renal on the bone issues for those tenofovir alafenamide components or those medications with that. And so we have those here listed. And then of course, chart notes and lab tests are required for the prior authorization requests. So just want to reiterate that if any provider is requesting this medication, that of course, it should be accompanied with chart notes and lab tests that are applicable. And I believe that's it for this combination form.

Donna Sullivan: Hi, Marissa, this is Donna. So it's just come to my attention, going back to the policy, that Dovato has also received a new indication to switch if they're currently virally suppressed. So can we go ahead and make that change as well while we're here? So that they are just like the Juluca. They can switch if they're virologically suppressed as well. You can just add Juluca and Dovato down in B.

Marissa Tabile: Sorry, I'm just making a note. Right here.

Donna Sullivan: Yeah. And then delete the "only". And then add Dovato up above. To the individual components of Juluca or Dovato. Thank you.

Marissa Tabile: Okay. This is Marissa. Any other questions from the committee about the combination form?

Ginni Buccola: I do have a question, Marissa and it came up as we were looking at the form and they actually applied in the policy. It's about the criteria for active psychosis being one of the complications, social [indistinct]. I'm just how active psychosis would be defined. Would it be using a diagnostic code? Would it be [indistinct]? And my curiosity is that you want to be sure that people with other severe and chronic mental illnesses such as bipolar disorder [indistinct] are not eliminated from that category of people living with a chronic mental illness.

Marissa Tabile: Sorry, Ginni, can you repeat the first half of your question? It was breaking up. I apologize. was breaking up,

Ginni Buccola: So my question is about the definition of active psychosis and how that would be determined by the reviewer. Would they be using, for example, a DSM diagnostic code? Or would they be going on the verbal report and description of the prescriber that is prescribing the HIV medications? I want to be sure that people with other chronic and

severe mental illnesses aren't excluded if they don't carry a specific diagnosis of psychosis.

Marissa Tabile: Yeah, I would imagine that it would be mostly from the clinic note that is provided. So if the provider has notes of that in their visit note then I think that would consider that active psychosis. And of course, if there is a diagnostic code in the clinic note as well are the provider lists it, that would be helpful as well.

Ginni Buccola: Okay. And I'm wondering if it seems pertinent to change the language around active psychosis to “active and poorly controlled mental illness” to be a little more inclusive.

Marissa Tabile: Okay, I'm actually going to go back to the policy since it's listed right there.

Ginni Buccola: I saw it in the policy and it didn't come up as a question until I read it on the form.

Marissa Tabile: That's fine. What was your suggestion again, Ginni? I’m sorry.

Ginni Buccola: Okay, I would say “poorly controlled chronic mental illness”. Thank you.

Marissa Tabile: Thank you for the recommendation.

Ginni Buccola: And then turning it back to the bigger committee for more comments or questions on the form.

Alex Park: Marissa, Alex Park here. Two things. Number one, just wanted to make sure that the updated GFR degradation criteria transmits from the policy down into the form as well. We would probably just have to add a box under the renal criteria for the Biktarvy.

Marissa Tabile: Yes, yep, I will make sure that that gets updated here.

Alex Park: And then the other question is, I think you've been really thoughtful about allowing providers and patients an opportunity to access a fixed dose combination in certain unique circumstances beyond what might be delineated in the policy, and that was in that sort of first paragraph

that you showed us, where even if all criteria are not met, they have the opportunity to have a clinical reviewer assess the situation. Where on the form does that go?

Marissa Tabile: This is Marissa. I don't believe that that is here on the form. But would you recommend us adding that statement to this form?

Alex Park: Not necessarily. I just want to understand what the workflow would be. Would they be denied from this form first? And then would they get a follow up form as an opportunity to appeal that, and that's when they document the other medically necessary or situational circumstance? If that workflow already exists then I don't think we need to add anything to this form.

Donna Sullivan: Hi, Dr. Park. This is Donna. Marissa, can you scroll down a little bit? I think what we did is number nine. So if there's additional circumstances that the provider feels warrants a consideration for a non-preferred drug that are not already listed, they can write it in under number nine.

Alex Park: I see. Okay, that makes sense. Thank you.

Donna Sullivan: So I have a comment going back to the policy. I'm a little concerned with the "active or". I think it's just poorly controlled mental illness that impairs their ability to manage multiple medications a day, I think is what that should read. Because if you have an active disease, that might be well controlled. I think the concern is really the poorly controlled mental illness.

Ginni Buccola: This is Ginni. I would agree. Thank you for that clarification.

Donna Sullivan: Thank you.

Ginni Buccola: Committee members, checking in to see -- oh, go ahead.

Marissa Tabile: Donna, did you want me to add for the controlled mental illness and then add that they can control their medications? Or do you want me to leave it just "poorly controlled mental illness"?

Donna Sullivan: I think it's fine the way it is.

Marissa Tabile: Okay. Thanks.

Alex Park: Marissa, Alex Park here. I'm looking at number nine on the form again with regard to my prior question about the opportunities that providers and patients have if all criteria are not met. I'm wondering if we can be clearer about that part of the form. When I read that, I don't know that I as a provider would know that that would be the place for me to insert those other comments and that such an opportunity exists and I think it's a well thought out consideration that you put into the policy. So how do you feel about that?

Donna Sullivan: So Dr. Park, this is Donna. Maybe "any additional circumstances that are considered to be medically necessary".

Alex Park: I think that could work. What if we just said, "if not all criteria are met but there are documented medically necessary situational circumstances, requests may be approved on a case by case basis." And what additional circumstances should we consider? I mean, that might spell it out too much. You might make the form a little bit convoluted, but I think it would be the clearest form of intent with regard to that question.

Donna Sullivan: I think we can make that change. I don't think we need to try to wordsmith it here. We can take that feedback and update the form.

Alex Park: Thank you.

Marissa Tabile: And this is Marissa. Any other feedback from the board about the form? This is all great feedback, so thank you.

Ginni Buccola: This is Ginni. It sounds like we've answered all questions from the committee.

Marissa Tabile: So, I'll go ahead and just go through the Deskovy policy and the form. And I'll just go through the policy and the form together and then take any questions that the committee might have all at once, so then we can kind of compare both of them. So this that I'm presenting is the Deskovy policy. And it is, I want to say, largely the same as the other policy, especially for the HIV treatment. And it is an update on the

current policy that we have posted online. This policy was implemented at the same time as the combination policy, which was August of 2020. And we have included this statement as well about the case by case basis. So that is now included in this policy, as well as if clients are new to Apple Health or new to an MCO, that the continuation of therapy should be reviewed following the reauthorization criteria that's listed below. And just going to go through it very quickly. The policy that we have posted online separates HIV treatment and prep. But now with this updated version that I'm presenting, it's pretty much put together for the Deskovy. So for prep, we have number one is if it's prescribed for prep in adults and adolescents at risk of HIV-1, that they have a negative HIV-1 test prior to initiating treatment, and their body weight is greater than 35 kilograms. And then two, if they are using it for treatment, that they have the body weight greater than 25 kilograms. And then the bone and renal issues are essentially the same. The treatment, what we put in the Biktarvy and the other alafenamide containing products, that criteria is pretty much the same as the other ones that we've gone through. So I won't go through all of them. And the reauthorization criteria, so we do have two different EAs or expedited authorizations. So codes, so one is for the continuation of prep therapy and then one is for the continuation of antiviral treatment. So the codes just differ as far as the numbers but it works the same way as if a pharmacist got a claim for it or is trying to process it at the pharmacy, if they see that it's a continuation of therapy, they can enter in these expedited authorization codes and the claim should go through. And of course, it's the same thing for this Deskovy criteria. It's for new starts only and if they're continuation of therapy, they can use the expedited authorization. And here we just have the dosage and quantity limits for Deskovy. And that's just the policy. So I'll go ahead and move over quickly to the Descovy form.

Donna Sullivan: Marissa, before you do that, can you make a note to add the 25% reduction in renal function as policy as well? Thank you.

Marissa Tabile: Yes, thank you. I will add a note. Thank you, Donna. This is the form that a provider would fill out for Deskovy. Of course, we have the expedited authorization codes listed here as well for both prep and continuation. And then the questions are pretty much the same as the other form, probably just a little bit different nuances, but we do have

the renal and the bone. And I will add here that we need to take into account the 25%, renal decline into this criteria. So that will be added as a recommendation. And then of course, chart notes and lab tests are required for this request as well. And I believe that is it for the Deskovy. So if the committee members have any feedback on either/or I'm welcome to take any feedback.

Ginni Buccola: This is Ginni. Just checking in with the committee. Sounds like we did get our questions answered.

Marissa Tabile: Thank you so much.

Ginni Buccola: You're welcome. Thank you. Donna, I can see you and I'm wondering if you have a question or a statement.

Donna Sullivan: I do. We had a request before the stakeholder testimony if we could display the motions that were on the table. So I was just wondering if we could do that before we go to stakeholders.

Marissa Tabile: Donna, this Marissa. So you want me to present the motions for the class in the policies?

Donna Sullivan: Yes, please.

Marissa Tabile: Okay, I'll go ahead and do that. Let me pull them up. So I have the drug class motion because we did not have a motion for them in October. So I do have it. First, we'll do the motion for the drug class and then we can move on to the policy.

Alex Park: Ginni, this is Alex Park. Are we doing this motion now or are we waiting for stakeholders?

Ginni Buccola: We're showing this for the benefit of the stakeholders so they can be aware of what motions we'll be considering after stakeholder input.

Alex Park: Oh, okay, understood. Thank you.

Ginni Buccola: No need for us to respond yet.

Marissa Tabile: Hi, this is Marissa. I'll go ahead and post. Did the committee members get a chance to read through just this motion. I'm just going to move on to the policy so that then the stakeholders can see. Just want to make sure I'm not moving too fast.

Ginni Buccola: Donna, this is Ginni. I haven't been watching the questions. But I just want to be sure, just double check that there weren't any other questions that needed to be addressed before we go to stakeholders.

Donna Sullivan: Sure. So, there was another question regarding some recommendations that the Office of Infectious Disease from Department of Health had submitted to us. I'm trying to find them. One of them was like the age of 50. And another one was, other considerations for approving a nonpreferred drug, which included swallowing. Dr. Photinos and I considered those and we looked at those and we didn't agree with all of them but we did incorporate some, for example, the diagnosed swallowing difficulty. And we felt that the renal criteria already would apply to an older person that would be potentially at risk for renal disease. And then we added in the uncontrolled mental health illness or psychosis, which we edited, and then the altered mental status with the inability to manage your activities of daily living. So we felt we complied with the spirit of those recommendations. So that's why they're not in there verbatim.

Ginni Buccola: This is Ginni. Donna, then are we ready to go to stakeholders?

Donna Sullivan: Sure.

Ginni Buccola: Okay, so again, this is Ginni, committee chair and we have quite a few stakeholders with us. The way that will proceed, I'm going to start by listing the stakeholders that I have been given. If you don't hear your name called please make sure that your hand is raised so that Leta Evaskus can add you to the stakeholder list. We'll go in the order that I call and I will introduce you by name. I'm going to ask each time if any stakeholder has any conflicts of interest to disclose including payments from any pharmaceutical companies. Once I call your name, you'll have three minutes to present. I will take my face away while you're talking and then turn myself back on as we get to about 15 seconds left. And if we're at the full three minutes, my apologies but I will go ahead and interrupt you and let you know that your time is

done. So the stakeholder list as I have it includes Stephanie Yamamoto with Janssen Scientific Affairs, Terra Stone, and I believe it's ViiV Healthcare. My apologies if I'm saying that company name incorrectly. Erick Seelbach with Pierce County AIDS Foundation, Lauren Fanning with HIV Justice Alliance, Tony Radovich. PLWHA member. And again, pardon me if I'm misstating your title, but a member of the HIV Justice Alliance. Wendy Austin, Pharmacist with Met Meds, Dr. Warren Dinges with Seattle Infectious Disease Clinic, and Dr. Bienvenido Yangco, with Madison Kitsap Clinic. So that's who I have listed. Again, if you're here as a stakeholder and I did not call your name, please raise your hand so that we can make sure you're added to the list. And we will go ahead and we'll start with Stephanie Yamamoto of Janssen Scientific Affairs. And Stephanie, as you come on, if you could please go ahead and again state your name and tell us if you have conflicts of interest including any payments from pharmaceutical companies. Thank you.

Stephani Yamamoto: Will do, thank you so much, Ginni. Hello, my name is Stephanie Yamamoto. I'm a pharmacist with Janssen Scientific Affairs, and I'm here to discuss the protease inhibitor based complete single tablet regimen called Symtuza. We have made great strides since Governor Inslee issued the proclamation to end AIDS in Washington in 2014. And the number of new HIV and AIDS cases has steadily decreased until 2018 when King County experienced its largest one year increase in the number of new HIV diagnosis since 2002. And that was based on the 2019 semiannual report. The antiretroviral therapy regimens that are available are highly efficacious and that translates to a very powerful form of prevention given the decrease in risk of HIV transmission when patients are adherent to their medications. It also means the early intervention program and clinics are working to rapidly initiate treatment, efficient access to antiretroviral therapy is paramount. With all of these local statistics in mind, Symtuza is a once daily complete regimen containing the protease inhibitor darunavir, which confers a high genetic barrier to resistance, combined with the safety and tolerability profile of tenofovir alafenamide. Single tablet regimens are important to promote adherence and in several analyses using Medicaid claims data, up to 70% of HIV patients exhibited suboptimal assurance and greater healthcare resource utilization, then those with optimal assurance. Additionally, a meta analyses of 63 studies showed patients are two times as likely to be adherent to antiretroviral therapy, single tablet regimen versus multiple tablet

regimens. As a reminder, the DHHS guidelines retains darunavir based regimens, including Symtuza as the only A1 recommendation for initial regimens in certain clinical situations, such as for patients with a poor history of adherence, when resistance results are not available, when a single tablet regimen is desired, or when there is a need for rapid initiation. Thank you so much for your consideration and including Symtuza on the Washington Apple Health PDL without a PA to enable DHHS guideline recommendations around rapid initiation and treatment for patients. Thanks.

Ginni Buccola: Thanks, Stephanie. Committee members, are there any questions for Stephanie? Okay, thanks very much. We'll move to our next stakeholder, who is Terra Stone with ViiV Healthcare. Are you there? And Tara, could you go ahead and state your name, conflicts, and any payments that you receive from pharmaceutical companies?

Terra Stone: Absolutely. So good morning everyone. My name is Terra Stone. I'm a ViiV Healthcare MSL and I'm here to provide information on Dovato. Dovato is a two drug combination of dolutegravir and lamivudine and it's indicated for treatment in treatment naive adults as well as to replace current regimen in virologically suppressed patients and thank you for updating your policy. Dovato is the lowest cost integrates-based single tablet regimen on the market and it has been studied in rapid initiation reported in the stat trial Glasgow this year demonstrating Dovato's efficacy in this setting. The DHS and the IAS HIV guidelines both state the key goal for persons living with HIV is viral suppression. Both guidelines recommend Dovato as initial ART regimen with their highest rating. IAS states Dovato is an option offering cost and safety advantages. Switching to Dovato may reduce bone, kidney, and cardiovascular complications and reduce costs with durable viral improvements. There is a disproportionate impact of HIV on racial and ethnic minorities. Diverse patient populations were studied in the Dovato trials, such as subjects with comorbidities and in different ethnic and racial groups. For example, 14% were African American or African heritage, 30% were Latinx or Hispanic, 10% were Asian, all well within the demographics found in the state of Washington. Likewise [audio dropout].

Ginni Buccola: Terra, this is Ginni, we have dropped you. Are you still there? This is Ginni again. We're just going to pause for a minute and see if Terra is able to come back online to finish your testimony.

Leta Evaskus: This is Leta. Maybe we can move on and then I can try Terra again. I see that she's still there.

Ginni Buccola: Okay, so if she comes back then she still has a full minute left in her time. So I'll go ahead though and move to Erick Seelbach with Pierce County AIDS Foundation. Eric, are you there?

Erick Steelback: Hi, good morning. Do you hear me?

Ginni Buccola: Eric, we'll have you go ahead and introduce yourself including a statement as to whether or not you have any financial disclosures and receiving payments from pharmaceutical companies. Thanks

Erick Seelbach: Good morning. My name is Eric Seelbach. I'm the executive director of Pierce County AIDS Foundation, co-chair of the Pierce County HIV Collaborative, chair of the Pierce County Human Services Coalition, and member of the Washington HIV Justice Alliance. My organization does receive a few $1,000 from pharmaceutical companies. But I'd also like to point out that I received almost $2 million from the Washington State Department of Health. So in terms of conflict of interest, just want to state that. I'd like to address a few points from the presentations this morning. Some questions and just some observations. So first, in the first presentation with the updated report, one of my questions was, was there any comparison of the study populations in that research with the Apple Health population? So are we looking at apples to apples? Or are we looking at different population characteristics? So that's one question I have. The statement was made that HCA treats HIV like any other serious chronic disease. And I think that is hugely problematic given that, while there have been many advances in HIV, HIV is not like any other chronic disease. The stigma related to HIV is immense. And so with that statement, we need to really have a conversation about what that actually means. A lot of the conversation this morning also talked about most patients can do okay on the less costly alternatives. And my question is, what about those who are hardest to serve. So not the most patients, but the fewer patients, and those are the ones that

we're trying to reach, particularly in light of the effort to end the epidemic in Washington State. We're trying to reach the hardest to reach folks. And so when we make statements like, it's okay for most people, we leave out those who are hardest to reach. And again, those are who we're trying to get to. I also want to point out that the message that was being received or sent from this morning's presentation, too, is that HIV positive people are just way too expensive and aren't necessarily as deserving of these treatments. And I think that is problematic as well. I'm guessing you'll hear from long term survivors and folks living with HIV later that the triggering of PTSD related to cost of treatment is huge. And so having those kinds of messages doesn't really help our cause. In terms of the policies, you listed a number of groups that were consulted in the development of those policies. But missing entirely from that list of folks is consumers of services. And this goes against long standing efforts in the HIV world. Going back to the beginning of the epidemic, where HIV positive people have stood up to be included in the conversations about policies that impact their lives. There's a statement, nothing about us without us. And so I would really encourage you to step back and not vote on these policies, to be able to engage in consumer input separately.

Ginni Buccola: I'm sorry to interrupt. You're at your three minutes.

Erick Seelbach: Oh, okay. I'll just finish up and just say that I don't think these policies are in alignment with the goals of ending the epidemic in Washington State. Thank you again for the opportunity.

Ginni Buccola: Thank you very much, Erick. Committee members, are there any questions for Erick Seelbach. Okay, thank you. Moving next to Lauren Fanning with HIV Justice Alliance. Are you there, Lauren?

Lauren Fanning: Yes.

Ginni Buccola: Great. Lauren, can you go ahead, if you could state your name and any potential conflicts you have, including payments from pharmaceutical companies? Thank you.

Lauren Fanning: Lauren Fanning and I have no alliance with pharma or any other organization other than Washington HIV Justice Alliance. So HIV is a

bio psychosocial disease. And we would like to see that perspective reflected in your decisions in achieving whole person care and value. It's a chronic disease that is infectious. Hepatitis B is also a chronic infectious disease. Its formulary appears to have all of the commonly used antiviral drugs available as preferred drugs. The difference between HIV and other chronic diseases is that the infectious aspect of it. If you have nonadherence it can lead to drug resistance. This is a complicated and multi-dimensional issue with potentially critical outcomes. In many cases, medical adherence relies on more than regular visits to a medical provider, obtaining and filling prescriptions, and getting labs taken. It relies on assistance with medical coverage, access to other providers, transportation, housing, and other life support issues, not the least of which are the various stigma of racism, homophobia, poverty, and often other multiple stigmas. We agree that other chronic diseases often face stigma. However, the HIV stigma cannot be ignored. It has its own particular implications that affect a person's life in many, many ways. It is also multi layered and can affect all aspects of their life. Mental health issues, particularly depression and anxiety disorders and substance use are higher among PLWH than the general population. Stigma mental health issues and substance use issues are significant contributors to non-adherence. Despite that fact, in Washington, 82% of PLWH in care are virally suppressed, the results of adherence. Viral suppression in the United States is only 69.5%. By contrast, diabetes 2 has a medication adherence anywhere from 20 to 55%, depending on the group you're looking at. The two most common reasons cited for this low adherence are lack of physician trust and perceived complexities and convenience of a medication regimen. Viral suppression is a result of a robust system of care in Washington state that is funded by the federal government and Washington State, specifically the Office of Infectious Disease and the Health Care Authority. So my basic ask at this time, and I appreciate the fact that you're making changes in the prior authorization form and the expedited, that you consider including all stakeholders in your conversations because of the bio psychosocial nature of HIV.

Ginni Buccola: Thank you, Lauren. Committee, is there any questions for Lauren Fanning? Okay. I do see that Terra Stone with ViiV Health Care has a better connection. And she still has a minute remaining on her time to

share information with us. Terra, are you there and can we go back to you?

[unrelated discussion]

Ginni Buccola: If Terra can do that then I'll go ahead and actually move to the next speaker and then we can pick up Terra when we know. Okay, so Tony Radovich, member of the HIV Justice Alliance is up next. Tony, are you there?

Tony Radovich: I am, can you hear me?

Ginni Buccola: Yes, I can. Tony, if you could go ahead and introduce yourself. And if you could please make sure you disclose any payments from pharmaceutical companies. Thank you very much.

Tony Radovich: Thank you. Good morning. My name is Tony Radovich. I'm a person living with AIDS and a member of the Washington HIV Justice Alliance and I have no conflicts nor do I receive any payments from Big Pharma. It was just 25 years ago that anti retrovirals became available to people living with HIV. Donna Sullivan's presentation [indistinct] flashback to the 1990s upon the realization that I could not afford treatment because of lack of insurance. Fast forward to now, I am too expensive to be kept alive. Just a few years ago, we were working together to update and modernize HIV laws in Washington state with a goal of eliminating stigma. Thank you so much for stigmatizing me today and also singling me out as a scapegoat and targeting us for individuals highlighting cost analysis in regards to populations that are too expensive. This whole process is making me feel like we are sliding backwards unnecessarily, creating barriers and withholding and delaying life-saving medications from people. This notion that HIV medicine is a one size fits all, is not what it is made to sound to be. Step therapy is a harmful practice that forces patients to prove that a cheaper medication fail to meet their needs before they are permitted to use a drug originally prescribed by their physician. Step therapy is not a practice endorsed by current federal HIV treatment guidelines nor is it anywhere in the governor's proclamation to end AIDS. I am very concerned that the complex health issues of people living with HIV, which my colleague Erick Seelbach pointed out. Those are the people that we must want to reach as populations in regards to

medication adherence and getting them the appropriate care that they need to receive. I also want to point out that a lot of those individuals are unhoused. And lastly, I would like to address attempts at dismissing community members as ill-informed. This notion that a college education supersedes or is more important than the lived experience is both insulting and patronizing and is rooted in patriarchy, privilege, classism, and white supremacy. I appreciate the three minutes. I have [indistinct] this morning. Thank you and have a pleasant holiday season.

Ginni Buccola: Thank you, Tony. I want to pause here for a comment from Dr. Charissa Fotinos.

Charissa Fotinos: Yes, thank you. Good morning, everyone. This is Charissa Fotinos. I am the Deputy Chief Medical Officer for the Health Care Authority. I would like to respond to a couple of the comments I've heard so far from Mr. Radovich and Mr. Seelbach. The intent of Donna Sullivan's presentation in showing the different costs of the medication Apple Health funds was absolutely not intended to in any way suggest that persons living with AIDS are not valuable, are not worth spending any amount of money needed on. The intent was to show that the Health Care Authority is in fact supporting people living with HIV. And it was in no way intended to suggest that people with HIV are lesser than or don't deserve to have money and resources given to them. So I apologize that that is the spirit in which you took that. That was absolutely not the intention. We are bound to follow the laws that we are given to follow. And if there was offence taken by the way in which those slides were represented, please on behalf of the agency, that was not the intent. I want to make that very clear. So again, apologies for any inference that may have caused. It is absolutely not the agency's statement that people living with AIDS are less than or any less deserving than any other group of patients who are covered under Apple Health. Thank you, Ginni for allowing me the time.

Ginni Buccola: No, thank you very much for clarifying that point. And I did want to ask the committee if there had been any questions for Tony. Okay, so we'll move next to Wendy Austin, pharmacist with MetMeds. Wendy, are you there?

Leta Evaskus: Hi, this is Leta. I see Terra Stone on now so can we just finish up her testimony?

Ginni Buccola: Wendy, we'll get to you next. Terra, I'm ready for you when you're there.

Terra Stone: Thank you so much. I apologize. But I did want to just finish up by saying that recent reports from Ryan White and the Kaiser Family Foundation showed people with Medicaid coverage and the uninsured had the least number of persons living with HIV achieving viral suppression. Studies have repeatedly shown patients on single tablet regimens have higher adherence and better outcomes than multi tablet regimens. And in such a vulnerable population with potential polypharmacy issues, guidelines approved single tablet regimens such as Dovato should be made available. And unlike other chronic diseases, HIV remains a public health issue and transmitted resistance can occur unlike other medications or other treatments, such as diabetes medications. The use of single tablet Dovato without restriction provides a safe and effective option for a wide range of patients and provides an additional opportunity for improved outcomes and cost savings for the state of Washington. Thank you and please let doctors and patients choose the right treatment for HIV treatment.

Ginni Buccola: Thank you, Terra. Committee members, do you have any questions for Terra stone? Okay, now Wendy Austin, are you ready to go?

Wendy Austin: Alright, can you hear me now?

Ginni Buccola: I can hear you now. Yes, Wendy, if you could introduce yourself and as with the other speakers, just let us know if you have any payments to disclose or affiliations to disclose. Thank you.

Wendy Austin: Yes, good morning. My name is Wendy Austin. I'm the pharmacist in charge at Metropolitan Medications in Lacey, Washington. I receive no monetary -- any contributions from any pharma. I want to point out first and foremost that pharmacies make money off of generics. So I am here still trying to help my clients get the best treatment. Even though we may lose a little bit of money, I feel it's the best representation for them. My clients are a little confused about using

Truvada when they were on Descovy. I have had a couple go backwards. I have had to tell them the reason because I don't lie to them, that it's a cost saving medication and that we are trying to save cost, especially with the pandemic going on. My clients are not uneducated and my biggest kickback I'm getting back on this is that they are pretty well aware of a certain class action lawsuit that's going on. And while I do explain to them that Descovy has just as many side effects as Truvada, that's not what's being put in front of them. I have been sent requests for pharmaceutical records from a couple lawyers. So I just want that to be known. Also, I kind of want to make a comment on the fact that on Monday, Governor Inslee made a speech about how he is going forward with a plan of stopping inequality. This kind of goes against that message. We want inequality to be ended. And again, even though this is not the message you want to be sending, it is the message that my clients are receiving. I just want you to remember that they're not uneducated. They do know that there are better options out there than what we're presenting to them. And the try and fail is just a disturbing message to them. So thank you for letting me speak. And I hope you guys have a happy holiday.

Ginni Buccola: Thank you, Wendy. Committee members, are there any questions for Wendy Austin? Alright, our next scheduled stakeholder is Dr. Warren Dinges with Seattle Infectious Disease Clinic. Warren, are you there?

Warren Dinges: I am. Can you hear me okay?

Ginna Buccola: Yes, I can. And if you can go ahead and just please reintroduce yourself and let us know if there's any conflicts of interest, including payments from pharmaceutical agencies.

Warren Dinges: Sure. My name is Warren Dinges. I'm an infectious disease and internal medicine physician in downtown Seattle. I've been taking care of HIV patients for my entire medical career and also prep patients. I have a lot of experience with HIV therapy and I've watched it from horrible regimens to now one tablet taken daily that's very well tolerated. Pharmaceutical involvement, I was part of the Descovy trial. My clinic got a large amount of money for that. And I've gotten about 2k a year for the last two years from Gilead so to speak, and that's about it. So, one of the comments I have first of all, is that the DERP, I did kind of go through the full study they had and it can be a

bit mind numbing. I don't know how well y'all followed it as committee members. But I'm an HIV practitioner, know the medications and the studies and it was difficult. So what I'll say is that I noticed that all the quality of evidence was low for 80%. And some was moderate, which means at best, the quality decisions you're making relying on is bad. What I do know is the Descovy trial showed head to head trial, double blind, placebo controlled trial with TAF versus TDF. In every way TAF is safer, highly significantly than TDF. That doesn't mean we can't, and I used Truvada for years. But I also monitor my patients much more closely. I am concerned about this, that you're making changes to a policy and there's no time for feedback as you make the edits today, and we can't really review those and the policy. So that concerns me. I'm also concerned that there is a severe adverse event required before someone can get a medication. And again, I'd like to stress the importance of a single tablet regimen. It's not captured in clinical trials. There's someone monitoring medication use, as opposed to in real life, there's not. The one patient who I have now failing antiretroviral therapy is specifically due to this policy. So that is the impact of it. And I had 100% viral load suppression until this policy was implemented on that patient. And he's just the one. I don't want to have an anecdote. But he's a bellwether and you will see more and you will see renal failure due to TDF use. And I guarantee there will be legal repercussions from those. And it's just reality of the world. In the $40 million that is Medicaid funding that you're talking about $6,000 per patient is the current budget, and a total of less than 6% for the entire Medicaid budget for the state for all medications prescribed. So I also don't like the repeated parallel of dental as if every time someone swallows a pill of Biktarvy or Dovato, they're pulling a tooth out of someone else with Medicaid. It's a fallacious and ridiculous comparison. So, please, single tablet regimens are important. They're required.

Ginni Buccola: Thank you. Committee members, are there any questions for Dr. Dinges? Okay, thank you.

Donna Sullivan: This is Donna. I would just ask Dr. Dinges, if you're saying that a patient was asked to switch medication, I would please contact the Health Care Authority or give me a call because that is not our intent.

And we can make sure that that patient gets the right medication that was successful for them.

Warren Dinges: Can I comment?

Donna Sullivan: Yeah, so the in this case, the problem is it's two separate prescriptions, one for dolutegravir and a separate one for Truvada. And they're two weeks staggered. And there's no way in our current prescribing system for me to write the paired medications that you have to pick up at the same time. So, if you instituted some way, a law that says that when I write something a pharmacy has to dispense both of them, just like a single tablet regimen, that would be great. But right now, the problem is this patient is homeless, he's going between different pharmacies, and they're staggered by two weeks. And you will see that repeatedly. And it was because originally, I wrote Tivicay and Deskovy and the Deskovy was sent to a PA and they filled the Tivicay alone as a solitary treatment, which is outside the standard of care. He finally was then started on Truvada additionally and we can't prescribe two meds at once than guarantee they're filled.

Donna Sullivan: So, again, if you can provide me the patient information, we can reach out to the pharmacies and make sure that they're able to fill them both at the same time rather than having a refill too soon to stop the dispensing of the second drug at the same time.

Warren Dinges: Yeah, but we need a system for that for everybody.

Donna Sullivan: That actually is a system that is allowed for everybody. The pharmacies are able to override an early refill to synchronize medications. So that is a program that is allowed. I'm just offering to try to help for this one particular person that you have identified.

Warren Dinges: I appreciate the help but I think it's most Walgreens and Rite Aids and Bartels don't know that. And it's nothing like the pharmacy that's well supported at the Madison clinic.

Donna Sullivan: Okay, so I think what we'll do, based on that feedback, we'll take a look and make sure that we create a communication that we can share with pharmacies to remind them of their ability to do that. So thank you for your feedback.

Warren Dinges: Thanks.

Ginni Buccola: This is Ginni and our next stakeholder is Dr. Bienvenido Yangco with Madison Kitsap Clinic. Are you there, Bienvenido?

Bienvenido Yangco: Yes.

Ginni Buccola: And if you could go ahead and introduce yourself and of course, make us aware of any conflicts or payments from pharmaceutical agencies. Thank you.

Bienvenido Yangco: I am Dr. Bienvenido Yangco. I'm infectious disease and internal medicine specialist. I have no conflict of interest. I acknowledge and extend my respect to all HIV providers in the state. I'm speaking as an HIV provider on behalf of the HIV patients under my care. I've been providing medical care to patients with HIV in Florida since 1983 when there were no antiretrovirals to offer my patients. I moved here to Washington in April 2018. I have at least 30 years of experience in clinical trials and clinical use of antiretrovirals. I am respectfully requesting the Washington HCA do not restrict and cover newer single tablet regimens with no generic equivalent such as Biktarvy and newer components such as Deskovy which contain a new tenofovir formulation, which we have discussed just recently now as far as its side effects. Essentially TAF has less, no renal and bone adverse effects compared to TDF, which TAF is the new formulation. [indistinct] already contain TAF, which is in your unrestricted formulary. In other states like Florida where I practiced for many years, all of these drugs are in the same tier. [indistinct] is equivalent to Biktarvy [indistinct]. Any practitioner can prescribe this. I wrote a letter to the Washington pharmacy group following my presentation in October raising the issue of keeping some older drugs like [indistinct] and the [indistinct] drugs like [indistinct]. Essentially [indistinct] are the same except for the tenofovir formulation. Knowing [indistinct] of tenofovir -- TAF over TDF, at least from the long term safety standpoint, most HIV clinicians should by now have made a change from [indistinct] [indistinct]. It might be prudent to remove [indistinct] formulary, especially if the state is spending money to stop these medications or cover these medications. These may potentially make room for the not covered, more prescribed

medications. I'm not sure how many people are still using [indistinct] at this time but we still have this as a covered formulary, making our formulary look robust. But there are so many side effects with it and there are some better drugs to it. At this day and age when we cannot offer a cure for our HIV patients, the best that we can do is to give them better tolerated, less potential for adverse events, especially after chronic use and better adherence drugs. And it's my understanding that these drugs are covered by commercial insurance. And so [indistinct] patient should be offered the same as the commercially insured patients as well. There should be the same standard of care for these patients. Thank you very much.

Ginni Buccola: Thank you, Dr. Yangco. Committee members, do you have any questions for Dr. Yangco? I see three stakeholders have their hands raised. I see Stuart O'Brochta.

Leta Evaskus: I have a list going here, Ginni. This is Leta. First up is going to be Stuart O'Brochta from Gilead.

Ginni Buccola: Leta, can you list the stakeholders that are remaining for me?

Leta Evaskus: Sure. Right now I have Stuart O'Brochta, Shauna Applin, Scott Bertani, Dale Briese, Matthew Golden, and Mark Garrett. Stuart, you are up.

Ginni Buccola: Hi, Stuart. Can you hear us?

Stuart O'Brochta: Yes, Ginni, I can. Thank you.

Ginni Buccola: Great. And again, just go ahead and introduce yourself and make sure you give us a full financial disclosure statement. Thank you.

Stuart O'Brochta: Happy to do so. And I believe I'm known by this group. And I'll just remind you I do work for Gilead currently. But previously, I worked for Group Health Kaiser, which I would point out is an evidence based and cost conscious organization, which, Biktarvy, which I'm representing today is their preferred HIV therapy. And I'm also an HIV expert and I've taken care of HIV patients or been involved with their care for over 30 years. You know, I have first-hand experience as I mentioned in managing the toxicities, the older antiretroviral therapies, and the consequences of failed regimens. And this is

primarily drug resistance, has already been pointed out. Drug resistance is a lifelong consequence. And as many have pointed out, the single tablet regimens prevent that. As Dr. Dinges pointed out correctly is that misalignment of refills, either through system issues or through patient mistakes or pharmacies filling drugs that are not HIV competent lead to misalignment and mismanagement of this and resistance is a consequence that you can't go back from. The advantages of the newer, better tolerated drugs is not just convenience. This innovation is critical to the care of HIV patients as Biktarvy being an integrated space regimen with the TAF backbone as already pointed out by many. We've already gone through many of the details of TAF but I want to point out two things: the bone and renal aspects of TAF have been demonstrated in clinical trials. And if we could accurately monitor patients to know who is going to have those adverse effects then I would agree that using a generic alternative, such as TDF, would be reasonable. And we did that often at Group Health. But to date, we do not have a good way to monitor accurately in clinical practice who are going to have or who are going to predict those adverse effects. So waiting until they occur and being able to have to clean up afterwards is not good medical practice. And I would argue against that. The other thing that's been pointed out is the clinical trials. While they are robust and they have shown differences in safety, they do not reflect real world patients. They do not reflect the real world adherence or the potential for patients to not fill their medications or take them correctly when they leave the healthcare setting. They also do not reflect the other comorbidities that people have that could compromise. Now you'd listed those in your criteria but there are many reasons why people could have further issues with going backwards with a TDF based regimen. I see your face so I know I'm getting close to the end. So I'd just like to point out that for all these reasons, I would recommend that as we know right now, we want to follow the science. We're doing that with Covid. We want to follow the science with HIV and give the best patient care to our patients in HIV. And Biktarvy and the other single tablet regimens with TAF offer that and I would respectfully ask that you put them and allow patients and providers to make those choices rather than the Health Care Authority. Thank you very much.

Ginni Buccola: Thanks, Stuart. Committee members, do you have any questions for Stuart?

Nancy Lee: This is Nancy. Hi, Stuart. I was wondering, does Gilead have anything in the pipeline for long term, real world pragmatic clinical trials that do consider all these factors that we are wanting to know more about? I mean, it is challenging to do clinical studies that have a greater external validity or applicability and generalizability. So wondering if Gilead is pursuing that.

Stuart O'Brochta: Yes, thank you, Nancy. It's good to see you again. One of my colleagues from Group Health from way back. So it's nice to hear from you. And it's a very excellent question. There are multiple real world cohorts, but one of the largest is called Big Star. It's primarily a non US based because we have the trio real world cohort in the US. So those are the two large cohorts that are analyzing Biktarvy in the real world setting. I'd be happy to share that information with the committee and point out that they do show differences, not only from persistence but from outcomes. So thank you very much for that question. And I'm happy to share that.

Ginni Buccola: Thank you, Stuart. Any other questions from the committee? Okay, next up is Shauna Applin, lead infectious medicine provider at Community Health Care in Tacoma Shauna, are you there?

Shauna Applin: I am. Can you hear me?

Ginni Buccola: I hear you. If you can go ahead and reintroduce yourself and give us a financial disclosure statement including any payments from pharmaceutical companies. Thank you.

Shauna Applin: Sure. My name is Shawna Applin and I've been an HIV specialist at Community Health Care in Tacoma for the last 14 years. I care for over 500 people living with HIV, most of which are Medicaid insured. And we do clinical trials at this site for pharmaceutical companies. Currently, I'm caring for a 42 year old Caucasian female with HIV who was diagnosed in November of 2009. Over the course of her HIV illness, she has recurrent mersa infections, yeast infections, CMV retinitis that is left her blind, insulin dependent diabetes, leukemia, seizures, Mycobacterium avium complex, cervical spine abscess that required a surgical debridement, AIDS, CVA, which has now made her wheelchair bound, and now multiclass resistance. Just after the

Healthcare Authority's decision to restrict the Medicaid formulary this summer, she was found to be multiclass resistance. After doing resistance testing, tropism testing, and repeat viral load testing, the only fully active regimen found was a salvage combination of Biktarvy and [indistinct]. For a person who is blind and has multiple other barriers, finding a salvage regimen that is well tolerated and only two pills per day is extremely helpful. She was asked to stop her meds on September 2 because of the resistance. I began then a two month process with her United Medicaid plan that included one, multiple prior authorizations where I had to prove things that shouldn't matter when a patient needs a salvage regimen. She had to come back into the clinic via paratransit, which is paid for by Medicaid, just so I could prove she didn't have hepatitis B for the PA form. Two, multiple phone conversations with agents that then transferred me to pharmacists who didn't know anything about HIV. I complained enough that they sent me to a clinical pharmacist based in Minnesota who knew nothing about HIV but was kind and wanted to help. She walked me through an appeal and recommended that I do that. Three, I initiated an appeal that required another round of documentation that included all her labs, chart notes, and a history of her particular story. Four, I had a prior authorization and an appeal cancelled for no reason and no notification. Five, I talked to the clinical pharmacist every other day for two weeks before the approval of Biktarvy went through. The approval is for 12 months and I'm going to have to do this all again in 12 months. In the meantime, the patient had a CD 4 68 and was off meds for two months. She developed sepsis and was diagnosed with meningitis and was hospitalized. I believe this could have been avoided had she had access to a fully active regimen in September that would have suppressed her viral load and helped her immune system to recover to fight the infections that landed her in the hospital and cost United Medicaid much more than the cost of Biktarvy. So my request is, in your PA process that there be a place for salvage regimens where I don't have to go through the reporting status of Hep B, renal and bone status, and all these other history markers when someone is desperately in need of a salvage regimen. Thank you.

Ginni Buccola: Thank you, Shauna. Committee, are there any questions for Shauna Applin? Okay, thank you very much. Next is Scott Bertani with HealthHIV. Scott, are you there?

Scott Bertani: Hey, thanks for the opportunity to speak.

Ginni Buccola: I just want to make sure that you give us a full financial disclosure statement. Thank you.

Scott Bertani: Oh, absolutely. So again, thanks for the opportunity to speak. My name is Scott Bertani and I am part of the HIV Justice Alliance and I serve as director of advocacy for HealthHIV, a national capacity building agency. In the past, I was lifelong AIDS Alliance Director of Policy for 14 years, and the Office of Infectious Disease HIV planning steering groups community co-chair for several. But as the director of advocacy for HealthHIV, I do want to disclose that we received funding from ViiV and Gilead indirectly through Med Ed companies to support National Medical Education programs. And we receive educational grants from Janssen, Merck, ViiV, and Gilead as sponsors of our national synchronicity conference on HIV, hepatitis C, STI, and LGBTQ health. So that's my disclosures. As to this issue, the committee, to be fair, has done non inferiority studies to evaluate the efficacy and safety and tolerability of antivirals, but the P&T committee has to date failed to conduct any kind of equity analysis of the potential negative effects these step therapies and prior authorization decisions have on communicable disease populations, preferring single tab regimens, knowing how disproportionately HIV affects communities of color and LGBTQ people with multiple comorbidities. At a time when we're working together so vigorously to fight health disparities, access to vital, newer HIV class medications should not be made more difficult for the communities most deeply impacted by this epidemic, something the governor, the legislature, the Department of Health in the HIV planning steering group has outlined in its end dates Washington strategy input significant resources into. The whole rationale for expanding Medicaid under the Patient Protection and Affordable Care Act is to combine both aspects of those two federal parts, not simply to think of it in terms of cost alone and has no real conversations or even had with respect to the cost comparisons of drugs. This committee is only getting partial realities to the base world client decisions. Because the pharmacy benefit manager Magellan confidentially negotiates on behalf of the HCA. In July 2017, Donna, when I testified to the P&T committee about this issue, about the use of twice failed therapy protocols back then, at

the conclusion of the meeting, I approached you about our community's concerns. But three years later, the committee's still citing advocacy and blinded cost effectively studies, forums and statutes, not impact studies. We believe the P&T committee is moving in the right direction, going from twice failed to once fail, and now the use of case by case expedited prior authorization forms, but only after the HIV community stepped up to fight for patient accessibility on this issue. Or frankly, we'd still be talking about twice fail therapy protocols. So we're asking once again for the HCA, Sue Birch, Maryanne Lindblad and the P&T committee to use its authority to protect people living with or who are at risk of HIV acquisition by allowing access to all antiviral agents, not simply the ones the committee cites is safely affordable. And thank you for your time.

Ginni Buccola: Thank you, Scott. Committee members, do you have any questions for Scott? Okay, our next stakeholder is Dale Briese. Dale, are you there?

Dale Briese: Yes. Hi, good morning, everybody. Can you hear me?

Ginni Buccola: Yes, we can hear you. Continue with your introduction and give us a full financial disclosure statement including any pharmaceutical ties. Thank you.

Dale Briese: Well, good morning, everybody. My name is Dale Briese and I am from Spokane, Washington. And I'm a 35 year survivor, part of the Washington HIV Justice Alliance, and also a very involved community member in the Spokane area. I have no conflicts and I'm not receiving any pharmaceutical funding. I appreciate the time allowed to speak here today and appreciate the efforts you make in sitting on the HCA board. Boy, a lot has been shared here today. And I'm going to start off with, as a 35 year survivor, the trauma that was introduced earlier in this setting and how I feel more responsible than the responsibility of pharmaceutical cost sharing and what Scott had just shared about how we're not seeing the cost of the medications. And it feels like we're taking the weight of all this energy when the pharmaceuticals should show their intentions to reduce the costs to our communities and also to our state. The biopsychosocial aspect of management of the health conditions needs to be included in the review of any medications on a formulary. Long term management of a disease like HIV takes resiliency and effort. AIDS survivor syndrome is real and it

begins at the time of diagnosis. It is a complex trauma and needs to be reflected upon by the DUR. Policies should be morally neutral. Let me tell you a quick story of me doing volunteering efforts to an HIV positive woman that I have known for years. She is a Medicaid recipient. We met in the era of a serial killer in Spokane as she was high risk of being stalked. She had been homeless for an extensive amount of time in the Spokane community. She just could not decrease the use of substances to make it successfully into any of our community programs. She trusted me as a fellow HIV peer. One day in early 2019 upon seeing her, we sat down and I explained to her about what "u equals u" means. By the way, that hasn't been mentioned in here at all today. And how "u equals u" for her and for me is doing the psychological framework of the HIV positive person, potentially decreasing stigma for us in the community. She got emotional and shared with me that one of the reasons she has not been on medications is that she did not want to cost the state any more money than she already costs the state. She claimed that she gets rolled out on the streets for her medications and that it just did not make sense for her to get them refilled. She then stated if I only had one medication, I could hide it on me close and it would be safe. That's when I let her know that there is a single dose treatment option. She again got emotional and almost motivated at that point but then did get motivated because today, over 18 months later, she is house and undetectable on a single dose regimen. Single dose regimens are key to reducing stigma on many fronts and for gaining normalcy in general as a human with HIV. Let us move towards the future and figure out how to better review these medications and costs for our state. In closing, I want to remind you of the successful efforts of the HIV community and our fellow humans that are advocates for our health have created through the years. This is like Act Up all over again. A body like the HCA should reach out to us to see the successes because we should not change the successes regressively. We should be building upon them. Happy Holidays. Thank you.

Ginni Buccola: Thank you. Any questions from the committee for Dale? Okay, our next stakeholder is Matthew Golden. Matthew, are you there?

Matthew Golden: Can you hear me?

Ginni Buccola: I can hear you, Matthew. Yes, go ahead and introduce yourself and just give us a financial disclosure statement including any payments received from pharmaceutical companies. Thank you. Go ahead.

Matthew Golden: I'm Matt Golden and I direct HIV STD control program for public health [indistinct]. And I've been an HIV medical provider for approximately 25 years. I work in Madison Clinic and at the Max Clinic here in Seattle. I received research support from a company called [indistinct], which makes gonorrhea, chlamydia, syphilis, and mycoplasma [indistinct] diagnostics. That's my only disclosure. So first, I want to just say how glad I am that Tony Radovich received the care he needed. Because he's such a terrific guy and it's always great to hear his voice. So I'm glad you're around Tony. I also want to applaud Washington State's policy and their success in developing a policy that I think balances patient needs with the resources available to treat HIV. I'm optimistic that the policy that they have put forward with some modifications as suggested, will safeguard the comprehensive services we need to provide effective HIV treatment. In my opinion, the newer, more expensive HIV treatments generally offer relatively little advantage over somewhat older medications, often at a very much higher price. I share many of the speakers' perspective that we need to prioritize the needs of the most vulnerable patients. I think the state's policy will do that. It will help ensure that we can continue to provide people with HIV with the services that are most effective in helping them be successfully treated. At an estimated cost of $6,000 per patient per year, switching patients from two pills once a day to one pill once a day is not a most effective intervention in most instances. In fact, it is a threat to success. Comprehensive services, things like housing and mental health services and substance use treatment are much more effective in improving patient care and improving patient's lives. They are also a better value. And it's those services that are jeopardized by the high cost of medication. So I'd like to end by urging everyone on this call to work together to bring down the cost of HIV medication. The solution to this problem is not simply paying the pharmaceutical industry whatever they ask. We need systematic changes in our healthcare system that limit the power of the pharmaceutical industry to constantly increase the cost of care.

Ginni Buccola: Thank you, Dr. Golden. You cut off. It sounded as if maybe you were cut off at the end. Or I'm hoping that that was a natural finish.

Matthew Golden: That was what I had to say.

Ginni Buccola: Okay, good. Thank you very much. Any questions from the committee? Okay, great. Thanks again. And then moving next to Mark Garrett. Are you there, Mark?

Mark Garrett: Hi, everyone. Thank you for letting me speak. And I appreciate what's trying to be accomplished here. But I support my --

Ginni Buccola: I'm so sorry. I just want to make sure that you must have full disclosure statement before you start. Thank you so much.

Mark Garrett: I don't receive any money from pharmaceuticals, although I do invite them to do educational presentations and Eat-and-Learns, which are paid for directly by them and I will continue to do that.

Ginni Buccola: Mark, could let us know who you're affiliated with? I'm so sorry that I don't have that information.

Mark Garrett: Yeah, actually I am a co-facilitator for our HIV AIDS advisory board at Spokane Regional Health District. I'm a member of the CDC MMP medical monitoring project and have been since its inception. And I've been chair and co-chair of most of the state care and local care prevention planning groups.

Ginni Buccola: Thank you so much. Please feel free to go ahead.

Mark Garrett: You betcha. I am a 33 year survivor and most of the times thriver of HIV and I'm happy that we are talking about this being a chronic illness, but a very unique chronic illness. I currently take Prezista, Tivicay, and Deskovy. However, I took a TDF containing regimen for a number of years and I believe as a consequence, I've had three bone fractures, two spinal surgeries, the last one was about eight weeks ago, and I'm now receiving the bills. I am a proponent and have been for over 20 years now, it is my career to make sure that people's lives are improved with HIV and that we prevent new infections. We know that single pill regimens work and prevent nonadherence to a greater

degree than two-pill regimens. I currently take 14 pills a day, four of them in those three drugs treat my HIV. The rest treat the side effects and other conditions and mental health. I suffer from cognitive issues. I'm highly functioning but have had to go to pre-packaged pill containers so that I can keep track of the medications. We work with enfranchised communities in our area, disenfranchise, I should say. We've heard statistics on even the Covid vaccine that the African American community and maybe other disenfranchised communities will have a greater distrust for that treatment. That's the same for HIV. And many of us have worked very hard and have been very excited to finally see single regimen treatment come into play. I am concerned now with this kind of approach to cost and long term effects and outcomes when we right down the road have long term injectables that are about to be approved. And I'm wondering what this committee would do. I'm also wondering if your child, maybe a young man or young woman who had contracted HIV would be comfortable with them going on TDF and incurring the side effects to the point where they may qualify then to go on to the safer medication. There's a moral, ethical issue here and I would not want to be the doctor prescribing that treatment, knowing it's going to cause harm. We know that adherence leads to undetectable viral loads. Undetectable means you are unable to transmit the virus sexually. That's huge. So let's keep moving forward. I think this is a rushed process and something that should be slowed down a little bit. Let providers provide some input now on that preauthorization form. Look at a better system for getting community input. Thank you very much and happy holidays to all of you.

Ginni Buccola: Thank you very much. Committee members, do we have any questions for Mark? Okay and then our last listed stakeholder is Jonathan Frochtzwajg with Cascade AIDS Project. Jonathan, are you there? out there.

Jonathan Frochtzwajg: Yes, hi. Can you hear me?

Ginni Buccola: I can hear you. Yes, if you can go ahead and give us your introduction and your affiliation and then a financial disclosure statement including payments from pharmaceutical companies. Thank you.

Jonathan Frochtzwajg: Yeah, great. My name is Jonathan Frochtzwajg. I'm here on behalf of Cascade AIDS Project. I'm the public policy and grants manager. We receive unrestricted contributions from pharmaceutical companies. But as Erick Seelbach noted, we receive far more from the state of Washington and comparable amounts from private payers. CAP is opposed to prior authorization requirements for many of the reasons other stakeholders have already raised up. But that said, I appreciate the revisions that have been made to this policy and for today, I just actually wanted to ask a couple of questions. The first is along the lines of the discussion about mental illness. I'm wondering how severe substance use disorder is defined and whether that requirement leaves room for providers to determine when substance use disorder is going to be a barrier. I also had a question about the appeal process. I've heard Donna Sullivan offer several times in this meeting and previous meetings to resolve issues that people who have come here and testified have raised. And that's very generous. But the appeal process should not be to contact Donna Sullivan. So I am just curious if providers are aware of how to pursue an appeal. 'Cause we heard from Shauna Applin that that process is often not very smooth. And then, this isn't a question but I wanted to raise an issue. Earlier, I think Donna noted that homelessness was not considered a situational factor in the prior authorization process. But we've heard from several folks who have testified that homelessness really -- it seems like there should be a way to capture that, given that that's something we at CAP see among our clients. Theft of medication is a really common issue. Transportation barriers that come along with that. So I would just encourage that in the interim we consider making those changes to the prior authorization process.

Ginni Buccola: Thanks, Jonathan. Donna Sullivan, are you there?

Donna Sullivan: Yeah, I'm here. So Jonathan, I just wanted to respond back to you. And I want to make it clear, I'm not promoting that the appeals process is to contact me. What I'm really wanting is when providers are experiencing situations where a patient might have been inappropriately denied their medication, where a plan might not have followed the policy, to contact me so that we can work with the plans and make sure that they get those approvals in place. The appeals process is submitted to the provider and the patient whenever there is a denial. And so it does go out to them. So what I'm asking for is if

providers are having difficulty getting a patient the medication according to our policy, then I can step in and make sure that we educate the plans on those procedures.

Ginni Buccola: I believe we have heard from all of the stakeholders. I want to check with Leta.

Leta Evaskus: I see that Dale has his hand raised again. Just wanted to check. Dale Briese, did you want to speak again?

Dale Briese: No, I'm fine. Thank you. That was accidental. Sorry.

Leta Evaskus: Okay, thank you. That's all the stakeholders.

Ginni Buccola: Great. And thanks again to all the stakeholders for your patience and for taking the time to share information with us. So this is the time when we are going to move as a committee to consider the motion. So if my committee members are free to activate their cameras and come join me. And you're not my committee members. The committee members. I seem to have taken ownership of all of you, which is not the case. I'm being facetious, for the record.

Marissa Tabile: Hi, Ginni. This is Marissa. I'll go ahead and start with the drug class motion first for the antivirals, HIV, and antivirals HIV combinations. And then after that, I'll move to the policy.

Ginni Buccola: Okay. Thank you.

Marissa Tabile: If the committee has had adequate time to consider, I'll pause for a moment if anyone wants to speak up. Otherwise I'm going to make a motion.

Diane Schwilke: So this is Diane Schwilke. I move that all products listed in the drug classes on slide two 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. Non preferred products in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least one preferred regimen.

Jordan Storhaug: This is Jordan Storhaug. I'll second.

Ginni Buccola: All those in favor, please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? The motion carries.

Marissa Tabile: Hi, this is Marissa. Here is the policy motion.

Leta Evaskus: Sorry to interrupt. This is Leta Evaskus. Was there something that was supposed to be added into the motions from Alex Park's comments on the policy?

Marissa Tabile: Yeah, it's in regard to number nine on the policy, I believe.

Donna Sullivan: This is Donna. That was on the form. So that's not really part of the policy. That's just the form that we create. So we'll wordsmith that to try to make it more clear. And we'll add this renal function decline by 25%. And the clarification that it is for mental illness that is poorly controlled.

Leta Evaskus: Okay, thank you.

Alex Park Ginni and Donna, it's Alex Park. Can I ask a procedural question?

Ginni Buccola: Yes, please.

Alex Park: So if we as the DOR board approve the clinical criteria on the policy, what happens to that policy when it goes to HCA in terms of any options that they have for amending it further at that point?

Donna Sullivan: Hi, Alex. This is Donna. So what our process is, you know, it's actually a pretty long drawn out process. We have three internal reviews where the pharmacists develop the policy and then it gets reviewed internally amongst the staff clinicians, and it goes to our coverage parameters meeting. It then also goes to the managed care plans for them to review it with their clinical staff prior to it coming to the DOR board meeting. So when we bring it to you and present it, it's pretty

well complete or as complete as we have been able to make it. And then that's where we're asking for your feedback. So once we get your feedback, we will incorporate that into the policy and then it goes back out to the managed care plans for one final review. And then it will get implemented. And it usually takes about 90 days for us to implement it. This particular policy that has already been implemented but we will make these changes as soon as possible. So I hope that answers your question.

Alex Park: Thank you. That's good to know that the managed care plans have an opportunity to re-review it after our work. Thank you.

Mark Garrett: So it's Mark again. I'm sorry to ask one more question, Donna. In terms of the cadence of when the policies are re-reviewed, when does this come up again for re-review?

Donna Sullivan: We shoot to get them reviewed at least once per year. Sometimes we'll do a review more frequently if there are significant changes within a class where either new drugs or new indications that were not previously addressed.

Mark Garrett: Thank you. Well, if the committee has had adequate time to think about this, I would move that the Apple Health Medicaid program implement the clinical criteria listed on policy 12.10.99-2 as recommended with the addition of the criteria for renal function and clarification for mental illness as noted on the slide.

Susan Flatebo: This is Susan Flatebo. Second.

Ginni Buccola: All those in favor please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? The motion carries. This is Ginni. Just checking in with the committee members to see if there's any need for further questions.

Diane Schwilke: This is Diane Schwilke. I move that the Apple Health Medicaid program implement the criteria listed on policy 12.10.99.02-2 as recommended with the addition of criteria addressing renal function

decline by 25%, as well as clarification for mental illness being poorly controlled.

Mark Garrett: This is Mark. I second.

Ginni Buccola: All those in favor, please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? Motion carries. Does that conclude the motions that we needed to make, Marissa?

Marissa Tabile: Hi, Ginni. Yep, that takes care of it.

Ginni Buccola: Okay, thanks, committee members. I believe then we're ready to break for lunch unless there's any last minute pieces of work that we need to take care of.

Leta Evaskus: This is Leta. No, I think we're ready for lunch. We can take a half hour break and reconvene at 12:50.

Ginni Buccola: Thanks, everybody have a good lunch.

[break]

Ginni Buccola: Hi everybody. This is Ginni. We're just coming back from lunch and we're going to start the afternoon by hearing from Umang Patel with Magellan on analgesics, opioid agonist-long acting. Umang, just let me know when you're ready to go.

Umang Patel: Alright, there we go. Okay, so we'll get started with the therapeutic class reviews that we have scheduled. I do want to remind the committee that in terms of the classes that are reviewed, we do look at significant clinical update within the last one year. If it's been over a year, I either keep it in the slide as a reference but I won't go over it in detail for the committee's sake, or I have it in the appendix at the very end, for your leisure to review as well. And if it's not there, there's also additional comprehensive information in the therapeutic class reviews that are in the portal login that Leta sent to you. For the classes where we will go over relevant clinical information, there will

be an overview and disease state, any relevant updated indications or dosages or formulations along with guidelines as well. So if we go to slide four, the first class we'll be reviewing is the opioid long acting analgesics. Just to give a little background, while definitions vary, chronic pain is defined as pain lasting three months or longer, or past the time required for normal tissue healing. It has various etiologies, including injury, inflammation, and underlying medical conditions. Historically, data has suggested that pain may be undertreated but newer estimates imply that opioid treatment for pain may be over utilized. An estimated 20% of patients presenting to outpatient providers with non-cancer pain or pain related diagnosis, whether acute or chronic, receive an opioid prescription. In 2018 15% of the US population received one or more opioid prescriptions. Annually, from 2012, there has been a continued decrease in prescribing. Likewise, the yearly rate for high dose opioid prescriptions has decreased by 66% as well. Unfortunately, about 67,000 people have died from overdoses related to opioid pain medications in the US, and the related overdose deaths were higher among males than females, 20% to 9%, respectively. Despite this, the persistent pain that is uncontrolled may have clinical psychological and social consequences. Thus, it is critical to weigh the risks and benefits of opioid use and reevaluate patients routinely for appropriate dose, duration, and treatment choice. And this includes both pharm and non-pharmacological agents. On the next slide, there was a new guideline update by the Department of Health and Human Services last year. In October 2019, they published guidelines discussing the risk of opioid taper and they essentially advise the opioid should not be quickly tapered or discontinued abruptly due to potential withdrawal, which can result in symptoms such as pain exacerbation, psychological distress, and suicidal ideation. Except for life threatening circumstances such as impending overdose, it is not recommended to abruptly reduce or discontinue an opioid. The guidelines went into specific details, situations when it may be appropriate to taper to a reduced dosage, such as pain improvement, patient request. I apologize. There seems to be a comment saying -- is there difficulty seeing me or hearing me right now?

Ginni Buccola: This is Ginni. I can see you and see your slides but I can’t speak for everybody.

Woman: Everything looks good to me too.

Umang Patel: Thank you. Sorry, I just got a little pop up saying connection may have been lost. Okay, I'll continue onward. Other key recommendations include referring patients with serious mental illness, high suicide risk, of suicide ideation to behavioral health provider prior to tapering, assessing patients for opioid use disorder if they show signs of opioid misuse, and offering medication assisted treatment if appropriate. Advise patients for risk of overdose if they abruptly returned to their higher dose, tapering by five to 20% every month, but longer tapering schedules may be required and considering transition to buprenorphine for patients on high doses if they're unable to taper. On the next slide here, we have the guidelines from the National Comprehensive Cancer Network, NCCN, that came out last year as well. And on here you see the published guidelines on the treatment of cancer pain in adults in 2019 specific to pain scale rating, on a scale of zero to ten. The pain scale is a rating of one to three if it's mild, four to seven it's moderate, and eight or more is severe. The recommendations in opiate naive patients with mild pain is non opioid or adjuvant therapies unless contraindications due to adverse effects on current drugs. For moderate, they recommend adding a short acting opioid if needed. The guidelines define opioid tolerant patients by the FDA definition, which is a patient receiving at least 25 micrograms per hour, fentanyl patch, at least 60 milligrams of morphine daily, at least 30 milligrams of oral oxy codeine daily, at least eight milligrams of oral hydromorphone daily, or an equal analgesic dose of another opioid for a week or longer. The guidelines recommend for opioid tolerant patients is the same as opioid naive patients except that they specify titrating shorter acting opioid doses by 30 to 50%. Recommendations for both opioid naive and tolerant patients include opioid rotation, so limiting adverse effects are noted and opioid reassessment of efficacy and adverse effects in one to four weeks. Long acting opioids are recommended if three to four daily doses of short acting opioids are consistently needed. If pain is persistent, they recommend that the opioid should be scheduled with the rescue dose as needed. Consideration for treatment in the hospital or hospice setting for patients' specific goals is recommended if the pain is eight or higher. They recommend against the use of meperidine due to CNS toxicity and mixed agonist-antagonists, due to limited usefulness for cancer pain. And lastly, they recommend to

consider supplementing with doses of short acting opioid when using methadone as a long acting opioid. And they also provide extensive guidance on dosing adverse effect management campaign assessment. On the next slide here, we have our final guideline updates. And this is by the American College of Physicians and American Academy of Family Physicians. And this year, they published new guidelines on managing acute pain associated from non-low back musculoskeletal injuries in adults who were outpatient. Recommendations are provided for nonpharmacologic and pharmacologic treatment modalities. Clinicians are recommended to treat patients with topical NSAIDs with or without menthol gel as first line therapy to decrease or release symptoms and to improve physical functioning and the patient's treatment satisfaction. It is suggested that clinicians treat patients with oral NSAIDs to reduce or relieve symptoms and improve physical functions or with oral acetaminophen. Additionally, it's suggested that clinicians treat patients with specific acupuncture for reduction of pain and improvement of physical functioning or with transcutaneous electrical nerve stimulation to reduce pain. And lastly, it's suggested against clinicians treating patients with opioids including Tramadol. On the next slide here, just some announcements, changes. The FDA last year announced changes to the transmucosal immediate release fentanyl or TIRF REMS program. Changes include requiring prescribers to document a patient's opioid tolerance concurrently with each prescription of a TIRF medicine for outpatient use, requiring inpatient pharmacies to develop internal policies and procedures to verify opioid tolerance in hospitalized patients requiring TIRF medication. And TIRF meds for outpatient use must have evidence or other documentation of safe use conditions including concurrent documentation of tolerance and requiring the development of new patient registry to monitor for serious adverse events, which includes overdose, both fatal and non-fatal. Last year, the CDC clarified that their guidelines in opioid prescribing are not intended to deny opioid therapy for pain management for any patients with chronic pain, particularly in patients with sickle cell disease, undergoing cancer treatment, and cancer survivors with chronic pain. It aims to ensure that clinicians and patients consider all safe and effective treatment options. On the next slide here, there was a new DEA communication in April 2020. The DEA published their edition of drugs of abuse resource guide. Last time it was updated was 2017. It now includes information on drugs origin, street names,

mode of abuse, effects, and legal status in the US. And it also includes information on vaping as well as updated info on fentanyl, marijuana, and stimulant drugs. FDA communication in September 2020, the FDA issued warning letters to 17 website owners for the illegal sales of unapproved or misbranded opioids. And this includes those sold without a prescription and products without adequate direction for use. And there was a new generic in January 2024 for hydrocodone extended release. It's the first generic for Zohydro ER, which was approved by the FDA from Alvogen. It has launched its generic formulation and in addition, Macoven has launched an authorized generic of this hydrocodone extended release as well. On the next and final slide for this class, there was another FDA communication that came out about six months ago. The FDA released a drug safety communication and a MedWatch for opioid pain relievers and opioid use disorder agents, recommending healthcare practitioners discuss and consider naloxone use with all patients at time of prescribing. FDA is requiring manufacturers for all opioid pain relievers and OUD treatments to add recommendations on naloxone to the product labeling for healthcare practitioners to discuss and consider prescribing naloxone. When these meds are prescribed or renewed, the FDA is recommending the potential need for a naloxone prescription be evaluated. Corresponding updates will be made to the med guides. In addition, for patients that are not receiving a prescription for an opioid analgesic or od treatment, consideration should be given to prescribing naloxone for them if they are at higher risk of opioid overdose. For example, if they've had a current or prior diagnosis of OUD or a prior opioid overdose. The FDA also recommends practitioners consider prescribing naloxone when the patient has a household member such as children close contact who may be at risk for accidental ingestion. In terms of discontinuations, there was a discontinuation for Embeda, again, morphine sulfate naltrexone in October 2019. Pfizer discontinued manufacturing and distributing all strengths of Embeda capsules. The stop sale date was November 15 of last year and the anticipated availability timeframe was up until early this year. And lastly, there was a discontinuation for Duragesic, which is fentanyl extended release film. The FDA reported that Janssen will be permanently discontinued as a business decision. And again, this is only brand name that will be discontinued. The FDA is recommending product remain on formularies until July 31, 2021

when the last batch expires. That is all I have for this class. I'll go ahead and pause there for the committee.

Ginni Buccola: Thanks, Umang. Any questions from committee members? Okay, and I don't see any listed stakeholders. Leta, do we have anybody?

Leta Evaskus: Hi, this is Leta. I'm going to check if there's any hands raised. I do not see any. So, I'm going to bring up the motion here.

Ginni Buccola: Thanks. Committee members, if you want to turn your cameras on, we can take a look at this and get ready to make a motion.

Leta Evaskus: Let me know when you're ready for me to go to the next slide.

Ginni Buccola: I think we're okay. Is everybody okay? Move to the next slide? Yep.

Jordan Storhaug: This is Jordan Storhaug. I move that all products in the analgesics opioid agonist long acting drug class are considered safe and efficacious for the medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in this class may require prior authorization to determine medical necessity. All non-preferred products require a trial of two preferred products for the same indication before a non-preferred drug will be authorized unless contraindicated, non-clinically appropriate, or only one product is preferred.

Catherine Brown: Catherine Brown. I second.

Gina Buccola: All those in favor please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? Alright, motion carries. Okay, so we'll move back to Umang who will review antiemetics and anti-vertigo agents.

Umang Patel: Perfect, thank you. Alright, on the next slide, just a little background. So for antiemetic and anti-vertigo agents, as you can imagine, they're kind of split apart. For antiemetic, chemotherapy induced vomiting or emesis and nausea can significantly impact the patient's quality of life, leading to poor compliance with future chemotherapy or radiation

treatments. In addition, nausea and vomiting can lead to several adverse events such as nutrient depletion, metabolic imbalances, erosion of self-care, anorexia, diminished performance and mental status, wound dehiscence, tears in the esophagus and cessation of potentially useful or cured of cancer treatments. Approximately 70 to 80% of all cancer patients receiving chemo experienced nausea and/or vomiting whereas 10 to 44% experienced anticipatory nausea and/or vomiting. Furthermore, more than 90% of patients use highly emetogenic chemotherapeutic agents and will experience acute emesis, however, only 30% of these patients will experience a vomiting episode if they receive an antiemetic prior to their highly emetogenic chemotherapeutic agent. On the next slide, in terms of the anti-vertigo, motion sickness is a result of a conflict between the various senses in regard to motion. The overall incidence of dizziness, vertigo, and imbalance is about five to ten%. There are multiple causes of vertigo such as trauma, head trauma specifically, cerebellar lesions, vestibular disease, or migraine. Symptoms include nausea, vomiting, pallor, sweating, and often a sense of impending doom. There are both non pharm and pharmacological interventions for the prevention of poor management of motion sickness. None are ideal and the medications typically cause drowsiness or similar adverse effects. Symptomatic treatment of motion sickness generally includes the use of anti-histamines, benzos, or antiemetics. And vestibular rehab rehabilitation in select patients may be used with the goal of treating the underlying cause. Morning sickness or nausea and vomiting of pregnancy can occur at any time of day. It can affect pregnant women with varying symptoms from nausea, severe vomiting. Lifestyle changes for women with nausea and vomiting of pregnancy include rest, avoid nauseating stimuli, eating small frequent, low fat meals that are low in spices. On the next slide to pivot over to updated guidelines, again, the NCCN guidelines updated and they recommended the choice of antiemetics should be based on the emetic risk of the chemotherapy, prior experience of antiemetics, and patient factors. It should be initiated prior to the start of chemo to provide maximum protection against chemotherapy induced emesis. The therapy agent should be continued for the same timeframe as the duration of the emetic activity of the chemo agent being used. The guidelines identify and emesis prevention treatment options for high, moderate, low, and minimal emetic risk, IV chemo, oral chemo, and radiation therapy as well as breakthrough treatment for chemo

induced nausea and vomiting. To prevent acute and delayed emesis in patients with IV, high emetogenic chemo risk, three or four drug combinations of a NK1 receptor antagonist, a five HT3 receptor antagonists on day one, and dexamethasone day one through four with or without olanzapine days one through four are recommended. Or a three drug regimen of olanzapine, palonosetron, and dexamethasone may also be used. Continuing on the next slide, these guidelines were broken down further. So patients who have IV MEC, so moderate risks, they recommend a 5-HT3 antagonist and dexamethasone as a three day regimen. NK1 antagonist can be added on for select patients with additional risk factors or previous treatment failures of the steroids and 5-HT3 antagonists alone from days one to three, based on the treatment regimen selected. The guideline does not specify one 5-HT3 antagonist or NK1 over another. And equivalent alternatives to this include a three day olanzapine containing regimens. So that would be olanzapine, palonosetron, and dexamethasone that I alluded to in the previous slide. For low emetogenic risk chemo, dexamethasone and Metoclopramide or prochlorperazine or an oral 5-HT3 antagonist may be used and repeated daily for multi-day doses. There's no routine prophylaxis for patients who receive minimum emetic risk IV for breakthrough treatment of chemotherapy induced nausea and vomiting. The general principle is to add one agents in different class as needed to the existing regimen. And that can be things like antipsychotics, benzos, cannabinoids, dopamine receptor antagonists, phenothiazine, 5-HT3 antagonists, scopolamine, or corticosteroids. For radiation induced nausea and vomiting associated with the upper abdomen or localized site or total body radiation, oral granisetron or ondansetron with or without oral dexamethasone as pre-treatment for each day of therapy is recommended. Alright, on the next slide, here, we have a new medication. And again, just to remind the committee, I tend to try to bold the relevant information. And since this is a new medication, everything is bolded. And then if there are new formulations or indications, I try to bold just the relevant updated parts. So in February 2020, Barhemsys was approved by the FDA, indicated in adults for either prevention of post-operative nausea and vomiting, either alone or in combination with an antiemetic from a different class and it was also indicated for treatment of post-operative nausea and vomiting in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis. So,

as you can see the indications. In terms of limitations there, there are a few, one being QT prolongation. So, as one can imagine, it occurs in doses and concentration dependent matter and is recommended to avoid in patients with either QT syndrome already or medications that may cause QT prolongation an ECG is recommended. Another limitation is lactation. A lactating woman may pump and discard breast milk for 48 hours after administration of this medication as it can be passed. In terms of dosing, as you can see here, it is stratified by the two indications and the formulations are all injections in single dose vials there at the bottom. In terms of other special populations, so for pregnancy, the available data for this is insufficient to establish a drug associated risk. And for renal impairment, there's no dose adjusted needed for mild to moderate but it is recommended to avoid in severe renally impaired patients. On the next slide, we have Gimoti. That was approved in June 2020 by the FDA. And it's technically a new formulation of Metoclopramide in the form of a nasal spray. So technically it's a new medication, but its mechanism of action is an aerosol nasal spray of an existing medication. Again, it is indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. Limitations, it is not recommended for the use in pediatric patients and moderate or severe hepatic impairment defined as Child-Pugh B is in beta or C as in Charlie. It is recommended to avoid in patients with depression or suicidal ideations. And lastly, there is a black box warning for this medication for tardive dyskinesia and other EPS symptoms and neuroleptic malignant syndrome. The dosing is stratified by age based here and as I mentioned earlier, is a nasal spray. It's essentially 15 milligrams of metoclopramide in a 70 microliter spray. And on our next and final slide for this class, we have a Akynzeo. And so in August 2020, the FDA approved a new dosage form of the injection, which is a solution in a single dose 20 milliliter vial for IV infusion and it contains 235 milligrams of - and I apologize for my pronunciation here - of fosnetupitant and .25 milligrams of palonosetron. Previously it was only available as a capsule of this two combos and a lyophilized powder in a single dose vial for reconstitution. Again, I didn't bold anything else out of the formulation since that was the only update here. As you can see, the indications, limitations, and dosing all remain the same and are here for the committee. And, again, the updated formulation is a new injection in the single dose vial here. I'll pause there for the committee and see if there are any questions I can answer.

Ginni Buccola: Thanks Umang. Committee members, any questions? Leta, do we have any stakeholders?

Leta Evaskus: Just checking really quick. No hands raised so we can go to the motion.

Ginni Buccola: Okay.

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

Nancy Lee: This is Nancy. I second that motion.

Ginni Buccola: This is Ginni. All those in favor, please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? Alright, the motion carries. Thanks, committee members. We'll go back to Umang to review antihypertensives.

Umang Patel: Perfect. Alright, so the next class is antihypertensives. And this, according to the Apple Health kind of breakout includes direct renin inhibitor combinations, direct renin inhibitor sole medication, and ARNI angiotensin two receptor antagonists combinations as well. It's just to kind of give the committee example. So direct renin inhibitor would be things like Tectura hydrocortisone combo, direct renin inhibitor in turn would then just be Tectura, [indistinct] and ARNI would be Entresto. On the next slide here, again, quick little background on hypertension. Approximately 108 million or 45% of adults in the US have high blood pressure along with one in three Americans having prehypertension. The highest prevalence is among African American men and women. Approximately 54% of African

American men and women have high blood pressure compared to about 46% of white men and women and 39% of non-Hispanic Asians and 36% of Hispanics. It is estimated that hypertension is controlled in only about 54% of those with the conditions. On the next slide, the only relevant updated clinical information was regarding Entresto which, as you may recall, I said was ARNI. So Entresto, which is a combination of sacubitril and valsartan, in October 2019, FDA approved a new indication for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients one year of age or older. It already has a second indication here for heart failure patients with chronic heart failure in stage two to four with reduced ejection fraction. And now this pediatric indication has been added on. In terms of warning and precautions, as you can imagine, it is pregnancy category X because of it being an [indistinct]. Monitor renal function, potassium, and blood hypotension Naidu edema, as this is a blood pressure medication. Dosage for this is stratified by indication weight based and that can be found in the TCR or in the package [indistinct]. And it is a film coated tablet as well. In terms of this medication for special populations, again, avoiding pregnancy, patients who are pregnant, in renal dose impairment. There is dose adjustment recommendation for severe renal impairment, which is GFR less than 30. And there is a hepatic dose adjustment recommended for moderate to severe hepatic impairment, which is Child-Pugh B as in beta or C as in Charlie. I know this class is short and sweet so I will pause right there for the committee if there are any questions.

[unrelated discussion]

Ginni Buccola: We could go to stakeholders and I believe that we have a stakeholder from Pierre Fabre Pharmaceuticals, Dylan Bassett.

Dylan Bassett: Hi, Ginni. Hi, Umang. This is Dylan. Can everyone hear me okay?

Ginni Buccola: Yes, and Dylan, just state your affiliation and if you have any disclosures such as your association with [indistinct].

Dylan Bassett: Absolutely. Thank you, Ginni. Hello, all. Good afternoon. My name is Dylan Bassett. I'm a pharmacist and I am part of the medical affairs team at Pierre Fabre, a French pharmaceutical company in New

Jersey. I'm here today to talk about hemangeol. So first off, thank you for the opportunity. I'm going to kindly request the committee to consider placing hemangeol, the only FDA approved drug for infantile hemangioma, or IH on the preferred drug list. IH is the most common tumor of infancy affecting approximately three to five percent of all infants born in the US. Among the 20,000 IH patients a year, some will present with severe complications that are potentially debilitating and associated with life threatening conditions. These include but are not limited to airway obstruction, congestive heart failure, functional impairments, such as vision, hearing, or feeding impairment, and ulceration with bleeding and pain. The majority of these patients are at risk of permanent disfigurement if these lesions are untreated or untreated or mismanaged. It is highly likely that they will lead permanent disfigurement or scarring. Hemangeol is the only FDA approved drug indicated for the severe forms of IH. It was developed in compliance with existing guidelines for pediatric drugs and evaluated to ensure efficacy, safety, ease, and acceptability of use for these young pediatric patients. It is the only beta blocker that has been evaluated by a randomized double blind placebo controlled clinical trial for efficacy and safety with the primary endpoint being complete or near complete resolution of the target hemangioma. The most common adverse effects that were seen are sleep disorders and respiratory infections. But these are not unique to just hemangeol and these are also seen in other oral beta blockers and also in adult formulation of propranolol. If the affected children in Washington don't receive hemangeol, they will have the adult solution of propranolol which is not well tolerated because it contains alcohol and [indistinct], which induce osmotic diarrhea. The constant and chronic diarrhea is a real struggle for the families during treatment. It is also formulated with flavors that are not well tolerated by infants. So consequently, adherence is decreased and the duration of treatment is longer with poor outcomes. I would like the members of the committee to realize that we are referring to very small babies, most of the time premature babies suffering during their first months of life with a condition that can have lasting detrimental impacts on their social, psychological, and emotional well beings as well as their immediate families. It's important to remember in the state of Washington, we're only dealing with about 30 children a year who need to be clinically treated for IH. In 2019, the American Academy of Pediatrics published a clinical practice guideline for the management

IH and here are two quotes from this guideline: Quote one: Oral propranolol hydrochloride hemangeol was approved by the FDA for use in proliferating IH requiring systemic therapy. This therapy has now replaced the previous gold standard therapy. Quote two: Infantile hemangioma is a disease with a window of opportunity to intervene and prevent poor outcomes in this critical timeframe for optimizing outcomes can be missed if there are delays in treatment. In conclusion, hemangeol was the only safe treatment option for infants affected with severe forms of infantile hemangioma. Therefore, we asked that the committee consider placing hemangeol on the preferred drug list. Thank you so much for your time today.

Ginni Buccola: Thanks very much. Committee, do you have any questions for Dylan? Okay. Alright, so then we can come on as a committee and look at the motion.

Nancy Lee: This is the Nancy. I move that all products listed in the drug classes on slide 10, are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in this class may require prior authorization to determine medical necessity. All non-preferred products require a trial of two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated of not clinically appropriate.

Connie Huynh: This is Constance Huynh. I second.

Ginni Buccola: This is Ginni Buccola. All those in favor, please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? Motion carries. We'll move to the next topic, antivirals, Hepatitis C agents.

Umang Patel: Alrighty, so the next topic will be Hep C. This one will be a little bit more overarching than the previous one. For Hep C here, to give a little background, Hep C infection is the most common chronic blood borne infection in the United States, approximately 15 to 25% of patients who become infected. The virus is eliminated during the acute phase of the infection which T cell-mediated antiviral

mechanisms occur. However, in the other 75 to 85% of patients, it can persist for decades. An estimated 23 to 46,000 children in the United States have Hep C. New infections in children are primarily the result of perinatal transmission from mother to child. Approximately 2.7 million people in the US are chronically infected. Although it is estimated that nearly 75% of these people may be unaware of their infection due to the insidious progression of the disease. Hep C does account for 40% of chronic liver disease in the US and in patients with chronic Hep C infections followed for 20 years. The disease progression to cirrhosis occurs in about 20 to 25%. Transmission occurs primarily through percutaneous exposure to infected blood, and the most important risk for Hep C infection is injection drug use, which accounts for at least 60% of acute Hep C infections in the US. Other modes of transmission include mother to infant, receiving a blood or organ donation prior to 1992, occupational exposures, chronic hemodialysis and contaminated devices sharing for non-injection drug use such as intranasal illicit drug use. Sexual transmission also occurs, but generally seems to be inefficient, except among HIV infected men who are having unprotected sex with men. Other risk factors include incarceration and receiving a tattoo in an unregulated setting. It is estimated that 29% of incarcerated persons in North America are anti Hep C positive. On the next slide here, we see that there were slight little updates here for the US Preventive Services Task Force in 2020. They expanded the population for a one time screening to asymptomatic adults 18 to 79 years of age. Similarly, joint guidelines for the American Association of liver disease and IDSA recommend a one time routine opt out Hep C treatment for anyone 18 years of age or older. This year, the CDC recommended that in areas where Hep C infection is at a rate of greater or equal to .1% all adults be screened at least once for Hep C virus and all pregnant women be screened during each pregnancy. On the next slide here, there was a slight update to those AASLD/IDSA Hep C guideline recommendations. The guidelines as you can imagine, are extensive. However, this was kind of the main treatment guideline update and I wanted to put it here. So as you can see, it stratified by any genotype, simplified treatment and any genotype, and its treatment naïve, treatment experienced, and previous treatment as well. And so it is stratified by [indistinct]. And so glecaprevir and pibrentasir is going to be [indistinct]. We have sofosbuvir, velpatasir - which is [indistinct] - and then adding [indistinct] plus sofosbuvir. And we have Vosevi, the

triple combo as well. And so it's broken down by treatment, duration, and the clinical rating level as well. Kind of oddly enough, there was no rating for the treatment naïve. I went back and double checked that and there wasn't any update there. These are kind of the primary changes and all others have been broken down into tables and placed in the appendix for the committee's review. And so they do break it down even further. This is just the any genome type that was updated. But there are, as you can imagine, stratified genotypes that had no changes in the guidelines for the last few years. And that's in the appendix. On the next and final slide for Epclusa. So there were two updates for this medication this year. First in March of 2020, where the FDA approved Epclusa for the treatment of Hep C genotype 1,2,3,4,5, and 6 in pediatric patients six years of age or older or weighing 17 kilograms or greater. Previously, this is only approved in adults. And the FDA also approved a 250 milligram tablet strength and previously it was only a 400 100 milligram fixed tablet dose. And then moving forward in 2020 in July, this included use in treatment naive and treatment experienced liver transplant recipients without cirrhosis or with compensated cirrhosis. And that's what was updated in the slide I just mentioned previously. As you can see, there is a black box warning with Epclusa and that's where Hep B as in beta reactivation has been recorded in some cases, resulting in fulminant hepatitis, hepatic failure, and death. The dosing is stratified by adults and now pediatric patients as well. And then the formulation is an updated formulation of a 250 milligram combo strength. To give some additional information about this medication, for patients who are pregnant, if Epclusa is administered with ribavirin, the combination regimen is contraindicated in pregnant women and men and the men for whose female partners are pregnant. So it is recommended to discontinue or stop or hold back or to inform the patient about it. And if they are going to continue being pregnant to switch over to a different treatment. There is no adjustment necessary in hepatically impaired patients and there is no adjustment necessary in renally impaired patients, and there's no safety data available for pediatric patients with decompensated cirrhosis or severe renal impairment. I'll go ahead and pause there for the committee.

Ginni Buccola: Thanks Umang. We have two stakeholders. It looks like we have Margaret Olmon with AbbVie and Dr. Laura Hill with AbbVie. Margaret, are you here and ready to go?

Margaret Olmon: Yes, I am. Thank you so much. Laura will not be speaking since I'm available today. So I want to thank her for being my second but I'm available so I'd be happy to share my information today.

Ginni Buccola: Good, thank you. Go ahead and [indistinct] your association disclosure.

Margaret Olmon: I'm Dr. Margaret Olmon from Medical Affairs at AbbVie. I'd like to thank you at the committee for [indistinct] treatment option for HCV patients. And we respectfully request that Mavyret can continue to be available for the Medicaid patients in Washington. Mavyret is the only once daily pan genotypic ribavirin free regimen FDA approved to treat patients above the age of 12 or 45 kilograms with chronic hepatitis C virus across all genotypes one through six. This includes those without cirrhosis or with compensated cirrhosis, have treatment experience, have HIV, or chronic kidney disease. Mavyret can also be administered to patients after a kidney or liver transplant regardless of baseline renal disease. Up to 95% of patients with HCV can be treated with Mavyret and the vast majority of patients awaiting treatment in Washington are eligible for an eight week course of therapy. In a recent study in patients who inject drugs, a study including over 1000 subjects, the overall SVR 12 rate was 98% in former non [indistinct] subjects and 89% in current recent subjects, including those who were asked to follow up. Virologic failure rates were similar in both groups: 2% in the current subjects and 1% in former [indistinct] subjects. Relative to safety, Mavyret carries a boxed warning regarding the risk of a Hepatitis B reactivation in patients coinfected with HCV and HPV as to all direct acting antivirals. Mavyret is contraindicated in patients with moderate or severe hepatic impairment, Child Pugh B or C, or with any history of prior hepatic decompensation and in patients taking concomitant [indistinct] or rifampin. The most common adverse reactions and clinical trials in greater than 10% of patients were headache and fatigue and the AEs were comparable among patients with compensated cirrhosis and those without cirrhosis. Mavyret is well tolerated. It requires no liver monitoring or baseline resistance testing and no dosage or duration adjustments are needed for patients with HIV coinfection or for any level of renal impairment, including dialysis. This has been only a short summary. For complete safety and

full prescribing information, please refer to rxabbvie.com. As you decide the next steps for treatment of patients with HCV in Washington, I respectfully request that you keep Mavyret available as a preferred medication. Thank you so much and I'd be happy to answer any questions you have at this time.

Ginni Buccola: Thank you, Margaret. Committee, are there any questions for Margaret? Okay, so let's come up as a committee and look at the motion.

Marissa Tabile: Hi, committee. This is Marissa. I just wanted to mention that we still do have the hepatitis C elimination project going on where right now Mavyret is pretty much open access. There's no prior authorization on it. So just wanted to mention that the language in this motion might seem a little bit different compared to what you've seen before. But that's just taking into account the current hepatitis C elimination project that we have right now.

Ginni Buccola: Great, thanks Marissa.

Alex Park: This is Alex Park. I'm going to ask what is probably an obvious question, but Mavyret is currently on the preferred list. Is that right?

Marissa Tabile: Hi, Dr. Park. This is Marissa. Yeah, that is the preferred agent on the PDL.

Leah Marcotte: This is Leah Marcotte. Should we have the generic name in the motion?

Marissa Tabile: Hi, this is Marissa. We can go ahead and add it if that's what you recommend. Would you like us to add that in?

Leta Evaskus: This is Leta Evaskus. The hepatitis C elimination project is a partnership between AbbVie and HCA. We put out an RFP for drug companies to give us a lower price for Medicaid population and all state agencies, Department of Corrections, Labor and Industry, the public employees and school employees boards. So it is Mavyret that is preferred.

Nancy Lee: This is Nancy. I guess just to clarify for future. Something that that medication, specifically with that trade name as being part of this not study but sort of study.

Donna Sullivan: Hi, Nancy. This is Donna. I didn't understand what you what you said there. Could you please repeat it?

Nancy Lee: Oh, I was making a suggestion for the Mavyret. If you wanted to indicate for the future that this is part of a special protocol or whatnot just so that for the future we're reminded that there's a reason why we specified that specific medication.

Donna Sullivan: Okay. And we could change the motion to say when the preferred product is not indicated as well. And that way if the preferred product should happen to change, we're not in conflict with the motion. So Marissa or Leta, whoever's in charge --

Leta Evaskus: Yeah, I have it. Do you want that at the beginning or do you want this last sentence changed?

Donna Sullivan: Just change Mavyret where it says Mavyret to preferred agent, when the preferred agent is not indicated.

Alex Park: This is Alex Park. I'm feeling good about the Mavyret being preferred. I'm looking at Umang's report. I mean, there's many different subtypes and situations and genotypes and cirrhosis and not and treatment failure and etc. Where among all those, the Mavyret seems to be the one that is kind of the common denominator. It works for almost all of those classes. In the handful of situations where it's not one of the guideline recommended first lines, do we have on the preferred list one of the guideline recommended medications?

Donna Sullivan: Hi, Alex, this is Donna. We have all of the other HCV agents on prior authorization. And basically they are allowed for people with more advanced cirrhosis and whatever, Mavyret would not be clinically appropriate. So they're not listed as preferred but there is access to them through prior authorization.

Alex Park: Okay, so patients do have access to them. Okay, good. Thank you.

Connie Huynh: This is Constance Huynh. I move that all products in the antivirals hepatitis C drug 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. Non preferred products in this class may be considered medically necessary when the preferred agent is not indicated.

Alex Park: This Alex Park. I second.

Ginni Buccola: This is Ginni. All those in favor, please say aye.

All: Aye.

Ginni Buccola: And are there any opposed? And the motion carries. We'll move next to endocrine and metabolic agents back with Umang. Thanks everyone.

Umang Patel: Okay, perfect. So the next class will be the endocrine and metabolic agents, specifically, androgen or testosterone. A little bit of background, male hypogonadism is caused by an insufficient production of testosterone characterized by low serum concentrations and may present as testosterone deficiency, infertility or both. Approximately 20% of men aged 60 to 69 years and 30% of men aged 70 to 79 years have serum testosterone below normal levels. After 30 years of age, testosterone levels in men decrease at a rate of 2% annually. Symptoms at presentation will primarily depend on the patient's age at the time of disease onset and can include impotence, decreased libido, fatigue, loss of energy, mood depression, and regression of secondary sex characteristics. Potential risks due to male hypogonadism can include osteoporosis, sexual dysfunction, depression, and cardiovascular disease. The only main update here in this class on the next slide is just a small update to the ACP guidelines in 2020, the American College of Physicians. They published a clinical guideline on testosterone treatment for adult men with age related low testosterone. This guideline has been endorsed by the AAFP and suggests a discussion between clinicians and patients regarding if testosterone therapy should be started for men with age related low T with sexual dysfunction who want to improve sexual function. Patients' preferences as well as benefits and risk of therapy should be

considered. It is suggested symptoms be reassessed within 12 months and periodically and testosterone therapy be discontinued in patients with no improvement in sexual function. As clinical efficacy and safety are comparable for transdermal and IM testosterone treatment, costs are lower for IM formulations. These formulations are suggested for improving sexual function when starting testosterone therapy. It is suggested not to start testosterone therapy for improvement of energy, vitality, physical function, or cognition in men with age related low testosterone. Again, there were no major updates in the medications that fall into this class. So that was it in terms of angiogenic agents. I'm going to go ahead and put a pause right here for the committee.

Ginni Buccola: Thanks, Umang. Committee, any questions for a Umang? Alright. So let's come back together and we'll look at this motion.

Leta Evaskus: Ginni, we do have one stakeholder Carrie Johnson.

Ginni Buccola: Okay, thank you so much. Carrie, are you there?

Carrie Johnson: Yeah, actually, this was for the osteoporosis update. Sorry about that.

Ginni Buccola: That's okay. Just go ahead and let us know what your affiliation is and if you have any financial disclosures to share.

Carrie Johnson: Yeah, Amgen, and no financial disclosures. Just I work for Amgen. So my name is Carrie Johnson. I'm a pharmacist with Amgen Medical Affairs. Thank you for the opportunity to speak in support of [indistinct]. Evenity was approved in 2019 and is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture. Evenity carries a box warning which states that Evenity may increase the risk of MI stroke and cardiovascular death. Evenity should not be initiated in patients who have had MI or stroke within the preceding year. If a patient experiences MI or stroke during therapy, Evenity should be discontinued. Please see the full prescribing information for further details. Evenity is unique as the only treatment for postmenopausal osteoporosis that has a dual mechanism of action. By inhibiting the activity of sclerostin, Evenity both increases bone formation and decreases bone resorption resulting in rapid increases in trabecular and cortical bone mass and

improvements in bone structure and strength. The patient at very high risk for fracture needs rapid fracture risk reduction in the near term. Using the anabolic agent Evenity, which both increases bone formation and decreases bone resorption first as initial therapy is optimal based on the pivotal ART study and current guidelines. The 4000 patients phase three registrational ART study demonstrated that those who received Evenity for 12 months prior to switching to a [indistinct] had significantly lower fracture rates than patients on [indistinct] throughout the study. Through 24 months, patients on Evenity first treatment group experienced a statistically significant 48% relative reduction in risk of [indistinct] fracture, 27% relative reduction in risk of clinical fracture, and 38% relative reduction in hip fracture. Overall, adverse events [indistinct] adverse events were generally similar between the treatment groups. The two guideline updates support the use of Evenity. According to the recently updated and published endocrine society guidelines for the pharmacologic management of osteoporosis in postmenopausal women, Evenity should be considered first line therapy in patients with multiple vertebral fractures or hip fracture and BMD in the osteoporotic range. Second, the recently published update to the American Association of Clinical Endocrinologists and American College of Endocrinology, the ACE guidelines, just recently now includes Evenity and recommends its use in patients unable to use oral therapy and as initial therapy for patients at very high risk for fracture. Of note, in the phase three randomized international structure study, Evenity demonstrated a statistically significant increase in hip bone mineral density and strength compared with Teriparatide in postmenopausal women with osteoporosis transitioning from bisphosphonate treatment. The overall incidence of adverse events has bounced between the [indistinct]. The patient at very high risk for fracture needs rapid fracture risk reduction in the near term. Using the anabolic agent Evenity, which both increases bone formation and decreases bone resorption, first as initial therapy is optimal based on the results described from the arch pivotal study Evenity dual mechanism of action and current recommendations by the Endocrine Society and the American Association of Clinical Endocrinologists and American College of Endocrinology, I respectfully request the committee consider including Evenity as an option for patients with postmenopausal osteoporosis at high risk for fracture. Thank you for your time.

Ginni Buccola: Thanks, Carrie. Committee, as there any questions for Carrie? Okay, so now we should be good.

Leta Evaskus: This is Leta. Marissa, I have a question. I see that these are both in one motion. Should we have Umang do the bone density regulators now and then do the motion?

Marissa Tabile: This is Marissa. Yeah, if he can do that, yeah. I didn't realize that they were separate presentation. So yes, please. And then we can move on to the motion for those.

Leta Evaskus: Okay, great.

Umang Patel: No problem at all. So just to clarify for the committee, endocrine and metabolic agents, it kind of got broken down where we had the androgen or testosterone agents, and then we have the bone density regulators here, and then it'll be one motion and we had one manufacturer testimony as well. So, okay, well go ahead to the next slide here. A little bit of background, so for osteoporosis, it's characterized by the deterioration of bone tissue and low bone mass. Approximately 10 million Americans have the diagnosis and an additional 43 million have low bone mass, placing them at an increased risk of the disease. As many as one in two women and one in five men are at the risk of osteoporosis related fracture during their lifetime. One in four men in the US over the age of 50 will have an osteoporosis related fracture in his remaining lifetime. Osteoporosis is common in all racial groups but most common in Caucasians. And the three categories are postmenopausal, age related, and secondary. So in postmenopausal, it affects mainly the trabecular bone in the decade after menopause as estrogen deficiency increases bone resorption more than bone formation. Age related osteoporosis results from increased bone resorption that begins shortly after peak bone mass is obtained, cortical and trabecular bone are both affected. And for secondary, it's caused by medications such as glucocorticoids, excess thyroid replacement, anti-epileptic meds, and long term heparin use or diseases such as hyperthyroidism or type one diabetes. On the next slide here, the endocrine society updated their 2019 guidelines with a 2020 update on the management of osteoporosis in postmenopausal women to include Evenity. Evenity was concluded to

be a potential treatment option for postmenopausal women at very high risk of osteoporotic fracture. However, the patient should be carefully selected due to the serious CV events observed in a clinical trial with an active comparator. To reduce the risk of vertebral, hip, and nonvertebral fractures, treatment with monthly Evenity 210 milligrams is recommended for up to one year in postmenopausal women with osteoporosis at very high risk of fracture, including those with low bone density T scores, which is less than -2.5 and fractures or with multiple vertebral fractures. Women at high risk of stroke or CV disease should not receive Evenity until further evaluation of the CV risk from this agent. After completing the course, it is recommended that patients receive treatment with an antiresorptive therapy to maintain improvement in bone density and reductions in fracture risk. Again, I'll pause right there for the committee and answer any questions

Ginni Buccola: Thanks, Umang. Alright, so we already heard from our stakeholder. Committee, do you have any questions for Umang on bone reabsorption? Okay, so we can go to the dual motion then.

Diane Schwilke: This Diane Schwilke and I move that all products listed in the drug classes on slide 15 are considered safe and efficacious for their medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in this class may require prior authorization to determine medical necessity. All non-preferred products require a trial of two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred.

Susan Flatebo: This is Susan Flatebo. I second.

Ginni Buccola: This is Ginni Buccola. All those in favor please say aye.

All: Aye.

Ginni Buccola: Any opposed? And the motion carries and we'll move to migraine agents.

Umang Patel: Perfect. Alrighty. So the next class will be migraine agents. And this will be broken down for CGRP antagonists and selective serotonin agents as well. Alrighty, on the next slide, migraine headaches account for about 10 to 20% of all headaches in adults and affect over 39 million men, women, and children in the US. Headache is one of the most common complaints by patients when presenting to a physician. 64% of physician diagnosed patients who experienced migraines and 41% of undiagnosed migraine sufferers reported severe impairment or the need for bed rest due to their migraine symptoms. In addition, 18% of women, 6% of men, and 10% of children experienced migraine and epidemiologic profile that has remained stable over many years. Approximately 85% of patients with migraine headaches suffer less than three to four attacks per month. The median frequency of migraine attacks among migraine sufferers is 1.5 per month. Migraine headaches must be differentiated from tension type headaches. Key criteria for the diagnosis of migraine headaches include an episodic headache lasting from four to 72 hours with at least two the following symptoms: unilateral pain, throbbing, aggravated by routine physical activity, pain of moderate to severe intensity. And during the headache at least one of the following are present: nausea and/or vomiting or photophobia and photophobia. To pivot over to cluster headaches, it is a severe primary headache disorder characterized by extreme pain on one side of the head and autonomic symptoms such as nasal congestion or lacrimation. Cluster headache periods can persist for weeks to months, with daily or more frequent attacks of 15 to 180 minutes in duration. Estimated lifetime prevalence of cluster headaches is more than one in 1000. And it can either be episodic or chronic in nature, with episodic being the predominant form. Individuals with episodic cluster headaches experienced periods of attack followed by periods of remission, whereas individuals with chronic cluster headaches have minimum to no periods of remission between headache attacks. On the next slide here we have the American Headache Society in 2019 published its position statement on integrating new migraine treatments in the practice. There were no changes in recommended usage or place in therapy for agents in this class. It included recommendations regarding non triptan, injectable agents, Botox, monoclonal antibodies, CGRP agents, which are like Ajovy, Aimovig for the migraine prevention in patients who experience episodic or chronic migraines. Additionally, in 2019, the American Academy of Neurology

and the American Headache Society updated their 2012 practice guidelines, which were reaffirmed in 2015 for the pharmacologic treatment of episodic migraine prevention in adults. And they advise that anti-epileptic drugs and beta blockers are established as effective in migraine prevention, with the exception of frovatriptan, which is established for short term menstrually associated migraine, MAM, prevention. Naratriptan, zolmitriptan, antidepressants, beta blockers are probably effective in migraine prevention, but no triptan at that time was approved for prevention of migraines. In 2019, they updated their guidelines for acute treatment of migraine in children and adolescents. They endorsed the use of sumatriptan, naproxen, and almotriptan oral tablets, rizatriptan ODT, nasal zolmitriptan in adolescents to reduce headache pain. Triptans have more supportive evidence in adolescents than in children where NSAIDs and acetaminophen are recommended options. On the next slide here to give updates on medication specifically, the first one we have is Reyvow. And in October 2019, FDA approved Reyvow, which is a serotonin 1F receptor agonist indicator for the acute treatment of migraine with or without aura in adults. The limitation of use here, not indicated for the preventative treatment of migraine. In terms of warnings, there's driving impairment, CNS depression, which in turn has a driving impairment warning, and serotonin syndrome as well. The dosing is 50, 100, or 200 milligrams taken orally no more than one dose in 24 hours and it is a tablet availability. To give additional information on these medications, in terms of patients who are pregnant safety and efficacy has not been established. Pediatrics safety and efficacy has not been established here either. If a patient has hepatic impairment, it has not been studied in patients with severe hepatic impairment. Therefore, the use is not recommended. And there is no dose adjustment needed for renally impaired patients. On the next slide here we have Aimovig. In October 2019, the FDA approved 140 milligram per milliliter prefilled syringe and autoinjector. Previously, they had a 70 milligram per milliliter already approved. No changes in indication or warnings of hypersensitivity, constipation, or hypertension. The recommended dose is still 70 milligrams once daily. Some may benefit from a dosage of 140 milligrams once daily, hence the updated formulation. And as you can see, they're available in autoinjector and prefilled syringes of 70 and 140 milligrams, respectively. For additional population, patients who are pregnant and pediatrics, the safety and efficacy has not been

established. And for hepatic and renal impairment with Aimovig, no dedicated studies were conducted to assess the effects of renal or hepatic impairment on the PK of Aimovig. On the next slide here, Emgality. So, January of this year, FDA approved and expanded indications for the treatment of episodic cluster headaches, and it was already approved for the preventative treatment of migraines. As you can see, the only update for this medication was that treatment for CH. Warnings remained the same in terms of dosage for treatment of episodic cluster headaches. It is recommended to be 300 milligrams at the onset of the cluster period and then monthly until the end of the cluster period. The availability is in prefilled syringe and single dose prefilled pens at the 120 milligrams. For special populations, there are no adequate studies or patients who are pregnant or pediatric patients as well. And the hepatic and renal impairment is not expected to affect the PK of Emgality. On the next slide here we have Ajovy. In January again of 2020, this year, FDA approved a new formulation of Ajovy, a 225 milligram, 1.5 milliliter autoinjector. It was already approved in this strength as a prefilled syringe and both are approved for the preventative treatment of migraines in adults and can be self-administered subcutaneously following appropriate training. So again, no changes in the indications or warnings or dosage. The only change is it is now available as a single dose prefilled auto injector that patients can take very similar to those auto injector [indistinct] pens. Very similar to the other medications in this class, no adequate data for pregnancy or pediatric patients. And the hepatic and renal impairment is not expected to affect the PK of this medication. On the next slide here we have Ubrelvy. Again in January 2020, FDA approved Ubrelvy, a CGRP antagonist indicated for the acute treatment of migraine with or without aura in adults and it is not indicated for the preventative treatment of migraines. So again, it is new medication for the acute treatment of migraines with or without aura in adults, not indicated for preventative treatment. The warnings, there is a pregnancy warning based on animal data. It could cause fetal harm and it is recommended to avoid use in patients with end stage renal disease. The dosage here is 50 or 100 mgs orally daily is needed. If needed, a second dose may be administered at least two hours after the initial dose. The maximum dose in a 24 hour period is 200 milligrams. If a patient does have severe hepatic or renal impairment, there is a dose reduction recommended for 50 milligrams. If needed, a second 50 milligram dose may be taken at

least two hours after the initial dose. And the availability for this is a 50 or 100 milligram tablet. On the next slide here we have Nurtec ODT. In February 2020, the FDA approved Nurtec ODT indicated for the acute treatment of migraines with or without aura in adults. It is not indicated for the preventative treatment of migraines. In terms of warnings, there's a hypersensitivity reaction with this medication. If that occurs, discontinue the treatment and initiate appropriate therapy. And hepatic impairment, it is important to avoid use in patients with severe hepatic impairment. In terms of dosage, the recommended dose is 75 milligrams orally as needed, maximum dose in a 24 hour period is 75 milligrams. And the safety of treating more than 15 migraines in a 30 day period has not been established. And Nurtec ODT is an orally disintegrating tablet in one strength of the 75 milligrams. Similarly to its colleagues in this class, there are no adequate studies for patients who are pregnant or pediatric patients and there's no dosage adjustment required in mild, moderate, or severe renal impairment. On the next slide, our final medication specific update we have Vyepti. In February 2020 FDA approved Vyepti for the preventative treatment of migrants in adults. Again, very similar warnings as its colleagues: hypersensitivity reaction where it's recommended to discontinue treatment and treat the symptoms. Dosage is 100 milligrams as an IV infusion over approximately 30 minutes every three months. And some patients may benefit from a dose of 300 milligrams. Again, this kind of differentiates it from the others where this is an injection in a single dose vial here. In terms of pregnancy and pediatric, no adequate data, and in terms of hepatic and renal impairment, there were no dedicated studies to conduct the assessment of the effects of the renal or hepatic impairment on the PK. On the last slide here, we do have just some discontinuation information. In April of 2020, Imitrex, the FDA reported GSK has made a business decision to discontinue manufacturing Imitrex six milligrams single dose vials. Distribution of this product is expected to conclude in August 2020. And only brand name product will be discontinued. And for Cafergot, in July 2020 Sandoz reported to the FDA discontinuation of Cafergot manufacturing. I'll go ahead and pause there and see if anyone has any questions that I can answer.

Ginni Buccola: Thanks Umang. Anything from the committee for Umang? Okay. I see three stakeholders listed. I see Jennifer Shear with Teva

Pharmaceuticals, Chelsea Leroue with Biohaven, and then Carrie Johnson with Amgen. So we'll start with Jennifer Scheer. Are you there?

Jennifer Shear: I am. Can you hear me?

Ginni Buccola: Yes, I can. So I'll have you go ahead and introduce yourself and your affiliation and any financial disclosures you need to make.

Jennifer Shear: Great, thank you. My name is Jennifer Scheer. I am a medical outcomes liaison with Teva Pharmaceuticals and I'm here to provide information about Ajovy fremanezumab injection. Ajovy is an indicator for the preventive treatment of migraine in adult patients. Ajovy may be administered by healthcare professionals, patients, and/or caregivers subcutaneously as once monthly 225 milligrams or quarterly 675 milligram dosing. That's given as three 225 milligram injections. The Ajovy autoinjector became available on April of this year. Ajovy is the only long acting self-administer subcutaneous anti CGRP with the option of monthly or quarterly dosing, allowing it to be dosed four times per year, either with the auto injector or the prefilled syringe. The Halo clinical trial program included two multicenter randomized 12 week double blind placebo controlled studies and provided the pivotal data presented in the prescribing information. [indistinct] market approval of Ajovy data from two additional studies have been made available: focus, a phase 3B randomized 12 week double blind placebo controlled study in patients who previously had inadequate response to two to four classes of preventive therapy, and a long term expensive study. The focus study examined a subset of 838 adult episodic and chronic migraine patients. In the primary endpoint analysis, patients treated with Ajovy experienced a statistically significant reduction in the monthly average number of migraine days for both monthly dosing with a reduction of 12.1 days and quarterly dosing with a reduction of 3.7 days versus placebo with a reduction of point six days over the 12 week period. Efficacy was sustained in open label period through six months of treatment with 4.7 to 5.5 monthly average migraine day reduction from baseline. The most common adverse events were injection site reactions, such as injected by erythema and there were low rates of adverse events leading to discontinuation and serious adverse events. Across 24 clinical studies in the Ajovy clinical development program, 4077

patients with migraine have been exposed to Ajovy. No additional safety signals we're seen across the exposed population. Pool data from the three phase three trials indicate that treatment with Ajovy over 12 weeks has a cardiovascular safety profile, similar to placebo, and 1.08% of phase three clinical trial participants reported constipation. I respectfully request the community to consider adding Ajovy to the PDL. That concludes my statement. I'm open to any questions.

Ginni Buccola: Thanks very much, Jennifer. I appreciate it. Committee members, do you have any questions for Jennifer? Okay, we'll move next to Chelsea Leroue with Biohaven.

Chelsea Leroue: Hi, are you able to hear me?

Ginni Buccola: Yes, I can hear you. Go ahead and introduce yourself and let us know about any financial disclosures. Thank you.

Chelsea Leroue: Thank you. My name is Chelsea Leroue. My only disclosures that I am employed by Biohaven Pharmaceuticals as a Medical Affairs Director. Today, I would like to highlight for the committee the following four key features that differentiate Nurtec ODT from other acute migraine treatments. Number one, ease of use for physicians and patients. Nurtec ODT is available in one dosage form, one dose strength of 75 milligrams, and one package size of eight tablets. This is the only [indistinct] available as an ODT or orally disintegrating tablet which dissolves rapidly within seconds without the need for water, making it convenient for patients to take Nurtec ODT up to once daily as needed whenever or wherever a migraine occurs. Number two, favorable safety profile. The most common adverse reaction in the placebo controlled trial was nausea occurring in 2% of patients treated with Nurtec ODT, and 0.4% of placebo treated patients. Nurtec ODT is not associated with abuse potential or medication overuse headache, is not contraindicated in patients with cardiovascular disease or risk factors and has been studied in patients taking preventive migraine medication, including the injectable CGRP monoclonal antibodies. Number three, sustained benefits of a single dose. Nurtec ODT has a half-life of approximately 11 hours, which is longer than that of many triptans and roughly twice that of the other commercially available [indistinct]. Pain relief, pain freedom, freedom from the most

bothersome symptoms and ability to function normally were sustained for 48 hours with a single dose of Nurtec ODT. Only one tablet of Nurtec ODT is needed to treat a migraine which may lead to less utilization than other acute medications, or a redoes may be needed. And lastly, number four, restores patient's ability to function normally. Nurtec treated patients reported functioning normally as soon as 15 minutes after taking their medication and this was sustained through 48 hours. In the long term study, patients experienced a clinically significant reduction in migraine related disability and lost productivity time. These benefits may favorably impact healthcare costs, workplace productivity, and migraine patient wellbeing. In closing, Biohaven respectfully asks the committee to consider adding Nurtec ODT to the preferred drug list after trial and failure of up to two triptans or a contraindications of triptans, as this was in accordance with guidance from both the American Headache Society and the Institute for Clinical and Economic Review or ICER. Thank you for your time and attention. I'd be happy to answer any questions.

Ginni Buccola: Thank you, Chelsea. Are there any questions from the committee for Chelsea? Okay, I will move to our next stakeholder. Carrie Johnson with Amgen.

Carrie Johnson: Thank you. Can you hear me?

Ginni Buccola: I can, Carrie. Thank you.

Carrie Johnson: Thanks. This is Carrie Johnson again. I'm a pharmacist with Amgen Medical Affairs. Thank you for the opportunity to provide the committee with a couple of updates and testify in support of Aimovig erenumab. Aimovig is a fully human monoclonal antibody to the CGRP receptor and is indicated for the preventive treatment of migraine in adults. Aimovig can be self-administered using the sure-click auto injector and comes in two dosing options. Of the injectable CGRP products, Aimovig is the only one that specifically targets the CGRP receptor. Aimovig has an established safety and tolerability profile, the most common adverse reactions in clinical studies occurring in greater than or equal to 30% of Aimovig treated patients and more often than placebo were injection site reactions and constipation. Worrisome precautions include hypersensitivity reactions,

constipation with serious complications, new onset or worsening preexisting hypertension. Please see the Aimovig prescribing information amgen.com for further details, updates specific to Aimovig. Results are available from two open label extension studies evaluating the long term safety and efficacy of Aimovig in patients with episodic migraine and chronic migraine. One, long term data is available from the registrational strive study in patients with episodic migraine. In this study, patients receiving Aimovig 70 milligrams or 140 milligrams experience statistically significant reductions in monthly migraine days from baseline to the final three months of 3.2 and 3.7 days respectively, compared to reductions of 1.8 days for patients receiving placebo. At the end of the five year open label period, patients receiving Aimovig demonstrated sustained reductions in monthly migraine days with an average reduction of 61.7% versus the study baseline. A total of 59%, 48%, and 35% of patients experienced [indistinct] 50%, 75%, and 100% reduction monthly migraine days respectively. So approximately 70% of patients achieve greater than equal 50% reduction monthly migraine days. Aimovig was generally well tolerated, no increase in adverse events over time was seen, and most new safety signals were observed. Second update, long term data is available from the registrational phase two chronic migraine study. In the original phase two chronic migraine study, patients who received Aimovig 70 milligram or 140 milligrams experienced statistically significant reductions in monthly migraine days of 6.6 days from baseline at week 12 compared to a 4.2 day reduction in the placebo arm. Efficacy was sustained through the open label one year period. Injection site reactions and constipation were the most commonly reported adverse events occurring at greater than 3% and no new safety signals were observed. Migraine pathophysiology is multifactorial and complex. Migraine is a very heterogeneous disorder and no two patient migraine experiences or response to treatment are the same. Aimovig was the first to market in this class and has demonstrated long term safety and efficacy showing sustained reductions in monthly migraine days. Of the injectable CGRP products, Aimovig has a unique mechanism of action as it’s the only one that specifically targets the CGRP receptor, and also comes in two different dosing options that can be self-administered. We respectfully request that the committee add Aimovig to the preferred drug list. Thank you for your time and I'm happy to address any questions.

Ginni Buccola: Thank you, Carrie. Any questions from the committee for Carrie? Okay, committee let's look at the motion then for migraine agents.

Alex Park: This is Alex Park. I move that all products listed in the drug classes on slide 18 are considered safe and efficacious for the medically accepted indications and are eligible for preferred status and grandfathering at the discretion of HCA. Products in this class may require prior authorization to determine medical necessity. All non-preferred products require a trial of two preferred products with the same indication before a non-preferred drug will be authorized unless contraindicated, not clinically appropriate, or only one product is preferred

Constance Huynh: This is Constance Huynh. I second.

Ginni Buccola: This is Ginni Buccola. All those in favor, please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? And the motion carries. So we're at a scheduled break time. And it looks like Leta has us blocked for ten minutes. Does that still work Leta?

Leta Evaskus: Yes, this is Leta. So it's basically 2:20. So let's come back at 2:30.

Ginni Buccola: Okay, great. See you then.

[break]

Ginni Buccola: Hello everyone. Welcome back. This is Ginni. We're moving into our last portion of the afternoon Umang is going to take us through pulmonary hypertension agents. Umang, whenever you're ready.

Umang Patel: Perfect. Thank you so much. So the next, and I believe the final class for my review will be the pulmonary hypertension agents. And this will include the subgroups of the endothelial receptor antagonists, the prostacyclin receptor agonists, the prostaglandin vasodilators, SGC stimulator, and the PDE inhibitors as well. Moving on to the next slide, again, a little background, the prevalence varies substantially

depending on the type, etiology, and underlying condition. Pulmonary hypertension is estimated to be about 15 cases per million people, characterized by an increase in pulmonary arterial pressure and secondary right ventricular failure is defined as a resting mean pulmonary arterial pressure of 25 millimeters per mercury or greater. Symptoms include dyspnea, dizziness, syncope, fatigue, peripheral edema, angina, palpitations, and other symptoms, all of which are exacerbated by exertion. Pulmonary hypertension does not have a cure and if left untreated, it is a life threatening disease with a poor prognosis. Management should be limited to specialized centers where clinicians are experienced in the evaluation and treatment of patients. Although the number of approved therapies has grown in the past year, the prognosis is still poor with approximately 50% mortality within the first five years after diagnosis. On the next slide, there are many causes which include idiopathic or underlying disease and hereditary causes. Cellular changes in the walls of pulmonary arteries and it appears that mutations in the bone morphogenetic protein receptor type two plays a key role in the pathogenesis of heritable pulmonary hypertension. Other etiologies include drugs and toxins, collagen vascular resistance, HIV, portal hypertension, chronic thromboembolism, and congenital heart disease. WHO classifies this into five groups based on etiology. One refers to pulmonary arterial hypertension. Two is due to left heart disease. Three is due to lung disease. Four is due to blood clots in the lungs and five refers to pulmonary hypertension due to blood and other rare disorders. In 2013, clinical classifications were updated to provide the same classifications for adults and pediatric patients. In addition, the individual categorization of the persistent pulmonary hypertension of neonates was included. On the next slide here, there was an update in October 2019 for Orenitram. FDA approved and expanded indication for a delayed disease progression in the treatment of pulmonary arterial hypertension, WHO group one, previously it was only approved to improve exercise capacity. The warnings and precautions are still the same, contraindicated and severe hepatic impairment, child Pugh class C as in Charlie. It is recommended not to discontinue abruptly. And in patients with diverticulosis tablets can become lodged in the diverticulum. In terms of dosing, you can see the starting and titration schedule. And it is an extended release tablet formulation. In this medication, safety and efficacy in pediatrics is not established and there's no dose adjustment for renal impairment. I

already mentioned hepatic earlier. On the next slide here and the final slide of my presentation, we have a REMS update, risk evaluation mitigation strategies. So for Adempas, in February 2020, REMS updated to make changes to the prescriber and patient enrollment forms for consistency and clarity. Nothing too significant but just worth mentioning to the committee. And Opsumit, in April 2020, the FDA approved a single shared system, SSS, REMS Opsumit and corresponding generics called the Macitentan REMS program. The new SSS REMS will replace the original REMS once the first generic for Macitentan is approved. That is all I had for pulmonary arterial hypertension. I will go ahead and pause and answer any questions that you may have.

Ginni Buccola: Thanks, Umang. Any committee questions for Umang? It looks like we have two stakeholders, Amy Heidenreich with United Therapeutics Corporation and then Stephanie Yamamoto with Janssen. Amy, are you ready to go?

Leta Evaskus: This is Leta. I am looking for Amy to see if she is on here. I don't see Amy. Stephanie is here so I'm going to unmute Stephanie.

Ginni Buccola: Just go ahead and state your name. I know you've already given your full disclosures earlier in the day today so thanks.

Stephanie Yamamoto: Will do Thanks so much, Ginni. Hi, it's Stephanie Yamamoto here again. I'm with Janssen scientific affairs as a scientific account lead. I'm speaking on behalf of Uptravi or selexiprag and that is a prostacyclin receptor agonist indicated for the treatment of PAH or pulmonary arterial hypertension, WHO group one, to delay disease progression and reduce the risk of hospitalization for PAH. PAH is a rare progressive disease that often affects working age patients and significantly restricts daily function and may lead to death in a few years. The goal of treatment is to achieve a low risk status. For functional class three and functional class three patients, [indistinct] five inhibitors and endothelin receptor antagonists alone may not adequately protect patients from disease progression and hospitalizations. The Griffin study was a multicenter, double blind, placebo controlled, parallel group event driven phase three study in 1156 patients. Of those, 80% of these patients were already being treated with a PAH background therapy at baseline with a PDE five

inhibitor and/or an ERA, and a third we're already receiving both an ERA and a PDE five inhibitor. When added on top of this baseline treatment, Uptravi demonstrated at that 37% risk reduction in disease progression across functional classes. In long term follow up of these patients, patients taking Uptravi had a 63% estimate of survival at seven years. In addition to this data, the 2015 European Society of Cardiology, the ESC guidelines listed Uptravi as a class one B recommendation for sequential combination in functional class two and functional class three patients. Based on this clinical data, as well as expert consensus and guidelines, we respectfully ask the committee to consider access to Uptravi without a prior trial and failure of an ERA, particularly in functional class two and three PAH patients in Washington. Thank you so much.

Ginni Buccola: Thanks very much, Stephanie. Any questions from the committee for Stephanie?

Leta Evaskus: Amy was under a different name. So I'm going to unmute her now.

Ginni Buccola: I'll just have you go ahead and introduce yourself, your affiliation, and make a statement regarding any financial disclosures. And you'll have three minutes.

Amy Heidenreich: Okay, thank you so much. So good afternoon. My name is Amy Heidenreich and I am a clinical nurse educator with the United Therapeutics Corporation. So I actually work for the corporation. So I have no financial disclosures to report. United Therapeutics was started by our founders after their daughter was diagnosed with pulmonary arterial hypertension, PAH, and they realized how few treatment options were available. Our first PAH medication remodulin interproximal injection was approved in 2002. And we continue to develop new therapies, including Tyvaso, Treprostinil, inhalation solution, Orentiram, all in our pursuit to find a cure for PAH and end stage lung disease. Today, I'm going to discuss the latest clinical update for Orenitram. Orenitram was FDA approved in December of 2013, with the indication to improve exercise capacity in patients with PAH. The study that established effectiveness included predominantly patients with WHO functional class two through three symptoms, and etiologies of idiopathic or heritable PAH, or connective tissue disease associated PAH. We continue to expand the efficacy and

safety dataset post approval. Based on results from the freedom EV clinical trial, United Therapeutics has received a label amendment from the FDA with the additional indication of delaying disease progression. This data was published in the American Journal of Respiratory and Critical Care Medicine. Freedom EV was an event driven study investigating the time to first clinical worsening event in 690 PAH patients receiving Orenitram or placebo in combination with a PD five inhibitor or an ERA. At baseline, the majority of participants had functional class two symptoms and a median six minute walk distance of 405 meters. Orenitram significantly reduced the risk of clinical worsening event by 25% when compared to placebo, driven by a 61% reduction in the risk of disease progression, both statistically significant. Orenitram also demonstrated statistically significant improvements in key secondary endpoints. Median six minute walk distance improved with Orenitram at week 36 and week 48 and trended toward improvement at week 24 without reaching statistical significance. NT Pro BNP Bohr score and functional class were significantly improved with Orenitram at week 24 compared to placebo. Orenitram participants shifted to lower risk criteria compared to placebo from week 12 through week 60. Orenitram was generally well tolerated and the safety profile was consistent with previous studies and no prostacyclin related adverse events. Given the findings of the Freedom EV study, we asked that you move Orenitram to preferred on the Washington State Medicaid PDL for PAH patients who rely on your organization to provide access to their medications. I thank you very much for your time and I'm happy to answer any questions. Thank you,

Ginni Buccola: Thank you, Amy. Committee, are there any questions for Amy? Okay, then we will move as a committee to look at the motion for pulmonary hypertension agents.

Jordan Storhaug: This is Jordan Storhaug. I would all products listed in the drug classes on slide 21 are considered safe and efficacious for their medically accepted indications and are eligible for group status and grandfathering at the discretion of HCA. Products in this class may require prior authorization to determine medical necessity. All non-preferred products require a trial of two preferred products with indication before a non-preferred drug will be authorized unless

contraindicated, not clinically appropriate, or only one product is preferred.

Catherine Brown: Catherine Brown. I second.

Ginni Buccola: This Ginni Buccola. All those in favor, say aye.

All: Aye.

Ginni Buccola: Any opposed? And the motion carries. Alight. We're moving back to Apple Health Policy. The next topic will be ALS agents specifically Radicava with Ryan Taketomo.

Leta Evaskus: This is Leta. Give me just a second. I'm going to make Marissa the presenter again.

Marissa Tabile: Hey, this is Marissa. I should have the policy pulled up, Ryan. Let me know if you can't see it. And whenever you're ready, go ahead and you can start presenting.

Ryan Taketomo: Good afternoon, everyone. This is Ryan Taketomo and I'll be presenting the Radicava policy. So just a brief history. This policy was previously presented back at the June PNT meeting, I believe. And there was feedback from the committee to have this policy reviewed by specialists. And since that time, we have had a specialist able to review the policy for feedback and we have incorporated that into the policy. So I'll give a brief background before we go into the clinical policy criteria as a refresher since it's been some time. So a little background about this drug, it's approved for Amyotrophic Lateral Sclerosis, ALS, also known as Lou Gehrig's disease. This disease is a neurodegenerative disorder characterized by loss of cortical and spinal motor neurons. This leads to weakness, muscle atrophy, and cognitive impairment and eventually could lead to paralysis. Currently, there's two drugs approved for the treatment of ALS. One is Radicava and the second is Riluzole. Riluzole is the only drug that has been shown to provide a mortality benefit for this disease. So a little brief history on the approval of Radicava. The first phase three clinical trial for this drug looked at 206 patients and it was over a 24 week period. Some of the key inclusion criteria were forced vital capacity of 70% or more and a disease duration of a max of three years. This

study found that there was no significant change in the ALS functional rating scale, the revised version, compared to placebo. However, the study did do a post hoc analysis and they found that a particular subset of patients could potentially benefit from this drug. These would be patients who had the disease and were diagnosed early or treated earlier. These were specifically patients with two or more on all items of the ALS FRS questionnaire: forced vital capacity of 80% or more and a disease duration of at most two years. The authors of the study also concluded or mentioned that there's no indication that Radicava might be effective in a wider population of patients who do not meet the criteria. So study two was conducted and included 137 patients who were randomized. These patients again had the more strict criteria of two or more on all items of the ALS FRS rating scale: forced vital capacity of 80% or more and a disease duration of at most two years. And this did show a significant benefit after 24 weeks when you compared the disease progression. There is also a follow up portion to this study in which patients who were on placebo were switched over to Radicava, and this continued out to 48 weeks, I believe. And again, it showed kind of the similar thing that patients who are on the Radicava did experience a slower functional decline than the projected amount. Since then, there hasn't been really any new strong clinical evidence for this drug. There have been a few retrospective studies with mixed results, some showing no benefit, and others showing a benefit. But the level of evidence is weak so I won't go into too much detail. So with that, we can start by going through the clinical policy, and I'll kind of go over the changes that have been made since the last meeting. Criteria one, two, and three remain unchanged. With criteria four, we did make the decision to change the requirement from having a score of two or more on all items of the ALS FRS scale to a cumulative score of 24. And that was because there might be one particular criteria where the patient may not have performed well. And these criteria are not necessarily all clinically meaningful. For example, some of the criteria talked about being able to get dressed or climbing stairs. And in some cases, we didn't think that those would be fair to deny if they did not have a two. So we changed it to have a cumulative score of 24 or greater. Scroll down a little please. With criteria five, that particular criteria with the forced vital capacity of 80% or more comes from the more strict trial which demonstrated that Radicava showed a significant benefit versus placebo with decline in the ALS progression. And then with

criteria six, it also remains unchanged from last version in that they have to have tried, or must be on, Riluzole. So looking at the reauthorization criteria, we did make a change here. Criteria one is unchanged. Criteria two is new. Previously, we had that the patient must have continued to have a score of two or greater on all items of the ALS FRS rating scale. But from our discussion with the specialist and learning more about the disease, using that scale would not be appropriate for measuring disease progression. It wasn't developed to do that. And patients may experience progression at the same time. It's not really predictable. Thus, these cases really need to be reviewed on a case by case basis. And that's how they are currently reviewed. And that kind of sums up the changes since the last presentation. So with that, we can go to the form. Okay, so the form is, again, what we use to help facilitate the prior authorization process and these questions represent the items we're looking for when reviewing these cases and that the clinical documentation that is provided support that. So with that, I'll provide a little bit of time for the committee to review the form and ask any questions that they might have.

Ginni Buccola: Thanks, Ryan. Anything from the committee?

Constance Huynh: So this is Connie. Is it possible to maybe see the whole page of that form? I apologize since I don't have the ability. Okay, demographic information. Okay. Thank you, Ryan.

Alex Park: This is Alex Park. Ryan, can I ask, when you said that consultations with experts remains -- I might have missed, who exactly we talked to. Who was included in that?

Ryan Taketomo: So we reached out to one of our internal doctors and they reached out to a neurologist specialist to review the policy.

Alex Park: And this specialist is someone who specializes in the treatment of ALS.

Ryan Taketomo: Yes. They are a chair of the neurology department at their organization.

Alex Park: Okay, thank you.

Ginni Buccola: Committee, do you have any other questions for Ryan?

Alex Park: Ryan, that's Alex Park again. Can I ask what did they have to say about the forced vital capacity requirement? Did they have comments about that?

Ryan Taketomo: The only comment they really made with that it was less friendly to prescribers. So I'm getting a little bit of feedback. So yeah, with some of these criteria, again, the prescribers stated that the policy was okay and just some of the criteria again, were less friendly to prescribers, and that's kind of what they commented. They did say that the efficacy of the drug was unimpressive. And with the reauthorization criteria, that particular one where we had a requirement that patient had to have a two or better on all items of the ALS criteria, that would be less appropriate because again, as I stated before, it was not developed for the purposes of determining when a patient would not meet the threshold for stopping therapy. Given the kind of risk highly intra patient variability, that patient experience with the disease. And I don't know if I forgot, but I did want to mention that the initial authorization criteria often included a point that patients had to have a diagnosis within the past two years as well. And I think that was one of the criteria you were also concerned with, Dr. Park, and that one was removed.

Alex Park: Thanks for remembering. I guess it's somewhat along those same concerns that I looked at this forced vital capacity requirement. I'm aware of the data and the fact that drugs seem to work best in the people who had earlier stage disease, better respiratory function, hence the forced vital capacity. And I understand the rationale for why we put that in there. But my heart breaks here because this is a just absolutely devastating disease. And there really is no treatment outside of this drug and Riluzole. And from a practical standpoint, I can't imagine why late stage versus early stage would be expected to respond differently other than the fact that the disease is more progressed. And I have some concerns about putting that restriction on there, though I understand why it's there I'd be open to the committee and their opinions on that.

Ryan Taketomo: And just to provide some additional rational - this is Ryan Taketomo - we do understand that it might seem limiting. But from the first study, again, they did state that there’s no indication that the drug would be

effective for populations who did not meet that stricter criteria. However, we did add some language below that states that if not all the criteria are met, they can be authorized on a case by case basis by a clinical reviewer. And because each of these cases are reviewed internally at HCA, these usually go to a medical director who will make that determination.

Ginni Buccola: This is Ginni Buccola. And I just want to follow up on Alex's excellent questions. And again, this is not my treatment area. But maybe I just want to follow or add on to that forced vital capacity question. I think what I'm hearing is that the evidence says there is no clinical benefit in early use of this medication. But my point of wondering would be around the quality of life, especially if there was an extension of a person's ability or capacity to work or be an active family member earlier while they still have some significant respiratory capacity or speech capacity compared to later. And again, I don't know. That may be captured in terms of that individual case review if there's a provider that's advocating for earlier treatment. But I just wanted to throw that out there.

Donna Sullivan: And this is Donna. I just wanted to chime in. Dr. Park, it sounds like you're really concerned about the forced vital capacity. I'm wondering if we should just remove it as a criteria altogether. Is that what you're kind of leaning towards?

Alex Park: If the committee is with me on this, that would certainly be a sort of where I would head. I mean, I'm just thinking about the practicality of an ALS patient getting spirometry done. It seems like a horrendously difficult thing for them to do in that stage. And doing so would kind of go consistent with the other requirement that we struck, which was the two year duration of diagnosis. So I would be open to that, Donna. Thank you.

Donna Sullivan: Okay.

Ginni Buccola: And this is Ginni. I would support that as well.

Leah Marcotte: This is Leah. I would as well. I think that the score of 24, that cut off is also just something that would be helpful to confirm specifically with ALS experts that that's an appropriate kind of edit versus the score of

each individual category being two or better. I totally appreciate getting a neurologist opinion. I just wonder whether asking ALS clinics and just talking to ALS specific experts would be helpful in answering some of these nuanced questions. I also agree with a forced vital capacity. In addition, people may have underlying lung diseases not from ALS that would appropriately exclude them.

Ginni Buccola: This is Ginni. Is everyone feeling satisfied with where we are? Are there more points for us to discuss? Okay, so I'm going to take that as a spot to then move to our one stakeholder, who is Bill Gittinger with Mitsubishi Tanabe Pharma America.

Bill Gittinger: Hi, can you hear me, Ginni?

Ginni Buccola: Yes, I can hear you, Bill. Go ahead and introduce yourself and share your affiliation and any financial ties to pharmaceutical companies. Thank you.

Bill Gittinger: Absolutely. Bill Gittinger. I'm the director of government accounts, which means Medicare and Medicaid, for Mitsubishi Tanabe Pharmaceuticals here in America. I addressed the committee back in June and we discussed that retreatment language on the ALS FRS score. So Ryan, I just want to thank you for incorporating the new softer language into retreatments. It's more compassionate and it will obviously make a lot more patients and their caregivers happy. So thank you for that modification. The one thing that I wanted to bring up today was not an issue back in June but it has been talked about over the last couple of minutes and that's the FEC score. Dr. Park, just to answer quickly here, one of the things that I wanted to bring up was that the FEC scores greater than or equal to 80%. We've seen that in other policies but I can tell you since June, our discovery has been that very few providers, clinics, and Centers of Excellence for ALS, will even conduct an FEC test now. And that is a byproduct of Covid. As you all know, the FEC the patient puts a mouthpiece for the spirometer in their lips and has an airtight seal and blows as hard as they can to expire anything or to [indistinct] anything out of their lungs. One of the issues with ALS patients is many, many of them experience bulbar problems in that they can't chew or swallow or control their tongue or their lips. So when an ALS patient submits to an FEC, sometimes they have to take two, three, or four times of

blowing just because their lips don't form an airtight seal until they can get it right. And now they forced everything out of their lungs and you have a whole exam room that's contaminated. So we started seeing this come in on a lot of the information or the prior authorizations was we're not doing the FEC. And we started talking to payers about this across the country back in August. Most payers that have FEC are doing what you're suggesting here, they are removing that as a requirement basically, because a new patient can come in and there's no FEC and anybody doing the prior authorization is going to see no FEC and possibly a denial. So what they're doing is they're either removing it or they're putting an asterisk on it and saying we're suspending the need for an FEC score until the federal government declares an end to the national medical emergency. So where [indistinct] is where a lot of payers have already gone. And that's what I wanted to bring up today.

Ginni Buccola: Thank you, Bill. Appreciate that. Any committee questions for Bill? Okay, committee, let's go ahead and look at the motion for Radicava.

Woman: Here's one clarifying question, just back to this score. Ryan, how is the score of 24 determined, that score cut off?

Ryan Taketomo: So the ALS [indistinct] scale consists of 12 questions, I believe, and they're rated from one to four

Leah Marcotte: Was that evidence based or was it just 12 times 2? Was there any expert insight into using that 24 and making sure that that was clinically appropriate or was it just using the initially had two or better?

Ryan Taketomo: Right. So that’s a good question. I'm not 100% sure on that. I'd have to look into that. But with the clinical trials, that's what they used as the inclusion criteria for identifying that subset of population who would benefit from the drug.

Leah Marcotte: And did the neurologists [indistinct] comment on that?

Ryan Taketomo: They did not specifically provide any specific feedback on that Criteria.

Alex Park: This is Alex Park. I think I see where you're going with that, Leah. And maybe we can ask the stakeholder. I don't know if that's appropriate. But I don't know what a score of 24 means, honestly. If that means we have a super high functioning ALS patient or not. In my reading before the meeting, I did read one reference in the Journal of Managed Care, there was some kind of a roundtable discussion that they had had a couple years ago. And they set as target of 20 after expert consensus opinion was generated. But along the vein of what we're doing in terms of lowering barriers for this, I think Leah brings up a good point about taking score into a more thoughtful account.

Bill Gittinger: Well, this is Bill, if it's okay for me to speak. [indistinct] what that score of 24 is, as Ryan pointed out, there are 12 different criteria that are scored by the provider as they look at the patient. One of the areas as I discussed was bulbar or malfunctions. It's walking, it's different physical motions for the human body. And a score of one is they're not doing very well or they cannot swallow. That's why you see a lot of patients on Riluzole. But a score of three or four means that they're functioning very well, maybe they're able to stay at work. And so if you look at a cumulative score, a patient may score a couple of months or a two. To Dr. Park's point, they function very well and everything else. So they may have a score of 40, which would be a high score if it was 12 boxes times a high score of four would be a maximum of 48. So you see cutting that down to half. That's why we're not really advocates, as I discussed in June, of not keeping a single score at a two or below but just looking for a cumulative score as your consultant specialist suggested. Because if somebody has a bad day or whatever it might be, they might have a temporary score that might take them from a three to a two, or a two to a one. And that old retreatment language, that one box, even though they had fours on everything else, if they had a one in that one box, they wouldn't be able to get retreatments. And that's what we talked about in June is instead of looking at each individual box, look at a cumulative score to, Dr. Parks point. I'm not familiar with that discussion or that document that he referenced of a score of 20. But I have MLS's and chief medical officers that are at my disposal at Mitsubishi. And if you want to further that discussion, I can certainly have one of them get in touch with you if you'd like.

Ginni Buccola: This is Ginni Buccola. Should we reverse slides so we can look at the form again? Would that be helpful?

Alex Park: Yes, Ginni.

Woman: I guess the question is whether or not that score of 24 is acceptable to the ALS specialists, like Ryan, you contact, if they thought that was within reason or reasonable.

Ryan Taketomo: This is Ryan Taketomo. All I can say with their comment for that specific criteria is that they were more in a neutral position with the ALS FRS score. I think part of it is the controversy with the patient population, which was studied, and where the drug showed a benefit. And then the patient population where it didn't show a benefit, and that's balancing the safety, efficacy, and the cost. So with that criteria, I think that's why he kind of remained neutral with regard to if it's a good or a bad criteria.

Constance Huynh: This is Connie. So I see on the policy that one, two, three, four, and five, which we just removed five, which is the forced vital capacity over 80%. If there is the controversy or the ambiguity of whether we want to put that 24 score as a requirement, we could change the “and” to an “or” as a possibility. I mean, that could be a proposed way of doing that. If we want to take the time to actually look into it a little bit more. I mean, Ryan, you're conferring with a neuro specialist and then Dr. Park was referring to a different reference. And then we had a stakeholder that also had his opinions. I think it probably would be good for us to maybe have a systematic look at the efficacy of 24 as a number, as part of our policy. So far, we only have three points of view. It might be better if we want to use it as part of the policy that we have some evidence base need for that 24. Or we can just take it out altogether like we did with number five

Alex Park: This is Alex Park. I would be in favor of striking it. I think lowering barriers for this is a good way to go. But I'm also open if the committee feels uncomfortable about that to getting more expert consensus review before we approve this policy.

Ginni Buccola: This is Ginni and I think it's interesting that the one expert that Ryan had the information from had a neutral response. So if the response is

neutral from that one voice from the specialty community, it seems to me that it would be a rational decision to remove it. I'm wondering if there's any comments from HCA leadership on this decision.

Woman: I mean, I guess the intent of four and five is to kind of figure out the target population that would respond to the medicine. Because that's kind of what was studied. So is there another way that we can kind of target that population without having to use a score and FEC that kind of tries to target that population? Or, like you said, just eliminate it.

Ryan Pistoresi: Hi, this is Ryan Pistoresi. You know, I appreciate a lot of this discussion. I think given the feedback that we're getting here and the feedback that we got at the last meeting, that it might be good for us to kind of take this back and take this all together. Because I know there's a lot of good discussion before on this and we just want to make sure that we're taking that into account and looking at the originally proposed -- I was just saying I think it might be right for us to take this back internally and review your questions, review the comments and review the evidence that we used to develop this policy again, make sure that we are able to answer these questions that are coming up. Because I do think that we do have the opportunity to regroup on this and better address your questions by being able to site the evidence and how we are planning on presenting this policy moving forward.

Ginni Buccola: How does that sound to the committee?

Alex Park: That sounds good to me, Ryan. This is Alex Park. It sounds good. But here's a question. So while we are in holding pattern with this policy, what's the existing policy where patients with ALS, need to follow once they need this drug?

Ryan Pistoresi: Hi, this is Ryan Pistoresi. So, great question. We are receiving requests for this drug and we are reviewing them for medical necessity. So without getting into specifics about the cases that we've seen, we are looking at using this criteria, but also looking at clinical judgment and seeing if these patients need this, or if they're close, to consider the rationale for approving it or for continuing care. So, we are receiving it and using this kind of as a guideline but not as a set policy.

Alex Park: I see. So are you saying that there is no set policy now? It's sort of a one on one assessment?

Ryan Pistoresi: Yeah, this is Ryan. So before we have a finalized clinical policy, if a drug comes to us while we're developing a clinical policy, or if it's a new pipeline drug, in which there is very limited evidence, we do tend to look at those on a case by case basis. And so we can review and approve drug requests before we bring a policy that is final to the DUR board and for it to be approved. And those are really done more on a case by case basis, really looking at the evidence and looking at the case that is being presented to us and knowing that at this time in which there is very limited evidence to look at the clinical circumstances of these cases. So sometimes we do see patients that were started on a drug in a clinical trial and then we get the request once that drug has been approved. Other times we do get some cases that they may not have met that clinical criteria that was in the study but we may see that it's being evaluated on an ongoing clinical trial. So we do try to look at that and then at the same time develop a clinical policy that we can bring to you.

Ginni Buccola: This is Ginni. So if I'm hearing the committee correctly, it sounds like the preponderance of thought is to continue to ask for a little more information. Is that right?

Nancy Lee: This is Nancy. Agreed.

Ginni Buccola: Okay, do we need to make a motion then as I see it been updated down there.

Marissa Tabile: Hi, this is Marissa. So I'm thinking maybe we don't make a motion on this one if it's something that needs to be re-reviewed and re-presented again. So I just went ahead and updated this slide for our reference but we won't proceed with the motion for this particular policy.

Ginni Buccola: Thank you, Marissa. Okay, so we will go ahead and move on. And so our next topic will be pulmonary arterial hypertension agents specifically prostacyclin with Marisa.

Marissa Tabile: Hi, this is Marissa. Just bear with me one minute. I just need to open up the policy in the form. Okay, great. This Marisa. So, hello, DUR board members. I will be presenting the pulmonary hypertension agents oral inhalation policy. So just to give you some background on this policy, this is an annual update of our current policy that we have implemented. And the current policy that we have posted online and implemented was effective August of 2018. So it has been about two years since this policy has been reviewed. And just to give you some reference on this policy, we did add a new agent that was approved in 2019, which is a leak and I apologize for the mispronunciation but it is [indistinct] formulation or product. And what caused the update for this particular policy was the current policy that we have right now is a little bit broad. All it really asks for is just a diagnosis. And that would just be a broad diagnosis of pulmonary arterial hypertension, as well as, have you tried and failed sildenafil. So this policy now with an update I will be presenting is really asking for a little bit more specific criteria. And then we also included some World Health Organization classifications to the policy. It's not previously on there, but in this update, it is listed there now. And with the current policy that we have right now, we do have chronic thromboembolic pulmonary hypertension separated out from the pulmonary arterial hypertension. So if you look on the policy, there are two separate indications. But just to make it a little bit more concise, we have combined them. So now it looks like a more concise policy for this update. So I won't get into any of the background. I think Umang did a really great job of talking about the disease state. So I'll just get right into the clinical criteria and the updates. So for this policy, we have now added, like I stated, the World Health Organization classification. So now, if a patient has PAH diagnosis group one, that is included, and we have also broken it out into the WHO functional class, which is listed here. So we required documentation of their functional class as well as their group, and if the patient has any acute vasoreactivity testing and the status of that test. That was not previously included in the policy that we have right now. So this testing requirement is included. And that testing would be if the patient had a positive response to AVT but have an inadequate response or intolerance or contraindication to amlodipine, diltiazem, or, long acting nifedipine, or if a patient had a negative response to AVT testing, or if AVT testing is not indicated for the patient. So if they have PAH due to connective tissue disease, congenital heart disease, HIV, portal hypertension,

pulmonary veno-occulusive, or pulmonary capillary hypertension, or if acute vasoreactivity testing is contraindicated in the patient. We have also now included, like I said, the CTEPH criteria is kind of put in one now. So now if they have a different diagnosis of pulmonary hypertension, diagnosis in groups three or four, and four, specifically for CTEPH, in which general treatment measures have failed and pulmonary hypertension is thought to be unrelated to underlying lung disease. And then we also have added criteria for if they meet one of the following. So if they are currently on a medication or documentation that the patient is currently established on a requested therapy. So if they're already taking it, that's means for approval. Like Umang had stated, you don't want to stop any PAH treatment abruptly. So that is kind of where that criteria has come from. If a patient is requesting for a non-preferred product, of course, it would require a history of failure, contraindication, or intolerance to a preferred product with the same Apple Health drug class, of course, where that is applicable. And then for Uptravi or Selexipag specifically, we would require a history of failure, contraindication, or intolerance to an endothelin receptor antagonist. That has been included in the criteria now. And we've also included this criteria number four, where the requested therapy is not for any of the following. So it would be a combination of a PDE inhibitor and soluble guanylate cyclase simulator, and a combination of Selexipag and parenteral prostanoid. And then criteria five has not changed. It's still the same, prescribed by or in consultation with a specialist in cardiology or pulmonology. So if the patient meets the criteria then the request will be approved for 12 months. And we have added the statement as well. You've seen it on some of the other criteria today, where if all the criteria are not met but there's a documented medically necessary circumstance based off of the professional judgment of the clinical reviewer, then of course requests can be approved by on a case by case basis, up to the initial authorization duration. And another change for the reauthorization criteria is just that right now, I believe our criteria just says a positive clinical response. But it's not specific to kind of what that response looks like or what we would be looking for. So we got a little bit more specific in the language. So it can be reauthorized if there is documentation of response. So if there's disease stability or mild progression indicated by a slowing of decline using the WHO functional class, that's provided. And then it can be reauthorized again for another 12

months. And so here are some of the codings, the HCPC codes, the dosage and quantity limits. And this has been added into the policy as well. So we've added an appendix with the WHO clinical classification of PH as well as the functional classification, just for reference for some providers. So that is now included in the policy. And then moving over to the form. So this is a form for this particular criteria. I'm not entirely sure what the form looks like right now. But this is to help kind of guide providers through what the criteria we're looking for, what a patient would need to meet in order to get these medications. So of course, we asked now for the World Health Organization class and the functional class, what group, the specialty of the providers. So they have a vasoreactivity test? What were the results? Do they have a history of any of the following? So are they currently taking a PAH agent? Do they have failure contraindication to preferred product? Then it lists which product. If it's for an Uptravi request. Does the patient have a history of failure, contraindication or intolerance to an ERA? And then it asks, of course, will this be used in combination with any of the following? So I'll go ahead and pause for any feedback from the committee.

Ginni Buccola: Thanks a lot, Marissa. Committee, any questions about the form or the policy? I don't see any stakeholders listed. Oh, go ahead, Alex.

Alex Park: Thanks, Ginni. Marissa, quick question. I just want to make sure I understand this correctly. So it's meeting criteria number one or two and one of the ones under three. Is that right?

Marissa Tabile: Hi, this is Marissa. Yes, Dr. Park, that is correct.

Alex Park: Okay. So then under number three, it says documentation that the patient is currently established on the requested therapy. So does that mean that the drug that they're requesting, they have to already be on it at the time that they're requesting this authorization?

Marissa Tabile: Hi, Dr. Park. This is Marissa. Yeah, so this really covers for patients that are kind of already on [indistinct]. So if they were [indistinct] again, then we would just need documentation that it's pretty much like a continuation therapy.

Alex Park: Okay, Thanks for clarifying. Is there a separate policy for initial authorization?

Marissa Tabile: Hi, this is Marissa. No, the only thing we have right now is the current policy that's posted online. And that's pretty broad as far as the criteria that they have. It's just, do they have PAH? Have they failed sildenafil? And I'm trying to think of what some of the other criteria are. But it's pretty broad. So if they met that criteria and say, this policy goes into effect, then if they've taken it before or gotten approved in the past, then it would just have to show that they have a medication history of getting it. And then they would get approved.

Alex Park: And what if I'm a pulmonary arterial hypertension patient? I've never been on one of these drugs and I don't need that third criteria. In other words, I can't document that I'm currently established on any of those treatments but I want to get on one of them. How does that work?

Marissa Tabile: Can you repeat your question one more time?

Alex Park: I'm just imagining if I was a patient with this disease not having been on one of these agents before. So I can't give you documentation that I'm currently established on the requested therapy. But me and my provider think I should be starting it. What would the workflow be in that case?

Marissa Tabile: So this is Marissa. Maybe just to clarify, I guess number three is as long as they have one of any, so one of these three. So if you're a patient and your provider is requesting for a nonpreferred product, then of course we would try to steer you into a preferred product first before you can get approved for a nonpreferred product.

Alex Park: Thank you very much. [indistinct] among a B and C. That makes sense. It's late in the day. Okay, thank you.

Donna Sullivan: This is Donna. So Marissa, I want to look at that one more time because I think what is happening is that there's no -- is this prior authorization only for nonpreferred products or preferred drugs on PA as well?

Marissa Tabile: It’s for preferred and nonpreferred products, Donna.

Donna Sullivan: Okay. I think that Dr. Park was correct that that pathway doesn't lead you to being approved for a preferred drug. So I think that they're either treatment naive and the request is for a preferred drug, or there's documentation that they're currently on a nonpreferred drug or they've had a history of trial and failure for a nonpreferred drug, would be the appropriate pathway.

Marissa Tabile: Hi, this is Marissa. So would we need to include language for a preferred product? Is that kind of what your --

Donna Sullivan: Yeah, we’ll take that back. So, letter 3A would be patient is treatment naive and the request is for a preferred drug or then blah, blah, blah. So good catch, Dr. Park.

Alex Park: Thanks, Donna. I didn't quite say it as well as you did. I definitely didn't say it as well as you did.

Donna Sullivan: I wasn't quite following you until I read through it one more time. And it was like oh, there is no way to get to a preferred drug.

Alex Park: Yeah, thanks.

Marissa Tabile: Yeah, thanks for pointing that out, Dr. Park. I apologize. It took me a minute to process what you were saying. But thank you.

Alex Park: Well, I got confused myself when you showed me the or’s and I thought maybe I was getting mixed up. This is why there's more than a couple of us on this committee. So thank you.

Ginni Buccola: This is Ginni. Thank goodness for many minds. So that will be held as well and we then can move to the respiratory agents for cystic fibrosis. Is that correct?

Marissa Tabile: Hi Ginni. This is Marissa. We do have the motion still.

Ginni Buccola: Okay, that’s fine. I just misunderstood. I thought there needed to be more work done to the policy before we move to the motion. Or if it's simply that wordsmithing then we can go ahead.

Marissa Tabile: Yeah, I think we could probably if it's just the wordsmithing for that. So we'll just make sure that what Dr. Park said gets added to the policy with the preferred product language or having a pathway to coverage for the preferred product. So I will put that into the motion.

Ginni Buccola: Okay, good. Then that's just fine. I don't see any stakeholders listed. So when you're ready, we'll go to the motion.

Jordon Storhaug: This is Jordan Storhaug. It seems to me that it's going to probably take some pretty big movements to make this happen. I'm wondering if it'd be possible to have that wordsmithing done and us just vote about it next time to see it in its final copy.

Ginni Buccola: This is Ginni. That's fine with me.

Alex Park: This is Alex Park. I'm on board with that too, Jordan.

[unrelated discussion]

Marissa Tabile: This is Marissa. Ginni, can you see the emotion up? Or can the board members see the motion?

Ginni Buccola: Yes, this is Ginni, I can see it. Donna had started to speak at one point.

Donna Sullivan: I was going to say I had lost audio. And so if you were trying to talk to me, I couldn't hear anything for a minute.

Ginni Buccola: Alright, well, let's hop on this motion then while we've all got some sort of connection.

Jordan Storhaug: I kind of made the request that we'd hold off on it, unless [indistinct] wouldn't be possible for us to see that pathway. And I think most of the time when we're changing things, it feels like we're just moving and changing an "and" to an "or". But it seems like the flow of this document is going change to be able to get a preferred product pathway. So if you could see it next time, that'd be my preference.

Ginni Buccola: This is Ginni. I agree completely. And my apologies that I flipped back. Yes. lost track of where we were. So I'm in absolute agreement with

that unless there are any other concerns from anybody else. Okay. Alright, then. So we will go ahead and move as a group to the respiratory agents.

Marissa Tabile: Hi, Ginni, this is just Marissa. I just wanted to confirm that we're not making a motion, right? You want to have this re-presented?

Ginni Buccola: Yes, you are correct.

Marissa Tabile: Okay, great. Let me go ahead and open up the cystic fibrosis agent policy. [unrelated discussion]

Luke Dearden: Alright. Can you hear me?

Ginni Buccola: Yes, we can hear you, Luke. Go ahead.

Luke Dearden: Great. This is Luke Dearden and I will be presenting the cystic fibrosis agent policy. So a little background to start off with, cystic fibrosis is characterized by mutations in the cystic fibrosis transmembrane conductance regulator, CFTR gene, which primarily causes dysfunction among other things of the chloride ion transport across epithelial linings. And as a result, thick mucus buildup occurs in the lungs among other organs as well. And CFTR modulators are relatively recently approved oral medications that are approved to treat cystic fibrosis. So in the medical necessity section here, it outlines each CFTR modulator FDA approved indication which is slightly different depending on which CFTR gene mutation the patient has. So we can move down to the clinical criteria. And this is a new policy, by the way. I forgot to mention that. So the criteria includes diagnosis of cystic fibrosis, appropriate CFTR gene mutation depending on the medication, so for example, at least one responsive mutation for Kalydeco or Symdeko. And those are outlined in table one in the appendix. Also homozygous F508del mutation for Symdeko or Orkambi. And just to note that that specific mutation is responsible for about 50% of cystic fibrosis cases. And then finally, for Trikafta, there has to be at least one F508def mutation. And that encompasses about 90% of cystic fibrosis cases. Moving on to criteria three, appropriate age, depending on the medication, baseline, BMI, FEV1 and LFTs. Number five, no severe hepatic impairment. And we're talking about really decompensated cirrhosis here, child-Pugh class C.

Baseline ophthalmic examination for pediatric patients. And that's because they've discovered a possible risk of cataracts in that population with these medication. So ongoing monitoring is needed for that. Number seven, patient hasn't had a lung transplant, and then not taken with a strong CYP3A inducer, which is a contraindication for these medications due to the drug interaction, and then prescribed by a qualified provider. Then if you could scroll down a little bit, we have a section here just outlining the requirement. If somebody wanted to switch from, say, Symdeko or another medication to Trikafta, it is allowable. They have to meet all of the initial approval criteria for Trikafta above. And it won't be effective until at least 85% of the patient's current supply of medication has been depleted. And then if we could move down to the reauthorization criteria, which just includes factors that represent disease, stayed improvement, or stabilization. So improvement in FEV1 over baseline, decreased pulmonary exacerbations or infections, decreased hospitalizations, increased weight or growth, or just a decrease in the decline of lung function. And if we scroll down, we have the dose and quantity limits. I will note here that use CYP3A inhibitors would require a reduced dose or a reduced dosing regimen of these medications. And then if we keep scrolling down, we have the responsive mutation to Kalydeco Symdeko and then a list of CYP3A4 inducers, which are contraindicated with these medications. And that's it for the policy. And we can review the form here. So I will allow the committee to read through the form and direct it back to them for any feedback or questions.

Ginni Buccola: Thanks, Luke. I want to make sure that the committee gets a chance to ask questions. I also wonder, we have two stakeholders listed. So I do want to make sure we get time to hear from them. We have both Dr. David Ricker with Mary Bridge Children's Hospital and Lisa Allen with Vertex Pharmaceuticals. Leta, are you able to see if either of our stakeholders are present?

Leta Evaskus: Yes, sorry. I'm looking up right now. Okay, Lisa Allen, I am unmuting you.

Lisa Allen: Yes, thank you. Can you hear me, Ginni?

Ginni Buccola: Yes, I can, Lisa. Thanks. If you can just state your affiliation and let us know if you have any financial disclosures to make. And then you'll have three minutes to speak.

Lisa Allen: Thank you very much. My name is Lisa Allen. I'm with Vertex Medical Affairs. I'm employed by Vertex. And so that is my potential conflict of interest. Thank you for the opportunity to provide public testimony on behalf of the cystic fibrosis transmembrane conductance regulator modulators for the treatment of patients with CF. I would like to begin by thanking the committee for continuing to list Kalydeco, Orkambi, and Symdeko as preferred drugs in alignment with their FDA approved indications. Today I'll focus my testimony on Trikafta, which is the triple combination of elexacaftor, tezacaftor, and ivacaftor indicated for use in patients with CF 12 years and older who have at least one F508del mutation in the CFTR gene. I respectfully request the committee to add Trikafta to the preferred drug list. The rationale for this request is based on the available clinical evidence from two phase three clinical trials. In trial two, a randomized double blind study of patients homozygous for the F508del mutation, treatment with Trikafta resulted in a significant improvement compared to Symdeko in lung function as measured by the absolute change in FEV1 at week four. Both key secondary endpoints, the reduction of sweat chloride levels and clinically meaningful increases in CFTR were also achieved. More recently, results of the post-marketing phase three study of Trikafta in patients with one copy of F508del and negating a residual function mutation showed that treatment with Trikafta resulted in a significant improvement in FEV1. This improvement was in addition to any benefits the patients may have had from existing CFTR modulator treatment with Kalydeco or Symdeko. The warnings and precautions associated with the CFTR modulators have been shared with this committee previously and are found in section five in the USPI for each medicine. These include important information on liver function test elevations, drug interactions, and cataracts. Elevated transaminases has had been recorded in the CFTR modulators. [indistinct] elevations have also been observed with Trikafta treatment. So guidance around the monitoring of LFTs are included in the USPI. If patients experience significant elevation of LFTs, there's also guidance for interrupting the CFTR modulator. Cases of cataracts have been reported in pediatric patients treated with ivacaftor containing regimens. Therefore, baseline and follow up

examinations, as Luke mentioned, are recommended with all four medicines. Additionally, for Orkambi, the warnings and precautions include information on use in patients with advanced liver disease, respiratory event, and effects on blood pressure. Finally, I would like to respectfully request the committee to consider removing initial approval criteria number seven, which is related to patients who have received a lung transplant from the clinical policy, as lung transplant is not a contraindication in the USPI for any of the CFTR modulators. Based on this clinical evidence, I respectfully request the committee to add Trikafta to the PDL in accordance with the FDA approved indication and update the clinical policy to allow access for CFTR modulators to eligible patients who may have received a lung transplant. Thank you for your time and I'm happy to answer any questions you may have.

Ginni Buccola: Thank you, Lisa. Are there any questions from the committee for Lisa Allen? Okay, so we can turn our attention -- unless Dr. Ricker has appeared.

Leta Evaskus: This is Leta. I don’t see him.

Ginni Buccola: I wanted to be sure I didn't miss him. So committee members, why don’t we turn our attention back to the forum and to the policy and see if there are any questions for Luke? So I don't hear any questions. Do we feel ready to move to make a motion?

Woman: [indistinct] stakeholder comment regarding lung transplant.

Luke Dearden: Can you repeat that? Sorry, you were cutting out.

Woman: Of course. Sorry. Can you comment on the stakeholder comment regarding the restrictions after lung transplant?

Luke Dearden: So the rationale for adding that is that there is really very limited to no data using these medications in this population. And in fact, there is, I guess, limited to anecdotal evidence that at least Trikafta can worsen outcomes in the setting of lung transplant. And then the other consideration here is that the immunosuppressant drugs such as cyclosporin, everolimus, et cetera, do interact with these medications quite severely, especially Orkambi. And it is tough to manage those

drugs appropriately when these are also being prescribed. However, with that being said, as we've brought your attention to the paragraph at the end of this clinical criteria many times today, that situation could be reviewed on a case by case basis by a clinical reviewer.

Constance Huynh: This is Constance. So, Luke, you were mentioning, so number seven, the lung transplant plant criteria was placed because of lack of evidence of showing efficacy. Is that correct?

Luke Dearden: Just lack of data in general when used in this population.
That was one of the reasons, yes.

Constance Huynh: If that's the case, I would actually think it shouldn't be there if we don't have enough evidence for it, yea or nay. So if you drafted this based off of - you're representing HCA - what the point is of having that clause. Is it to protect patients that potentially could have an adverse outcome even though there isn't evidence to support that.

Luke Dearden: So, as I mentioned earlier, there is some anecdotal evidence, or I would actually say limited evidence that Trikafta worsens outcomes in this population. This is something that I could take back and review more as well. And then also, I mentioned the serious drug-drug interaction concerns where use of the immunosuppressants post-transplant, the levels can be very unpredictable as some of these, for example, Orkambi has both a CYP3A4 inducer and inhibitor. So there is that drug-drug interaction concern, as well, realizing that it is very important in that post-transplant setting to maintain levels of those medications.

Constance Huynh: Okay, thank you, Ryan. I know you've probably said that three times and eventually it'll stick.

Luke Dearden: I will say, though, that I am open to feedback around this specific criteria. And if the committee thinks that it should be taken out, I have absolutely no problem with that.

Donna Sullivan: And this is Donna. I'm actually, I think, the one that put this in there. In one of the labels of one of these products, it is actually in the product label that it's not recommended in patients for lung transplant. So I would like to go back and do a little bit more research on that.

[indistinct] with the ivacaftor ingredient within the within the product.

Luke Dearden: That medication is Orkambi, like I said, that is actually contraindicated in this population. However, not only lung transplants, it would apply to all transplants, I will admit.

Constance Huynh: So this is Constance again. I appreciate you, Luke, saying there's some anecdotal evidence because we probably experienced certain reactions and have heard stories or personal experiences with our patients and certain medications. And it potentially couldn't be used as a flat type of understanding that it would happen across the board. So I appreciate you guys looking into that. And if it is showing evidence that there is a connection between any adverse effect and lung transplant, then I think it would be worthwhile putting it in the policy, but not based off of just anecdotal evidence. So I appreciate that.

Ginni Buccola: This is Ginni. So that sounds like this one, we will also skip over the motion for CF agents this month. Is that correct?

Marissa Tabile: Hi, Ginni. This Marissa. Yes, that's correct.

Ginni Buccola: Okay. Alright.

Woman: Hi, Ginni. Can I just make one suggestion? So as we're doing this for number seven, should we just make sure that it shouldn't be all solid organ transplant recipients, if there's significant interactions with immunosuppressants that are the concern? Not to be just for next time when we revisit the policy?

Nancy Lee: This is Nancy. I would agree with that just to also, I guess, address the significant drug-drug interactions with just transplant medications in general. So we're addressing the issue as well.

Luke Dearden: Yeah, we can look into that. And would just a blanket statement concerning as these have many drug-drug interactions in CYP3A4 inhibitors, inducers, [indistinct] CYP3A, which is the immunosuppressants like facrilemus, cyclosporin, would more

blanket statement like making sure that all drug-drug interactions are checked, be appropriate. That could be something as well.

Donna Sullivan: Hi, this is Donna. I have some follow-up on the lung transplant. So I had looked at other state policies and the state of Minnesota excluded patients that had had a lung transplant. And the response that they came back was that they had a pediatric pulmonologist on their committee that advised them to exclude the patients with a lung transplant because of the impact on Trikafta on lung function of CF transplant patients was not known. And then there is actually a case report where there have been unexpected detrimental effects on a patient taking Trikafta after a lung transplant. And they sent that to me. And then when they took the patient off of Trikafta, their lung function improved. So it was definitely related to the Trikafta product. And I can forward that to you if you'd like.

Alex Park: This is Alex Park. My concern here is that we're talking about one or two - there's just not a lot of data - one or two cases here and there. And there's probably not going to be a lot of experience in the literature on this topic. And to a certain extent, I worry about us doing too much micromanaging. We want doctors and pharmacists and providers to do their work. We want to trust them to do their work correctly and appropriately.

Donna Sullivan: So we can go ahead and remove that if you like. And if we remove that particular item, would you be able to approve the policy as written?

Alex Park: I would be or I'd be comfortable putting something into the effect of you know, if patient has had a solid organ lung transplant, the documentation of discussion with the transplant team.

Donna Sullivan: I would rather not do that. I would either remove it completely because if you say documentation, then a plan might deny it because they didn't have the proper documentation. And that just becomes kind of like another box to check. I wouldn't want it to be denied if there wasn't documentation if you thought it was okay to give to a patient with a lung transplant.

Alex Park: Well, I'm not saying I think it's okay. But I think I'm saying I trust providers to do their homework on this topic. And CF patients are

usually getting the cream of the crop, at least in our state, at dedicated centers. So I would feel comfortable removing this.

Donna Sullivan: Okay. I guess my point was, if a provider had that conversation with the patient and it wasn't adequately documented, I would not want it to get denied due to lack of documentation.

Alex Park: Yeah, that's a very good point.

Constance Huynh: So having said that, Donna, this is Connie, is there a way for us to word it [indistinct] where you don't have to have required documentation, but we could put a notation saying that patient has been adequately or will be discussed about potential adverse effects, or something along that? Can we put a recommendation for providers to be aware of that? [indistinct] So patients with history of lung transplants have been adequately [indistinct] of potential adverse effects.

Donna Sullivan: Okay, so we'll put a checkbox on the form and if they check the box, it'll be okay. But if they don't check the box, it'll get denied.

Jordan Storhaug: This is Jordan Storhaug. What I'm kind of hearing I think, is we have three options. Either, due to our lack of data, we can refuse to do it for lung transplants. But what we can make it a requirement that they do something to do this, of which case we risk -- it's kind of a supervisory role. I guess what I strongly want to suggest we do is try to get into the business of serving as a cystic fibrosis guideline for Washington prescribers. I think that would be a mistake. Personally, my inclination is due to the lack of data to [indistinct] number seven out and trust that our subscribers know what they are doing with this and use our other criteria to approve, but just have to trust them that they are making wise decisions about this.

Ginni Buccola: This is Ginni and I would support that statement.

Alex Park: This is Alex Park. I agree.

Ginni Buccola: This is Ginni again. So if there's consensus on removing number seven, and it sounds [indistinct].

Nancy Lee: This is Nancy. What about [indistinct] as well?

Alex Park: This is Alex Park. Did we have that?

Nancy Lee: Well, I guess [indistinct]. Never mind. I think it's been taken care of. [indistinct] Resolved.

Ginni Buccola: This is Ginni, again. We also have a hand raised from the stakeholder.

Leta Evaskus: I don't see any stakeholders.

Ginni Buccola: Okay, I thought I saw Lisa Allen's hand.

Leta Evaskus: I do see Lisa. I'm sorry. Go ahead, Lisa.

Lisa Allen: Thank you so much. Yes. So, I really appreciate the discussion about the lung transplant. It really does pertain to all solid organs. And this is something that some CF clinics are exploring in patients since cystic fibrosis is a systemic disease. And often patients do still need the benefit of CFTR modulators to treat their sinus disease, their GI issues, pancreatic issues, and things like that. Many CF clinics do have CF pharmacists available that carefully are able to monitor in cooperation with the transplant teams, the potential drug-drug interactions, and adjustments of those dosages. And lastly, that one case report of the two patients that had adverse effects on Trikafta on top of having had lung transplants, what they were experiencing was what's being called the purge. And they have an acute clearance of a lot of mucus that really affects their ability to breathe. And that caused the shortness of breath and it was alleviated when Trikafta was discontinued. But it isn't necessarily detrimental on the lung transplant. It's just the adverse event that some patients can experience as they're starting. And they clear out all the mucus that's in their lungs and sinuses.

Ginni Buccola: This is Ginni. Thank you. Any additional comments, committee members?

Alex Park: This is Alex Park. This is not a question but this is an extemporaneous, plea, Lisa. I hope that companies like yours are able to really think hard about getting the costs down on these drugs. Thank you.

Lisa Allen: Thank you, Alex, I understand very much what you're saying.

Ginni Buccola: So committee, let's go ahead and entertain this motion.

Jordan Storhaug: This is Jordan Storhaug. I move that the Apple Health Medicaid program implement the clinical criteria listed on policy 45.30.00-2 as recommended, with the exception that the removal of the lung transplant criteria.

Ginni Buccola: This is Ginni. All those in favor, please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? And the motion carries. And we have one more motion and that is Apple Health Policy opioids update with Ryan Pistoresi.

Ryan Pistoresi: Good afternoon, this is Ryan. So thank you. I will try to make this quick, knowing that we are over the 4:00 time. So the purpose of today's presentation is to one, go over the information that was presented at the October 2019 DUR meeting. This was related to updates and the opioid policy to add in an MME limit to be compliant with the Support Act. We are also working on a future Support Act implementation that will go live in 2021 that I will also preview. So two points for today's presentation. Do we have the slides? Yes, that one. Thank you. So we'll start with the slides and do an overview from here. So thank you. So as I mentioned, we'll review the changes that occurred to the opioid policy in November and also a preview of the upcoming changes for 2021 regarding checking the prescription monitoring program. On the next slide is just a timeline of the different changes that we have made over the last few years. So in 2017, we made the first major update which added the acute and chronic limits, so the 42 day supply cut off going between acute and chronic. We also created expedited authorizations that allowed overrides for the provider discretion for the acute limits. And we also created the opioid adaptation form for chronic opioid use. Last year, we updated the attestation form to include authorizations for prescriptions over 120 morphine milligram equivalents per day to align with the requirements of the Support Act. So the Support Act mandated that states have an MME limit in place for their opioid

prescriptions. And we look to align that by using the state's House Bill 1427 workgroup recommendations that then were put into the Washington Administrative Code for the five boards and commissions that prescribe opioids in our state. And then also, next year in 2021, we will be creating new guidance for how providers can check the prescription monitoring program prior to prescribing and dispensing prescription. So it'll be slightly different between the prescribers and then the pharmacists who are dispensing these prescriptions. On the next slide is just a quick overview of the changes for 2019. So the Support Act was federal legislation that passed in 2018 that directed federal agencies to focus on the opioid crisis that is occurring across our country. And one of the sections, section 1004, was specific to how state Medicaid agencies can address it through opioid clinical policies. On the next slide is a little bit more detail about section 1004, which really directed states to develop their own MME criteria. So because different states had already developed their own MME criteria, the federal law just directed states to develop their own state specific ones. And because it was a state specific one, we looked at what work was already being done in our state around MME limits. And there was already a workgroup going on for the implementation of Engrossed Substitute House Bill 1427 that was creating criteria around high dose opioid prescriptions. So the consult and the exemptions that we derived from the WAC were put into the policy and also updated on our attestation forms. So we created that criteria so that it applies the prior authorization criteria for claims that result in either alone or in combination a daily MME of over 120. But it does allow the providers to attest that they have completed the consult with a pain management specialist or that they meet one of the exemptions as it is outlined in the WAC. And so the WACs are dependent on the different boards and professions that are applicable to that provider type. So this is our attempt at really aligning with what clinical practice guidelines were for the providers in our state when we implemented this also in 2019. For claims that are over 200 MME, it does require the completion of an attestation and that the supporting documentation or the chart notes be submitted to HCA for review. This helps us better understand what clinical documentation and the rationale for the medical necessity for these treatments that are over 200 MME per day. And so this should be specific to the requested dose. So if someone is elevating their dose from 200 to 300, we would require the rationale for a jump like that. And this was

presented at the October 2019 meeting. It was presented as information only then. The reason that we're bringing it back and recapping this is that we did not have a DUR board motion for that policy that was finalized. And so we are bringing that back today with a board motion for you to make on the MME specific criteria. And we do have the policy and the pin form. I think they were up on Marissa's screen prior to transitioning over to this slide. So we will be able to look at that once we get to the board motion. But for the rest of this presentation, I'll just be highlighting the upcoming changes so that way you are aware of what we are doing to implement section 5042 of the Support Act. So in October of next year, we will be updating our clinical criteria to provide the guidance for how providers can meet this new federal law. So this is important to note that this is for all controlled substances and not just opioids like the previous other policies. But because this has a direct impact on opioids, we're bringing it here today and putting it in with the opioid policy. But do note that this law, which is now codified in the US code, is for all controlled medications. And the quotation there at the bottom of the slide is the relevant part of the law that we are going to focus on today. So these are going to be updated also and our administrative code will also be updated, our building guides to outline what is now expected. And in order for us to meet the compliance with the federal law, we're going to be publishing the clinical policy. And we're going to be creating a compliance monitoring process, which we are required to report annual reports to CMS. And we're also going to be providing communications. And this presentation today is one of the many communications that we are working on. We have also reached out to the different boards and commissions through DOH. We've also reached out to the different health professional associations in the state about this. But you are actually one of the first ones that we are actually doing a full presentation on about this. So the new clinical policy, so in order for the prescribers to meet the intent of the federal law, we are guiding providers that prior to writing a prescription for any controlled medication for a Medicaid patient that they must check the Washington State prescription drug monitoring program no more than ten days prior to writing the prescription. For pharmacists who are dispensing these medications, they would be required to check the PMP no more than 48 hours prior to filling and dispensing that controlled medication to that client. And these would be added to our WACs and provider guides. And what's important to know is that

unlike the other clinical policies that we put in place in 2017 and 2019 that this is not going to stop or limit opioid prescriptions. This is intended for the provider to use these tools to get more information about the patients that they are treating, to be able to look at a whole current prescription drug history for these clients, and to use that information when making decisions about the treatment plans that are right for them. So we are not going to stop opioid prescriptions and say, "Did you check the PMP ten days prior to writing this prescription or prior to dispensing this?" and then potentially stop the patient from getting their medication. This is a tool that is being used to help provide education to our providers prior to caring for these patients. So there are no new limits being applied to opioid or controlled substances as a result of this new policy. So the providers and pharmacist need to review all of the current prescriptions that are documented in the PMP. The providers and pharmacists are able to delegate this review to anyone within their practice setting with an authorization to access the PMP so long as they provide the provider and the pharmacist the opportunity to review all of the current prescriptions prior to either writing the prescription or dispensing that prescription. And in order to document this and to verify that this check did occur, they would review that and document the time and date that this occurred in the patient's record. We do know that sometimes the PMP is not available or that there are other emergencies that are going on in which it is not possible to access the PMP. And so there is a good faith effort that would be acceptable if they are not able to access the PMP but they intended to do so and are able to do so when the PMP is available. The new monitoring program that we are developing here at HCA will measure the amount of qualifying checks that prescribers, pharmacists, and their delegates do. So we are working with our partners at the Department of Health in order to develop these reports. So that way we can measure how often prescribers and pharmacists are checking the PMP within these limits. We will be using our claims data to identify the date that the prescription was written and the date the prescription was filled and dispensed to the client in order to be able to verify that these checks that occurred on this patient occurred at these dates. In the event that we need to do any further in depth reviews, we would be able to look at the notes that show that when a date or other good faith effort was done, would count as a qualifying check so long as they were meeting the intent of this policy. We are considering sending out educational

letters to prescribers and pharmacists who are below 80% qualifying checks. We had some success in the past with previous letters that were sent to prescribers related to opioid treatments. And we are considering using a similar model for that in order to help prescribers and pharmacists check the PDMP. And then we will need to be reporting this to CMS. Our first report we anticipate will be due, our drug utilization review report, which is due June 30 of 2023. Next slide. And so we are creating a robust communication plan. So, as I mentioned, we have already reached out to the boards and commissions, the state health professional organizations, and even here today. And we are looking at getting the message out prior to this going live for October. And we do have a few key messages that we have listed here that are central to our communication plan. And then here's a bit of information about where we are putting these updates related to Support Act implementation. And then that is a hyperlink to our Apple Health pharmacy policy mailbox here at HCA, which we are using to track and triage these questions. And so this is the end of this presentation. If we want to pull up the policy or the form, we are able to do that. But I realize we are a bit over and I wanted to open it up to the PNT DUR board to see if there are any questions or comments on this.

Ginni Buccola: Thanks, Ryan. This is Ginni. That is really informative and helpful for us to hear. I don't have any questions but I want to turn it over to my fellow board members. I don't want to jump the gun but I also don't hear or see anybody popping in. It sounds as if we need to make a DUR motion to the motion that was done last year. Is that right?

Ryan Pistoresi: Yeah. Hi, this is Ryan. And so yeah, so we do have the motion up. So this is for the policy effects that went live on November 1, 2019 related to MME requirements that are compliant with section 1004 of the support act and that are aligned with the boards and commissions rules that went into effect on January 1 of 2019.

Jordan Storhaug: This is Jordan Storhaug. Ryan, could I ask you a clarifying question?

Ryan Pistoresi: Yes, certainly.

Jordan Storhaug: For patients who transfer onto Medicaid but have been previously on chronic opioids, it seems the workflow now is a person’s not able to

do a chronic opioid attestation for that person 'til they've completed 42 days. Is there another workflow that those patients should be going through? Or does the system kind of make them an acute user for 42 days and then can get to the typical procedures?

Ryan Pistoresi: That's a great question. I'm pulling up the attestation form just to see how we had accounted for that.

Amy Irwin: Hi, Ryan. This is Amy. It's actually accounted for using one of the expedited authorization codes. So the pharmacy would recognize that the client was previously established on chronic opioid therapy and would enter the expedited authorization code and the claim would pay.

Jordan Storhaug: This is Jordan Storhaug. So if there's problems, it's a pharmacist who doesn't know the right code to submit, it sounds like.

Amy Irwin: Possibly, yes. There's been several different pathways that things could go down. But that could be part of it. It could be that maybe they're going to a pharmacy where they don't have the established history, whereas the provider can actually see that. The prescriber can see the history but they may be at a pharmacy that they haven't filled before. There's been several things that have popped up.

Ryan Pistoresi: This is Ryan Pistoresi again. So if there is a specific case that has been causing you issues, can we recommend that you email us and we can see what we can do in order to assist if this is a common issue.

Ginni Buccola: Are there any other questions? This is Ginni. I wonder if I could see who's still here. I want to make sure we still have a quorum of committee members.

Leta Evaskus: This is Leta. I just checked on that, Ginni. We do.

Ginni Buccola: Alright. Any other questions?

Nancy Lee: This is Nancy. I move that Apple Health Medicaid program implement the clinical criteria listed on policy 65.10.00 as recommended.

Susan Flatebo: This is Susan Flatebo. I second.

Ginni Buccola: This is Ginni. All those in favor, please say aye.

All: Aye.

Ginni Buccola: Are there any opposed? And this final motion carries. So that looks as if we've made it to the end of the agenda. Are there any comments from Leta or from Donna before we go?

Leta Evaskus: This is Leta. Thank you guys so much for finishing the agenda.

Donna Sullivan: I want to ditto that. And thanks for just serving on the DUR board. I know it sometimes isn't the funnest job when we're having a lot of opposition from stakeholders. So I really appreciate all the work that you do. Thank you.

[end of file]