State Pharmacy and Therapeutics Committee
Drug Utilization Review Board Meeting
April 20, 2016

Susan Rowe: Good morning everyone. I would like to call this meeting to order because we're still waiting for one committee member, but we do have a quorum. The first thing on the agenda today is I want to welcome everyone. Let's start with Christy and go around the room and everyone introduce themselves.

Christy Pham: Christy Pham from L&I.

Jaymie Mai: Jaymie Mai from L&I.

Doug Tuman: Doug Tuman from L&I.

Mason Bowman: Mason Bowman, committee member.

Amber Figueroa: Amber Figueroa, committee member.

Dale Sanderson: Dale Sanderson, committee member.

Lisa Chew: Lisa Chew, committee member.

Michael Johnson: Michael Johnson, committee member.

Susan Rowe: Susan Rowe, committee member.

Christine Klingel: Christine Klingel, committee member.

Eric Harvey: Eric Harvey, committee member.

Leta Evaskus: Leta Evaskus, Health Care Authority.

Donna Sullivan: Donna Sullivan, Health Care Authority.

Ray Hanley: Ray Hanley, Health Care Authority.

Susan Rowe: Good morning and welcome. We're going to have a packed meeting today with a lot of short subjects, but our first order of business is to elect a new chair and vice chair. I have truly enjoyed chairing this committee, but term limits are a good thing for everyone. I would like to first take nominations for a new chair.

Okay. Well, then I am going to nominate Michael Johnson to be the chair. And Michael, are you willing to serve?

Michael Johnson: Yes, I would.

Susan Rowe: Does anyone else have some interest or another nomination?

Christine Klingel: I'll second Michael Johnson's nomination.

Susan Rowe: Thank you very much, Michael, for agreeing to run. Let's elect Michael by acclamation. All say, aye.

Group: Aye.

Susan Rowe: Okay. Very good. And our second order of business is a vice chair. Is… may I have nominations for a vice chair?

Amber Figueroa: Can you clarify the duties of the vice chair?

Susan Rowe: Vice chair is to really learn as you go and then if Michael were not able to make a meeting or, you know, got in a traffic snarl up, which occasionally happens, would need to chair the committee. Because, and let me clarify for everyone, because of our law on open meetings you really serve as chair and vice chair at these meetings. And you do your background work as you would like any other committee member. So there's no extra really work involved other than kind of keeping track of the flow of the meeting and maybe studying up Robert's rules of order. Nominations?

Christine Klingel: I nominate Eric Harvey.

Susan Rowe: And Eric, are you willing to serve?

Eric Harvey: I am.

Susan Rowe: Okay. Any other nominations? Okay. Thank you very much, Eric. Let's elect Eric by acclamation. All in favor of Eric say, aye.

Group: Aye.

Susan Rowe: Very good. Thank you very much. Now, I have… I anticipated and I'm going to finish chairing this meeting and then I will ceremoniously turn over… we don't have a gavel, because we just aren't that boisterous. We're pretty calm and…

Donna Sullivan: You do have the egg timers.

Susan Rowe: I do have the egg timers. I'm going to ceremoniously turn over the three-minute egg timers to Michael at the end of the meeting. So thank you very much. Okay. We are already ahead of schedule and so are we ready to have our report on antiplatelet agents?

Donna Sullivan: We're calling Marian right now.

Susan Rowe: Thank you. I do want to call attention to our committee that Donna has compiled a really nice cheat-sheet for us in our notebooks. It tells us what needs motions, what doesn't and so I would advise everyone, whether you take your notebook or not, maybe take your cheat-sheet at the end of the meeting. Thank you, Donna.

Donna Sullivan: You're welcome.

Marian McDonagh: Hello?

Woman: I think we're ready to get started.

Susan Rowe: Good morning, Marian. We're ready to hear the review on newer platelet agents.

Marian McDonagh: Okay. Great. Thank you. Okay. So, let's see… let's go… I'm sure you're looking at that first slide. Why don't we go to the second slide? This is the history of the report to remind everybody where we are. The date of the last full report update was update #2 in June 2011. We did do… we have been doing scans, the usual scans since then, and the last one was done in February 2015 and the searches for this scan went through December 2015. Slide 3.

These are the populations that are included in this report. Acute coronary syndrome, patients' recent or ongoing coronary revascularization by stenting or bypass grafting. Patients with prior ischemic stroke or TIA, and patients who have symptomatic PVD. Those are what we were looking for. The next slide, slide 4.

This is the interventions that are included, the drugs, and those two that are underlined are the ones that were not in the last full update. So we have told you about some of that evidence in previous scans, but those are the ones not in the last full update. Next slide.

These are the effectiveness and efficacy outcomes. So we're looking for all the major outcomes that we would be looking for in these populations. On the next slide, slide 6.

These are the safety outcomes and in addition to our usual overall adverse events, withdrawal and serious adverse events, we're also looking for other adverse events known to be associated with these drugs and primarily we're looking for hemorrhage or major bleeding events. Next slide, slide 7.

This is a different type of scan than the usual scan. So I want to spend just a couple minutes going over how it's different. The DERP participants have not elected to do a full update of this report yet. So at this point in time the State of Washington asked us to do a little bit more than the usual scan. So this is what we came down to. We focused on the new drugs since the last full report. So for study selection it's narrowed. It's head-to-head trials only of the new drugs. We looked at placebo-controlled trials if there was absolutely no head-to-head evidence for what are these new drugs. We added quality assessment.

So for the usual scans we don't do that, but here we looked at the studies and did give you a quality assessment. And we did do a review of any that might have been poor to make sure we were in agreements on that. We also did some data abstractions. So this is also new. We typically put some information into a table for you, but here we provided more information. We looked at benefit outcomes looking primarily at mortality and cardiovascular outcomes and then a limited set of the adverse event outcomes, as well. We provided in the table in the report the author's conclusions, because in a scan like this we weren't able to do our own synthesis of the evidence, and again this is a really focused scan looking at just those new drugs. I guess I should also comment that we… there are a lot of secondary analyses, or secondary publications that come out of these big trials. So we did look at those and we're reporting a couple of those to you here that are… the rule we were using is if the results of the secondary analysis were strongly different to the overall findings of the main trial then we would tell you about those. Any questions on how this scan methodology is different? What you're getting that's different here to your usual scan? No?

Susan Rowe: Thank you. No, this seems good.

Marian McDonagh: Okay. Great. And as we get through the evidence, if you have any questions, I'll certainly address those then. Next slide.

These are the new drugs that we included and cangrelor is a drug that is intravenous only and used periprocedurally in very short… essentially in-patient setting. So we did not include that here. And as I mentioned we are including mainly new evidence on vorapaxar and ticagrelor. Next slide, slide 9.

Since the last full update report there are no new serious harms and by this we mean boxed warnings. And there are a few comparative effectiveness reviews out there that you could use if you wanted to, to look at the evidence more deeply. In 2015 there's a Cochrane review on antiplatelet agents for preventing thrombosis after peripheral arterial bypass surgery. And then there are two AHRQ reports from 2013 that I think we've probably told you about before. And one of those is looking

at peripheral artery disease and the other one is looking at patients with unstable angina and non-ST elevation MI. Next slide.

So then this is looking at what evidence we found since the last update report. So it's cumulative since then. So there are a total of 20 head-to-head trials, 39 secondary analyses, and then 15 placebo-controlled trials. So out of that set what we're going to present to you today is the bottom half of the slide looking at the new drugs. So there are four head-to-head trials comparing ticagrelor with clopidogrel or prasugrel. None of those were poor quality. They were all fair quality and then we also had five placebo-controlled trials of vorapaxar. Those were also fair quality. One of those we rated as good quality specifically for the bleeding outcomes. They did a really nice job with that—measuring those. Then as I mentioned, a couple of secondary post hoc or subgroup analyses we wanted to tell you about as well. Slide 11.

So I'm going to go through this by disease state or by population category. So for acute coronary syndrome… I want to draw your attention to Table 2 in the report because that's where there's more detailed evidence on the outcomes. So, for example, the odds ratio or relative risks for these findings are in Table 2, if you're interested in seeing those. So here for ACS ticagrelor resulted in lower cardiovascular outcomes rates them clopidogrel and this is the Plato study. And there was no difference in major bleeding. It was a year-long study and I have a type-o. It was actually 18,000 patients, not 16,000. We also included a subgroup analysis that found that patients who were using proton pump inhibitors that there's an association with a higher rate of cardiovascular events with either drug. So a drug interaction there. And then secondly on acute coronary syndrome, vorapaxar we found a study that showed that vorapaxar added to standard therapy did not reduce cardiovascular events, but did result in increased important bleeding. So that was a big study, almost 13,000 patients year-long. Standard therapy was everybody was receiving aspirin and 87% of patients were also receiving a thienyl pyridine. So clopidogrel mostly. Next slide, slide 12.

So this is a large study of vorapaxar looking at patients with stable atherosclerosis. So it's more than two years in duration, 26,000 patients, includes people who are post-MI, who have had an ischemic stroke, and

then I'm sorry I do have another type-o here. Peripheral arterial disease, not peripheral vascular disease, were included. So here vorapaxar added to standard therapy did reduce cardiovascular events and mortality, did result in increased bleeding, but there was no effect on all-cause mortality. And then in a subgroup analysis looking just at that group with peripheral artery disease there was no benefit on cardiovascular outcomes, but there was reduced acute limb ischemia and peripheral revascularization, and again increased bleeding. But of course it is a subgroup so the sample size is smaller and it may not have had adequate statistical power to find the difference in those cardiovascular outcomes. So it's really just a suggestion that they might need to do another study on that subgroup.

Now if we move on to slide 13 there was a group of some short-term trials, much smaller sample sizes. So these are one to two months. These are designed to look at harms and not… really don't have the statistical power to identify differences in benefit outcomes. So for patients undergoing PCI there were fewer peri-procedural myonecrosis events with ticagrelor than prasugrel. No difference in bleeding. This myonecrosis is defined as asymptomatic increases in troponin. And there were no deaths in this study. In the next line for vorapaxar there were two studies where vorapaxar was added to standard treatments in this PCI population and they were looking at bleeding events and there was no increase, no increase in bleeding events by adding vorapaxar in this population. So the studies were pretty small. There was one in Japan that had 117 patients. And they did find a statistically lower rate of peri-procedural MI in the group that received vorapaxar, but again it's a pretty small study so we need to see that replicated in a larger study. Next here in this small studies we have one, again, from Japan that's looking at post-ischemic stroke with vorapaxar added to aspirin and here there was no increase in bleeding events. Again, it was a small study so they didn't look at… or they did look at the other kinds of cardiovascular outcomes, but with 90 patients it's hard to make any sense of that. Slide 14.

So if we look at slide 14, then, the summary is just, again, summarizing what we found since the last full report in 2011. Two new drugs, no new boxed warnings, there's a few new comparative effectiveness reviews

out there and then a total of 20 head-to-head trials, 15 placebo-controlled trials and 39 secondary analyses.

And on the next slide summarizing the new evidence in this expanded scan is that there were four head-to-head trials out of those 20 total. These were of ticagrelor and then… versus either prasugrel or clopidogrel and then the five placebo trials of vorapaxar out of the 15 total. And then in patients with ACS ticagrelor reduced cardiovascular events and mortality more than clopidogrel and did not increase bleeding. Vorapaxar added to standard therapy did not improve cardiovascular events and did increase bleeding. In post-MI, ischemic stroke, or PVD patients adding vorapaxar did reduce cardiovascular outcomes and increased bleeding. No effect on overall mortality or all-cause mortality I should say. Next slide.

On the next slide, slide 16, then the short-term trials ticagrelor resulted in fewer peri-PCI events without worsening bleeding compared with prasugrel. Vorapaxar did not increase bleeding events when added to standard treatments in either PCI or post-stroke patients.

This summarizes the new expanded scan.

Susan Rowe: Thank you, Marian. Do any of the committee members have questions for Marian?

Eric Harvey: I have a question on slide 12. The post-MI study using vorapaxar. Marian, if you could clarify exactly what the subgroup analysis, what the population was in the subgroup analysis versus the total population because it seems like the total population they didn't see… they saw a reduction in the cardiovascular events, but in the subgroup they didn't see a reduction in cardiovascular event. So which were the two populations?

Marian McDonagh: Right. So the overall study population was broader and it included people who were described as post-MI ischemic stroke or peripheral arterial disease and then the subgroup is only the patients in that last category, the peripheral arterial disease excluding ischemic stroke or post-MI patients.

Eric Harvey: Thank you for that clarification.

Marian McDonagh: Sure.

Susan Rowe: Are there any other questions for Marian? Okay. Thank you, Marian. Can we let Marian go or do we want her to hang out for a little bit?

Donna Sullivan: I think we can let her go.

Susan Rowe: Okay. Marian, take a break. Thank you very much.

Marian McDonagh: Okay. Thanks a lot.

Susan Rowe: Next would be our stakeholder input. We have one stakeholder today, Dr. Jamie Hurst. Mr. Hurst, when you… just identify who you're speaking on behalf of and you have three minutes.

Jamie Hurst: Good morning. Jamie Hurst. I'm the medical science liaison with AstraZeneca and thank you for the opportunity to present new information on Brilinta this morning. So Brilinta is indicated to reduce the rate of CV death, MI and stroke in patients with ACS or a history of MI. For at least the first 12 months following ACS it is superior to clopidogrel. Brilinta also reduces the rate of stent thrombosis in patients who have been stented for treatment of ACS. The updated ACC AHA guidelines on the duration of dual antiplatelet therapy stated that Brilinta is preferred over clopidogrel for the management of ACS including both NSTEMI and STEMI patients who received a coronary stent. Brilinta is also preferred over clopidogrel and [inaudible] patients treated with medical therapy alone.

The indication for secondary prevention for MI is based on the Pegasus TIMI 54 trial. The Pegasus trial evaluated Brilinta in 90 mg or 60 mg twice daily plus low-dose aspirin versus placebo plus low-dose for the long-term reduction in thrombotic CV events in over 21,000 patients with a history of MI one to three years prior to randomization plus one additional risk factor. Brilinta 60 mg plus low-dose aspirin was superior to placebo plus low-dose aspirin in reducing the rate of thrombotic CV

events, which was a [inaudible] CV death, MI or stroke in prior MI patients with a relative risk reduction of 16% and an absolute risk reduction 1.27% at three years. Brilinta was associated with higher rates of the primary safety endpoint [inaudible] major bleeding and dyspnea versus placebo. A pre-specified subgroup analysis in the Pegasus trial evaluated the efficacy and safety of Brilinta versus placebo in 6,800 patients with a prior MI and a history of diabetes. In these patients there was reduction in major adverse cardiovascular events at three years with Brilinta 60 mg versus placebo. A subgroup analysis of the Pegasus trial evaluated the efficacy and safety of Brilinta versus placebo in over 1,000 patients with a history of MI and peripheral arterial disease at baseline. In these patients there was a numerically lower rate of composite end point at CV death, MI and stroke at three years for Brilinta 60 mg versus placebo.

The following is off-label information about Brilinta and AstraZeneca does not recommend the use of its products in any manner other than described in the full prescribing information. It is proposed that increased [inaudible] concentrations may result in dyspnea. Ticagrelor increases [inaudible] concentrations of [inaudible], which may cause dyspnea.

Finally, the most commonly reported adverse reactions are bleeding and dyspnea and there are boxed warnings for Brilinta related to an increased risk of bleeding and reduced effectiveness with the maintenance skills of aspirin greater than 100 mg per day. Please refer to the Brilinta prescribing information for complete product information including full boxed warnings and warnings and precautions. Thank you. I'd be happy to address any questions.

Susan Rowe: Thank you, Dr. Hurst. Does anyone have any questions for Dr. Hurst? Thank you very much.

Jamie Hurst: Thank you.

Susan Rowe: I think the next…

Donna Sullivan: Susan, I just wanted to explain a little bit about what the expanded scans are and the intent of them. So we asked the Drug Effectiveness Review Project to create a new product that might be able to suffice as an update to the report when we have new drugs in a class where there's not a lot of new information in the class and it's not likely to be voted by the governing board of the Drug Effectiveness Review Project for a full update. So this is our attempt to try to get you more information about the new products without doing a full update. So, what I'd like the committee to do is, you know, evaluate the information that you just received and decide, as a committee, do you feel that this is enough information to consider this an updated report, which would allow for the [inaudible] and the Brilinta to be considered as preferred drugs on the PDL or if you still want to wait for a full review of the class by the Drug Effectiveness Review Project, which at this point in time I couldn't tell you when that might happen or the state would have to find funds to update the class on our own.

Susan Rowe: Donna, I'm… as we deliberate that and then we accept the expanded scan as adequate…

Donna Sullivan: As an updated report.

Susan Rowe: As an updated report.

Donna Sullivan: Yeah.

Susan Rowe: Okay. So I'd like to hear from the committee how they feel about these extra… the nine… essentially nine new studies that were reviewed as part of this.

Eric Harvey: I think it's sufficient for myself to consider the two new drugs as part of the class.

Lisa Chew: I agree.

Susan Rowe: I agree, also. Does anyone else have reservations, though?

Mason Bowman: I agree. I just… I do hesitate with the small sample size in some of these studies, but I think overall I feel okay about it.

Susan Rowe: I would like to entertain a motion to accept this expanded scan as an adequate class review. Okay. Do I hear a motion?

Eric Harvey: I would move.

Michael Johnson: I would second.

Susan Rowe: Okay. For the committee, all in favor say aye.

Group: Aye.

Susan Rowe: All opposed, same sign. Okay. So the motion is great. Thank you. The next thing we are going to do is turn our attention to the last… the last time we approved this class of drugs, look at the motion, see if we would like to change the motion in any way. So I would like to take a couple of minutes to look at this.

What we're looking at, really, as we review it is we have three motions. One is looking at acute coronary syndrome. One is looking at ischemic stroke and one is the possibility of continuing not to have ticlopidine on our list at all.

I think what we were shown today is, with the new agents, really shown interventions in acute coronary syndrome, but not ischemic stroke. So I think I would be in favor of continuing with the three motions.

Mason Bowman: If we could clarify, on that third motion, we say we do not want ticlopidine to be on the PDL. But we have ticlopidine and aspirin combination to be considered. So, is that what we are discussing or are we discussing ticlopidine alone?

Susan Rowe: I would say no combination either.

Donna Sullivan: That is correct. There is a new combination ticlopidine I think aspirin product out there. So no, it's not under consideration.

Susan Rowe: All right. For the first one then I'll take a stab at that motion. After considering the evidence of safety, efficacy and special populations for the treatment of acute coronary syndrome, percutaneous coronary intervention, and peripheral vascular disease, I move that clopidogrel, prasugrel, ticagrelor and vorapaxar are safe and efficacious for the treatment of the approved indications. Now, I'm going to stop. I want a little discussion. What about therapeutic interchange? How does the committee feel? I guess I would venture forth saying that most physicians, as they are prescribing, do tend to choose clopidogrel unless they see a reason not to. And so I would say it should not be subject to therapeutic interchange, but I'd like to hear people's opinions on that.

Mason Bowman: When you asked the question, Susan, I initially just kind of felt like… I don't see why we wouldn't, but we have a lot more history with clopidogrel versus the others and I just don't know if we have yet seen the outcomes to tell us yay or nay on that. That's my feeling anyway. I kind of feel like to keep it as is. To have no therapeutic interchange at this point.

Christine Klingel: I'm trying to remember our history and I think this was maybe done right around when there was new evidence about PPIs and their effect on specifically clopidogrel and I think we wanted to keep them separate for maybe that reason. Maybe we could continue to keep them separate for that reason.

Susan Rowe: So we've got three brand name medications and clopidogrel. Are we saying that we don't want any therapeutic interchange or that we would be willing to therapeutically interchange one of our brand names… within the brand name, but not to clopidogrel? I thought it was also very interesting in this review, although Marian didn't really emphasize it, she attributed it to drug interactions, but actually the increased bad outcomes were seen with anyone on a PPI whether it was the clopidogrel or the other medication indicating that it may be kind of something out… maybe some co-existence or link, but it was maybe the patient population itself, not the drug that led to the bad outcome. I thought that was very interesting.

Amber Figueroa: Can we have a little more discussion regarding Paxar because I have concern that in a… on slide 11 in a study that had almost 13,000 people that it didn't reduce cardiovascular events and increase the risk of bleeding. On slide 13 then it shows an N of 1,100 that did not increase bleeding events over 60 days. Do we feel that this evidence is strong to… in reducing cardiovascular events based on these studies to approve it?

Susan Rowe: Amber, let me withdraw my motion right now and let's have some more discussion. Good.

Amber Figueroa: As we were reviewing and as I reviewed it at home, also on slide 12 it did reduce… vorapaxar did reduce cardiovascular events and mortality although it didn't effect all-cause mortality. Ultimately, we're trying to keep our patient alive. When we're looking at all-cause mortality; so although it did reduce cardiovascular events it didn't effect overall and it did increase important bleeding. So I guess I would like to hear some other opinions on whether or not we can comfortably say, as a committee that we feel that it's a… that we see that there is evidence of safety and efficacy of this drug.

Susan Rowe: As I looked at the vorapaxar data at home, also, I was a little underwhelmed. Again, you know, that's nice, you got out of the hospital for your CV event, but didn't live longer. We've seen other classes of drugs that decrease CV events and yet all-cause mortality doesn't change and eventually they sort of sort themselves out as not being used very well. But strong feelings about not included vorapaxar? No? We'll continue deliberations. Do we want to include it? Do we not? Do we want to take a straight-up vote on this before we make the motion? Yeah? Okay.

In looking at the evidence let's, as a committee, before we craft the motion, let's vote on including vorapaxar. All in favor say aye.

Group:

Susan Rowe: All opposed, same sign.

Group: Aye.

Susan Rowe: Okay. So we will not include it. All right. So I'm going to re-state this motion that I started.

Donna Sullivan: Excuse me. So I guess for procedural or operational issues are you saying it's not included in the drug class now or that it will be… your intent is to make it not preferred?

Susan Rowe: Let's make it not preferred.

Donna Sullivan: Okay. Please state that in your motion.

Susan Rowe: All right. I'm going to have to think really hard on this. Okay. After considering the safety, efficacy and special populations for the treatment of acute coronary syndrome, percutaneous coronary intervention, and peripheral vascular disease, I move that clopidogrel, prasugrel and ticagrelor are safe and efficacious for the treatment of the approved indications. Clopidogrel cannot be the subject to therapeutic interchange with prasugrel or ticagrelor in the Washington preferred drug list. At this time vorapaxar is included in the class, but is not a preferred drug on the PDL.

Christine Klingel: I just wanted to make sure that… the way that we did the interchange, does that cause like an operational difficulty at all?

Donna Sullivan: If you can just state your intent was that clopidogrel should not be substituted for ticagrelor or prasugrel was your intent. Correct?

Susan Rowe: Yes, it is.

Donna Sullivan: So do we want to amend that and just say clopidogrel shall not be substituted for… instead of saying cannot be. Shall not be substituted for.

Susan Rowe: Leta, you've done miracles with that. Thank you very much.

Chuck Agte: To have your motion be complete we would need you to then not remain silent on the rest of the drugs when clopidogrel isn't involved. So, are

you… we would need to know are you saying therapeutic interchange is allowed within the class just not with clopidogrel? Can the other drugs be interchanged with each other? Or are we not allowing therapeutic interchange, period?

Susan Rowe: Between prasugrel and ticagrelor. Can those be interchanged?

Amber Figueroa: Are you saying that or are you saying the other drugs in this class that aren't the three that were mentioned here?

Chuck Agte: No, we're talking about the three drugs that we're talking about we say so far in the motion that clopidogrel can't be substituted for the other two. But we haven't addressed what can happen between the other two. Can the other two be substituted for each other? Or is the intent that there is no therapeutic interchange in the class? Or is it that there can be substitutions, just not with clopidogrel?

Susan Rowe: I personally have some concerns about prasugrel in some of the elderly and a little bit more bleeding there, I think. Let's say no therapeutic substitution within the class. Yeah, I think that's… this is a pretty… these are specialized procedures. I'm comfortable with no therapeutic substitution.

Christine Klingel: I'll second.

Susan Rowe: Are there any other questions before we vote?

Eric Harvey: I would approve the motion.

Susan Rowe: Okay. All in favor of the motion say aye.

Group: Aye.

Susan Rowe: All opposed same sign. The motion carries. All right. The next motion is considering evidence of stroke and ischemic attack. Any takers on this motion? We didn't really see a lot of new evidence on TIA and ischemic stroke.

Michael Johnson: I agree. We saw no evidence of the use of these new agents in stroke. So I would just reiterate the motion and I can read this here. After considering the evidence of safety, efficacy and special populations for the treatment of stroke and transient ischemic attack, I move that the extended release dipyridamole aspirin and clopidogrel are safe and efficacious. Extended release dipyridamole and aspirin and clopidogrel cannot be subject to therapeutic interchange in the Washington preferred drug list for the treatment of stroke and transient ischemic attack.

Lisa Chew: I second.

Susan Rowe: All in favor of this motion say aye.

Group: Aye.

Susan Rowe: All opposed same sign. The motion carries. Okay. Can we turn our attention to our last motion to exclude completely ticlopidine products?

Lisa Chew: I'd like to reiterate the prior motion and move that ticlopidine not be put on the PDL due to safety concerns.

Susan Rowe: I'll second. All in favor of this motion say aye.

Group: Aye.

Susan Rowe: All opposed, same sign.

Mason Bowman: I do have a matter of clarification. So if we just say ticlopidine is that also including the ticlopidine with aspirin or do we need to list both of them separately?

Donna Sullivan: You can list them both or just ticlopidine products.

Susan Rowe: Change that to ticlopidine products. Do we vote? All in favor say aye.

Group: Aye.

Susan Rowe: All opposed, same sign. The motion passes. All right. Next we have over-active bladder medications.

Rebecca Holmes: Hi. This is Rebecca Holmes.

Susan Rowe: Good morning, Rebecca.

Rebecca Holmes: Hi. Let me know when you're ready.

Susan Rowe: We are ready, Rebecca.

Rebecca Holmes: Okay. So this is another expanded scan that was conducted in January of 2016. On to slide 2.

The previous report for this was a summary review in June 2013 and there was an original report back in 2003. The last preliminary update scan, our standard scan, was actually… we've done one since this expanded scan. That was in March of 2016 and the searches for this expanded scan were through November 2015. Next slide, number 3.

These are the inclusion criteria for the report. Just briefly we're looking at eight drugs. The oldest of these was flavoxate back in 1970 and the newest is mirabegron, which was approved in 2012. Next slide, number 4.

Marian talked about the expanded scan methods. In general, I won't go through that. For overactive bladder it turned out that all of the included drugs had head-to-head evidence so we didn't include any placebo-controlled trials. Again, we did dual review for poor quality studies and data abstraction for good and fair quality studies. For over-active bladder the benefits outcomes we looked at were incontinence episodes and micturitions for 24 hours and for harms we looked at withdrawals due to adverse events in dry mouth. Next slide, number 5.

Since the last summary review there have been no new drugs, boxed warnings or reviews. Next slide.

And also since the last report we found seven head-to-head trials. One of those was found in the current scan. That was poor quality and in the previous scans we found five fair quality trials and one poor quality trial. For most of these the comparator was tolterodine ER compared to various other newer treatments. Next slide, slide 7.

Again, these are authors' conclusions for results since the last report. Fesoterodine compared to tolterodine they found greater improvement in symptoms for fesoterodine [inaudible] tolterodine. That was actually the only difference in efficacy that we saw for the various comparisons reported. But with fesoterodine there were also higher rates of dry mouth. Next slide.

Comparing solifenacin to darifenacin, again, similar effects on symptoms. There is a type-o in that second bullet there. Solifenacin actually had lower rates of dry mouth. So that's 41% for solifenacin and 62% for darifenacin. And for solifenacin compared to tolterodine, again, similar effects on symptoms, but higher rates of dry mouth with solifenacin. Next slide, slide 9.

Comparing mirabegron to tolterodine, again, similar effects on symptoms. Mirabegron had lower rates of dry mouth than tolterodine. And let's skip to slide number 11.

In summary, since the last report, no new drugs, harms or comparative effectiveness reviews were found. We found seven head-to-head trials. Two of those were poor and one of those was new for this scan. For comparison that scan we did in March 2016 and just found one additional trial. So there were eight in that… as of a month ago. We found 28 placebo-controlled trials and nine of those were new this scan, but we didn't assess them because we had head-to-head evidence and, again, Marian talked about how we looked at secondary publications just looking for differences with the primary publication and we didn't find… we found 19 since the last report, but none new this scan. Next slide, slide 12.

So the trial authors' conclusions for this class, fesoterodine improved symptoms more than tolterodine but caused more dry mouth.

Solifenacin and mirabegron were similar to tolterodine in efficacy, but for harms for dry mouth, solifenacin had more dry mouth and mirabegron had less than tolterodine. And finally solifenacin and darifenacin had similar effects on symptoms but solifenacin caused less dry mouth. Again, that's a mistake. Solifenacin is less than darifenacin for harms. But that's the evidence we have for over-active bladder. I'll take any questions.

Susan Rowe: Does anyone have questions for Rebecca? This is Susan Rowe. I do have one. I always… when we review this class I always find it good that one of the harms, or one of the measures of efficacy is to… is trying to measure reduction of incontinence pads since a lot of patients pay for those on their own and they are quite costly. But I don't find that they are actually included in any of the trials. It's not one of the measures included in any of the trials. Did you find anything different, Rebecca?

Rebecca Holmes: In the number of pads that's used per day?

Susan Rowe: Yeah, was there a reduction in the number of pads used per day?

Rebecca Holmes: We did not choose that as one of our key outcomes. That's good to know that that would be valuable to you. We were going by the number of episodes instead of… but weren't really thinking about the cost of the pads themselves. I believe some of the trials do include evidence on that, but we didn't… that wasn't one of the outcomes we chose for this expanded scan. It kind of limited the number of outcomes.

Susan Rowe: Yeah, Rebecca, I think on the… not the slides, but the written material that we covered in preparation for this meeting, I thought it was on there. Anyway, yes, we would find that valuable. That's great. Thank you.

Rebecca Holmes: That's good to know. We can think about that for another round.

Susan Rowe: Any other questions? Okay. Is the… just for the committee, is the evidence here enough to include all of the medications in the class with the new trials that were presented? Yes? No? Okay, may I have a motion to accept this expanded scan as an adequate class review?

Amber Figueroa: I move to accept it.

Susan Rowe: Do I have a second?

Eric Harvey: I'll second.

Susan Rowe: Okay. All in favor say aye.

Group: Aye.

Susan Rowe: All opposed, same sign. I want the record to reflect that we don't have any stakeholders signed up and we can next turn our attention to our motion. Does anyone have any changes to this motion or concerns or updates?

Christine Klingel: I think we can reiterate the prior motion.

Susan Rowe: Wonderful. May I have a second?

Michael Johnson: I second.

Susan Rowe: All in favor say aye.

Group: Aye.

Susan Rowe: All opposed, same sign. The motion carries. Thank you.

Next we are on to the statins. Is Ian on the line?

Ian Blazina: Yes, I am. Hello.

Susan Rowe: Okay. Ian, we are ready when you are.

Ian Blazina: All right. So this is the drug class review for statins and fixed-dose combination products containing a statin from January 2016. The last report was update number 5 in November 2009 and the last scan was

scan number 4 in April 2015. The current scan searches through December 2015.

We included outpatients targeted for primary or secondary prevention of coronary heart disease or atherosclerotic disease and inpatients with acute coronary syndrome or those undergoing revascularization, as well as those with familial hypercholesterolemia and we included both children and adults and excluded adults with rare, severe forms of hypercholesterolemia. Next slide, slide number 4.

This is the table of interventions included. Next slide.

For effectiveness outcomes we included cardiovascular events and mortality, as well as all-cause mortality and LDL and HDL. For harms we included overall, serious and withdrawal due to adverse events, as well as specific adverse events. Next slide.

We included head-to-head trials of new drugs since the last update and we… for quality assessment we did dual review of poor quality studies only. We abstracted good and fair quality studies only and we limited our abstraction of benefits to cardiovascular outcomes if they were available and lipid outcomes and for harms we abstracted overall adverse events or withdrawal due to adverse events, as well as myalgia. For the results we only abstracted authors stated conclusions. Next slide.

Since the last report there have been two new drugs, one a fixed-dose combination of atorvastatin and ezetimibe and the other is pitavastatin, which was approved in 2009. There were no new boxed warnings. There was a 2014 AHRQ report on combination therapy compared to intensified statin therapy. Next slide.

Since the last update report we have identified 71 head-to-head trials, 12 of which are new in this scan, 19 secondary analyses, and 23 placebo-controlled trials, 2 new in this scan, 2 of those would be in children, and 23 secondary publications. Next slide.

Of the head-to-head trials identified in this scan 10 were fair or good quality and two were poor quality. Six studied evaluated atorvastatin

and ezetimibe compared to atorvastatin or rosuvastatin. And four trials assessed pitavastatin compared to atorvastatin or pravastatin. Next slide.

The six trials of atorvastatin as a comparator, two also included rosuvastatin arms. The sample sizes ranged from 30 to 1547. The duration from four to eight weeks in five studies, and a year in the remaining study. In five of the trials the authors concluded that the addition of ezetimibe to atorvastatin improved lipid profiles compared with atorvastatin monotherapy with no clear difference in adverse events. One study found no difference in lipid profiles and the combination drug doses were lower in that study than the other study. It was 5 mg of atorvastatin and ezetimibe. Two studies with rosuvastatin arms also found the combination product to improve lipids. Next slide.

The four trials of pitavastatin sample sizes ranged from 42 to 225. Two trials compared pitavastatin to atorvastatin over a 12-week duration and neither study found differences in changes in lipids, as well as adverse events. Compared to pitavastatin in two trials of duration 36 to 52 months the office concluded pitavastatin improved lipids more than pravastatin out of 12 to 18% more for LDL and adverse events were not clearly different. Next slide.

Since the last report in 2009 we've identified two new drugs – pitavastatin and atorvastatin/ezetimibe fixed dose combination. No new boxed warnings and one new comparative effectiveness review. Cumulatively we have 71 head-to-head trials, 19 secondary publications, and 23 placebo-controlled trials in 46 publications. Next slide.

The atorvastatin/ezetimibe combination resulted in better lipid profiles than atorvastatin or rosuvastatin. Five of six trials versus atorvastatin found improved lipid profiles in the fixed-dose combination product groups, one found no difference. And both trials assessing… comparing to rosuvastatin found that atorvastatin/ezetimibe combination was superior. Likewise pitavastatin resulted in better lipid profiles than pravastatin in two trials with no clear difference in adverse events. There were no differences found in lipid profiles between pitavastatin and atorvastatin in two trials and no clear difference in adverse events. And

no trial reported any rhabdomyolysis. That's the end of my presentation. Are there any questions?

Susan Rowe: Thank you, Ian. I really want to say thank you to all of you for these expanded reports. They are helpful, thank you!

Ian Blazina: Great.

Susan Rowe: Do any of the committee members have questions for Ian? Okay. Thank you, Ian. We'll let you go.

Ian Blazina: You're welcome.

Susan Rowe: So we have some short-term trials that give us some intermediate measures, no mortality outcomes. But that's the evidence that's available. May I have a motion to accept this expanded scan as adequate as a class review?

Mason Bowman: I accept this expanded scan as adequate.

Susan Rowe: Do I have a second?

Lisa Chew: Second.

Susan Rowe: All in favor say aye.

Group: Aye.

Susan Rowe: All opposed, same sign. The motion carries. I'd like the record to reflect that there are no stakeholders signed up to speak on this category. So we'll turn our attention next to our motion.

Does anyone have any changes, concerns, updates for this motion? I'm seeing shaking heads. I think it's actually pretty nicely written. I move to reiterate the present motion.

Eric Harvey: I will second.

Susan Rowe: All in favor say aye.

Group: All opposed, same sign. The motion carries. Thank you.

Okay. Next we are moving on to the nasal corticosteroids. Yes?

Donna Sullivan: Can I interrupt for just a second? I want to confirm that you were reiterating both motions to exclude the combination products in addition to the motion on the monotherapy products?

Susan Rowe: Thank you, Donna. I didn't address that very well. I would like to just move to not include the combination products as part of the statin class on the PDL.

Lisa Chew: I would second that.

Susan Rowe: All in favor say aye.

Group: Aye.

Susan Rowe: All opposed, same sign. Okay. So now… thank you.

Okay. So the nasal corticosteroids. We'll have a scan update and then discuss archiving.

Brittany Holzhammer: Hi. This is Brittany Holzhammer. Please let me know when you'd like me to begin.

Susan Rowe: Brittany, we are ready for you. Thank you.

Brittany Holzhammer: All right. Thank you. This is fifth preliminary scan report in the series for nasal corticosteroids. This scan was completed in June 2015. Next slide, please.

To provide a bit of history the last report was update 1, which was completed in June of 2008 with searches through September 2007. The last scan on this topic was May of 2014 and searches for this current scan spanned May 2014 through May 2015. Next slide, please.

We included populations of adults and children under the age of 18 in outpatient settings with seasonal or perennial allergic or non-allergic rhinitis. We excluded patients with rhinosinusitis with or without nasal polyps. And for outcomes we included symptomatic relief, and onset of action, as well as overall adverse events, withdrawals due to adverse events, serious adverse events, and a number of specific adverse events, which are listed here. Next slide, please. Slide 4.

This slide illustrates the included interventions for this scan. Next slide, please.

In terms of new drugs we identified one new over-the-counter formulation of fluticasone propionate. This is for the relief of hay fever or other upper respiratory allergies. In previous scans we identified four new drugs, an over-the-counter version of triamcinolone acetonide nasal spray, the combination of azelastine hydrochloride and fluticasone propionate. Also beclomethasone dry nasal aerosol and ciclesonide dry nasal aerosol as well. Next slide, please.

This is slide 6. We wanted to bring your attention to a number of drugs that have been discontinued since the last report and they are listed on this slide. Next slide, please.

We identified no new uses for the drugs in this scan… in the current scan. In previous scans we identified one new use for triamcinolone, which was approved for treatment of seasonal allergic rhinitis and perennial allergic rhinitis in children 2 to 5 years. We've identified no new serious harms in the current or prior scans. Next slide, please.

We identified no new comparative effectiveness reviews in this scan. However, in previous scans we identified two new comparative effectiveness review. One was an AHRQ review for the treatment of seasonal allergic rhinitis, which included nasal corticosteroids. And another was a CADTH rapid response report comparing the effectiveness of intranasal triamcinolone and intranasal beclomethasone for acute and chronic sinus inflammation. Next slide, please.

Cumulatively we have identified 10 new potentially relevant head-to-head trials for which were found in this scan and we've also identified 55 new relevant placebo-controlled trials; 6 of which were identified in this current scan. Next slide, please.

This slide illustrates the new head-to-head trials that we have identified since the last report and the shaded studies are those that we identified in this current scan. Next slide, please.

So in summary, since the last report, we have identified five new drugs, one of which was identified in this scan, which, again, is the over-the-counter fluticasone propionate. We identified one new use for triamcinolone and we've also identified 10 new head-to-head trials for this scan, and 55 new placebo-controlled trials, six of which were found in this scan. Thank you. Do you have any questions?

Susan Rowe: Thank you very much, Brittany. Does anyone have any questions for Brittany? Okay. Thank you very much.

Brittany Holzhammer: Thank you.

Susan Rowe: I want the record to reflect there are no stakeholders to speak. And we can turn our attention to our motion… Donna, do we move to… we have a motion to accept the scan?

Donna Sullivan: Correct.

Susan Rowe: Okay. May I have a motion to accept the scan?

Michael Johnson: I would like to approve the scan.

Susan Rowe: Do I have a second?

Eric Harvey: I'll second.

Susan Rowe: All in favor say aye.

Group: Aye.

Susan Rowe: All opposed, same sign. So the scan is accepted. Let's turn our attention to the motion. So we'll have two motions to craft or approve. One is the therapeutics of the class and then the second will be consideration of archiving this class of drugs from further review unless something new comes up. So we'll first look at the motion that approves the therapeutics.

Christine Klingel: So do we… or should we remove the medications that have been discontinued from the motion or is that not even necessary? Probably just go ahead and remove those? Okay.

Amber Figueroa: The budesonide AQ is not referred to as AQ anywhere else in here. I'm not sure… take away the AQ. Budesonide not beclomethasone. Take out the AQ right here. Budesonide.

Donna Sullivan: I don't think that the beclomethasone is available generically anymore. I'm looking in Micromedics. It's Q nasal. I think you can leave it in there, but it's the brand. It's not a generic. So that's why this one here is… they're not the same.

Susan Rowe: As we're spiffing up this motion I have a question. In the PDL selection process, is it also possible that this includes both a selection from the over-the-counter and prescribed?

Donna Sullivan: So as long as the over-the-counter products have a federal rebate then I do believe they are included in the cost analysis. Is that correct, Chuck?

Chuck Agte: Yes.

Donna Sullivan: So, yes, we will include the OTC products.

Susan Rowe: Okay. All right. We've got our motion spiffed up with the discontinued drugs taken out. Would anyone like to make that motion? Okay. Well, I will.

I move after considering the evidence of safety, efficacy and special populations for the treatment of seasonal allergic rhinitis, perennial

allergic rhinitis, and non-allergic rhinitis, I move that beclomethasone AQ nasal spray, budesonide nasal spray, ciclesonide nasal spray, fluticasone furoate nasal spray, fluticasone propionate nasal spray, mometasone nasal spray, mometasone nasal spray, triamcinolone AQ nasal spray are safe and efficacious. An FDA approved pediatric formulation must be included on the preferred drug list. Nasal steroids can be subject to therapeutic interchange in the Washington preferred drug list.

Amber Figueroa: I'd like to second that.

Susan Rowe: All in favor say aye.

Group: Aye.

Susan Rowe: All opposed, same sign. Okay. Let's move our attention next to archiving this class of drugs. Since the most that seems to be happening is the movement from legend to OTC and discontinuing products as far as the evidence. Okay? So we have a prototype of a motion on the screen before us. We have archived several other classes of medications. Does anyone on the committee have questions about that, that Donna could answer or are we good to go on this?

Okay. After considering the scans presented today move to archive the following drug class from further review by the P&T Committee: nasal corticosteroids with our motion of 4/20/2016. This drug class will remain on the PDL and the committee's last motion will remain in effect until changed by the committee. The agencies may conduct updated cost analyses of these drug classes without additional committee approval so long as any resulting changes in the preferred status of a drug remains consistent with the committee's motion for that drug class. The committee may review the archive status of this drug class upon its own initiative, or by request of the participating agencies at any time.

Dale Sanderson: I second.

Susan Rowe: All in favor say aye.

Group: Aye.

Susan Rowe: All opposed, same sign. The motion carries. Thank you. And it is time for a break. It is… we're a little over. It's 10:18. Our break was supposed to be at 10:05. Back at 10:25? Is everyone okay with that? Okay. Great. Thank you.

All right everyone. It's 10:27. I'll welcome you back from the break. I would like to just kind of briefly explain… I am going to adjourn the Pharmacy & Therapeutics Committee and open the Drug Utilization Review Board. The functions are different. The P&T Committee is for consideration of medications for the PDL. The Drug Utilization Review Board is how we are going to use them or are there any specific safety or utilization concerns that we have in each drug class. I do also want to amend the agenda. I guess we will not be talking about insomnia drug coverage today. Is that correct, Donna? So we'll take that off the agenda.

Donna Sullivan: That is correct, sorry.

Susan Rowe: Thank you. The first medication class that we are going to address today is the testosterone products.

Donna Sullivan: Okay. At the last meeting we reviewed our testosterone policy and the committee concerns that our criteria around the use for just older men with low testosterone was a little bit too broad and that allowed for misuse where hypogonadism wasn't actually the diagnoses. So this is our attempt, an altered attempt, on the policy for you to review and consider. So really the objectives are to provide a little bit of background relevant to the testosterone treatment and then present, again, the revised proposed policy and the background… I'm just going to show this slide. I'm not going to read it. It's all of the available testosterone therapies that are out there. Looking at the name, when they came onto the market, their particular indications, and then restrictions.

Then we're going to jump right into our medical policy. So for testosterone replacement therapy we… in adult males, the Health Care Authority will consider it to be medically necessary for the treatment of hypogonadism when the patient meets the following criteria: the patient

must be 18 years of age or older, they must have had two morning testosterone tests between 8 a.m. and 10 a.m. in the morning, and the tests need to be at least one week apart but no more than three months apart, and they have to demonstrate low testosterone levels. The second test should be done after the provider has excluded all other potential causes for a low testosterone result such as a reversible illness, any medications that the patient may be taking, or nutritional deficiencies. And we have defined low testosterone levels to be as below the normal range for the reference lab that was used by the provider or the lab assay or in absence of those, the reference on the actual report, the measures that are listed here. So a total serum level below 300 ng/dL or a total serum testosterone level below 350 ng/dL and free serum testosterone level lower than 50 pg/mL. Forgive me. I don't know what pg stands for.

Man: Picograms.

Donna Sullivan: Picograms. Okay. Thank you. So those are our cutoff levels for those… for determining what a low testosterone result is.

In addition to those first two criteria, the patient has to have received one of the following diagnoses: primary hypogonadism as defined by low testosterone, elevated FSH and LH, and have testicular failure due to such conditions as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, or Klinefelter's syndrome. I want to make sure that they have to have all of these. So in addition to the low testosterone they must have an elevated FSH, follicle stimulating hormone, and they must have a low LH, luteinizing hormone, in combination… in addition to the testicular failure. I think with the combination of those three occurrences you will see that it would rule out elderly men that just happen to have a low testosterone due to age. And we reviewed this with Dr. Hammond at the Department of Corrections and he's the one who gave us… he's an endocrinologist and he's the one that helped us develop these criteria.

In addition, another diagnosis would be the hypogonadotropic hypogonadism. I'm not going to read the definition. HIV-associated weight loss as explained there. Chronic high-dose glucocorticoid therapy and that is 5 mg per day of prednisone taking it for at least six months or

more. And then men less than 50 years of age with osteoporosis or with low trauma fractures.

And I just want to say for the record that this does not… this testosterone policy does not apply to patients that have gender dysphoria. That is a covered product for them.

Exclusion criteria are a patient who has any of the following contraindications: breast cancer, elevated hematocrit, untreated sleep apnea, severe lower urinary tract infections, and then uncontrolled or poorly-controlled heart failure. An addition exclusion criteria is if the patient has had a major cardiovascular event such as a heart attack or stroke in the last six months or they have uncontrolled or poorly controlled benign prostate hyperplasia or is at higher risk of prostate cancer. And also if testosterone is being prescribed for late-onset hypogonadism or for sexual dysfunction it won't be covered.

So the prior authorization approval will be… it will be approved with the following quantity limits when the above criteria is met. The approval will be for one year except for patients who meet the diagnostic criteria for HIV-associated weight loss for men with HIV-associated weight loss it will be approved for six months and then for men that are approved because of a high dose glucocorticoid treatment that we would approve it for a maximum of one year. And then patients must try and fail at least one injectable and at least one transdermal testosterone before getting the methyltestosterone therapy, which is oral testosterone.

This slide here just shows the quantity limits that we will be implementing for the various products. Basically it's limitations associated with the dosing on the label and that is all.

Susan Rowe: Does anyone have questions for Donna? Concerns? Changes? It looks really good. Thank you. Would you like a motion from us?

Donna Sullivan: Yes.

Amber Figueroa: I just want to clarify as a prescriber. So in the criteria, for example, I have a patient that has Klinefelter's. He's had it his whole life. Is this saying

that I would have to re-draw all of these levels or if he comes to me already at the diagnosis then I can continue the testosterone therapy?

Donna Sullivan: That's a good question. I believe that we would go ahead and… that we would go ahead and just continue it if they have like a Klinefelter's syndrome.

Amber Figueroa: Diagnosed.

Donna Sullivan: Yes. We wouldn't stop the treatment at this point in time. So we can talk about that, you know, grandfathering people if you would like to grandfather everybody that is currently on testosterone, implement this for new starts versus, you know, versus just starting it for new starts. So my recommendation would be to just impose this for new starts. The grandfathering would cause quite a bit of disruption on our part as far as, you know, having to review all of those cases in addition to disrupting treatment that's already been established. If you're on testosterone you're not going to have a low testosterone level.

Amber Figueroa: I agree with that for people with diagnosed conditions. But I also think that there are people on it that… I mean part of the reason that we're doing this is because there are people on it that really do need to be re-evaluated. I don't know if there's a way to… I don't know if you can tease out those two different populations. Thoughts? Comments?

Susan Rowe: I wonder… I agree with you, Amber. I wonder about grandfathering people in who actually have one of the diagnosis that we could go forward with that. If they don't have one of these A through E diagnoses that would do that… would do that then it may be, again, we're trying to protect people from taking this when they're not supposed to because they have low testosterone due to old age and we don't really have great data on what years of therapy will actually do for outcome or length of life. We don't know those things. Does that seem like a good way to do it? Any new starts and anyone who does not meet one of the diagnosis criteria.

Donna Sullivan: I'm just thinking operationally potentially an expedited authorization code, Chuck, would that work? Or… we don't have diagnoses… when we

get a claim we don't know what it's been prescribed for. So, you know, there's two options. One is to try to pull information on the patient's that we have on it and get diagnostic, you know, diagnoses off their medical claims and manually then put in overrides versus potentially an expedited authorization code for these… a combination of some of these diagnoses where the pharmacist could place the code in the claim on the prescription and it would go through. And if there's not that code it would be stopped. Chuck, what's your comments?

Chuck Agte: I think that the expedited authorization route may not serve our purposes because the reason we have the tests for the… the reason part of the criteria is the testing in combination with some of these diagnoses is we're trying… if we just go to the diagnosis, being an expedited code, then it's possible that some of the people… it will just get used, basically. My recommendation would be that we go ahead and just do prior authorization and the… and I can reassure you in regard to the PA process by explaining why. So when we put new limitations on a drug, even if we don't grandfather, everybody who is currently on it you would hit a PA stop one time. You'd hit that PA stop one time. We would authorization continuation. We never discontinue anything until something has been reviewed and actively determined either approved or denied. So we would approve one time for anybody who is already on it. We would then contact you, the prescriber for diagnosis, at the point at which we learn diagnosis they would get an ongoing approval for something like Klinefelter's and the easiest way, and the most direct way to actually get that diagnosis and know that it's right is to get it from the physician themselves. So I would suggest that we go ahead and PA it, and we review it, and there will be some potentially mild disruption for people who hit the PA stop the first time. The pharmacy is going to have to call. We would approve and then go from there. But once we collected the information there wouldn't be any further need for PA after that.

Donna Sullivan: Another option would be whether or not we want to stop injectable testosterone. Are we comfortable that injectable testosterone is likely to be used for one of these approvable diagnoses versus the topical products that are more likely to be used for just men that have low testosterone scores?

Susan Rowe: Let me clarify what you're asking. So just not use the injection and use the transdermal instead or…

Donna Sullivan: Never mind. I'm looking at squeezing the balloon and so I'm going to retract what I just said. I don't want to steer people towards injectable testosterone because there's not a prior auth on it.

Susan Rowe: So it would just be… so people would try one or the other.

Donna Sullivan: Right.

Susan Rowe: And they could use transdermal?

Donna Sullivan: No. Let me go backwards. What I had asked was whether or not we would just allow injectable testosterone to be covered without a prior authorization because people don't like to stick themselves. But then as I was thinking that the unintended consequence would be to steer towards injectable testosterone in lieu of using the topical. So I rescind my question.

Susan Rowe: Are we comfortable with this criteria? Yes? So I move that we accept the criteria as presented with a prior authorization one time for those who are already taking it. That will be approved, but that way we get the diagnosis. Do I have a second?

Eric Harvey: I'll second.

Susan Rowe: Okay. All in favor say aye.

Group: Aye.

Susan Rowe: All opposed, same sign. And then, Donna, can we ask that… just we have a review on this maybe in about a year and see how it's going?

Donna Sullivan: Sure.

Susan Rowe: Okay. All right. Next, antiplatelet coverage criteria.

Donna Sullivan: I think we have extended release metformin first. Sorry.

Susan Rowe: Oh.

Donna Sullivan: I think it's out of order on the agenda, but I do want to go through this policy first.

Susan Rowe: It's not on the agenda, but okay.

Man: It's at 11:45.

Susan Rowe: Oh, 11:45.

Donna Sullivan: It's at the end. See, we're at the bottom of the agenda. We're done.

Susan Rowe: Oh, in my notebook. I'm so sorry.

Donna Sullivan: Yes, there were several edits to the agenda that were sent out.

Susan Rowe: Thank you. I stand corrected.

Donna Sullivan: So you might be wondering, why are we talking about DUR edits on extended release metformin? The reason why is that Valeant Pharmaceuticals has increased the cost of Glumetza over 800%. It's now several thousand dollars a month and its generic is well over a thousand dollars a month, as well. So that's why we are here talking about metformin extended-release products.

So we're going to go over a little bit of background information that I just gave you and then we'll look at the policy. Here, this is the cost per tablet and this is before rebates. You can see that the osmotic-release products, Fortamet, which was at one time kind of considered a generic metformin. We traded it as a generic. It's now over $30.00 a tablet. It's generic formulation is $14.00… it ranges from $4.83 to $14.48 per tablet. And the cost for Glumetza, down at the bottom, you can see is over $100.00 a tablet and its generic, depending on which strength you're taking, is similarly priced. So we are going to look at what our policy is.

These are the number of unique utilizers. So most of our utilization is in the Glucophage generic formulation. We have 1,276 users there. We do have 114 patients that were on Fortamet and 17 patients on Glumetza and that was the last six months of 2015.

Background, you know, the diabetes treatment guidelines they all recommend metformin as the preferred initial treatment. So everybody is going to be on metformin before they are… all diabetes 2 patients will be on metformin before they go to another medication. I'm not going to read the rest of this slide.

We looked at what other payers were doing. Group Health put the generic for Glucophage XR, which is in tier 1 and they have Fortamet generic osmotic-release and Glumetza in their third highest cost tier. Premera does not cover Glumetza. They actually have a policy now that is titled Extensively High Cost Drugs Policy. I thought that was really interesting. And Regence they don't cover Glumetza, Fortamet or their generics. Humana requires previous treatment or intolerance to metformin. And then Uniform Medical Plan, which is our PEB program, we, I believe it was April 1st, quit covering the generic formulations of Glumetza and the Glumetza brand is in tier 3 with a 50% cost share. So if patients want to take it and pay thousands of dollars a month they are welcome to do that.

Our medical policy, for Medicaid, what we're proposing is that metformin extended release products with osmotic-release or gastric retentive modified mechanism (aka Fortamet and Glumetza and their generic equivalents) will be considered medically necessary for the FDA-approved indications when they meet the criteria 1 through 3 and none of the exclusion criteria. So the inclusion criteria, metformin extended release products with a gastric retentive modified-release and osmotic-release must have type 2 diabetes and they must have tried and failed or tried and are intolerant to five different manufacturers of the generic metformin extended release product, which is the generic for Glucophage that have a… and they have to have a documentation of medical necessity for an extended release metformin product specially for the gastric retentive modified-release product or the osmotic-

released mechanism instead of a dual hydrophilic polymer-release mechanism. That's a lot of words.

The exclusion criteria is really the contraindications for metformin. In general, the renal disease, acute chronic metabolic acidosis, hypersensitivity to metformin, and metformin ER being prescribed for anything other than the treatment of type 2 diabetes.

These are the quantity limits that we are recommending if it does get approved. And that is it.

Lisa Chew: I have a question. Are these… this drug class subject to therapeutic exchange?

Donna Sullivan: No. Metformin is not included on our preferred drug list. It has always been the comparator for the newer diabetic medications, but it's never been considered reviewed in the class. So it is not subject to therapeutic interchange.

Susan Rowe: I don't have any problem with this criteria. I think it's kind of a no-brainer. Nobody can really afford to pay that for their baseline medication. So I just wonder… if it were subject to therapeutic interchange would that give us anything? Would that help in anyway with the patient's, you know, access or…

Donna Sullivan: Actually, the therapeutic interchange program it would… to some extent would harm the policy or the intent of the policy as DAW would override any interchange that would happen. And because it's not on the PDL we can't implement therapeutic interchange anyway. So it's kind of a moot point.

Susan Rowe: Does anyone have any other questions? Does anyone have any objections? I move that we accept the criteria as proposed.

Lisa Chew: I second.

Susan Rowe: All in favor say aye.

Group: Aye.

Susan Rowe: All opposed, same sign. The motion carries. Thank you for bringing this to our attention, Donna.

Donna Sullivan: And there are no stakeholders.

Susan Rowe: Okay.

Donna Sullivan: Thank you.

Susan Rowe: Okay. So next then we're talking about antiplatelet coverage criteria? Okay.

Donna Sullivan: We are next going to just roll through the coverage criteria, the DUR edits that we have for several drug classes that we've reviewed in previous meetings, plus the drug classes that we reviewed today. And they are all in the same presentation, but I think I will have you make a motion after each class so that we remember what we're actually approving.

So the first drug class is the antiplatelets. Here is a list of all of the products with their brand names and their current preferred status on the PDL. The only preferred product right now is the clopidogrel generic product.

Our current limitations are… there's no therapeutic interchange as of today and then we have a dose limit on clopidogrel 300 mg product because it's used only for a loading dose. It's not intended for chronic use. So we do have that one-time dose limit for that. Our recommendation… I'm going to amend my recommendation based on your motion earlier regarding this drug class. One is to continue the dose limit on clopidogrel. My amendment is to not implement generics first since you did now allow therapeutic interchange. We would not want to have patients step through clopidogrel before they were to get a preferred or non-preferred brand. And so we'll go down to the third bullet, which will be… if there are any preferred brands in this class that… we will require the patients to step through all of the preferred brands in the class before a non-preferred brand would be approved. Typically,

what happens, is they only have to try one preferred during our PDL. So we're just trying to make sure that people start marching through all of our preferred products now before they get to the non-preferred product. And that of course is unless the provider signs dispensed as written.

I don't believe there are any stakeholder comments. Are there any questions?

Chuck Agte: I'm actually curious why we wouldn't still go with the second bullet. Because normally the interchangeability of the class doesn't directly impact generics first. So I would like to understand better.

Donna Sullivan: So the committee decided that they did not want clopido… to me it sounded like the committee's intent was that it may be inappropriate clinically to require use of clopidogrel before you try one of the other brand names listed. If I'm incorrect in my assumption, then please let me know.

Susan Rowe: I just wonder… I just wonder though if someone were to write Plavix and allow substitution then we would want generics.

Donna Sullivan: That's fine. This doesn't… this isn't generic substitution. It doesn't limit generic substitution. It's preventing the requirement of clopidogrel before you get to ticagrelor or prasugrel. Was that the intent that you didn't want to…

Susan Rowe: Correct. Yes.

Donna Sullivan: Okay.

Chuck Agte: Thank you.

Eric Harvey: Just to clarify, so Donna you're saying in this recommendation that we're looking at up here that the first and fourth and bullet point would remain, but the second and third would not? Am I getting that wrong?

Donna Sullivan: You are correct. I'm going to take those out of here, maybe. Oops! What did I do? There we go. Yes, I'm recommending that we go with the first bullet and the last bullet. I'll do that so I have a record of what we are approving.

Susan Rowe: Here I would take a motion to approve the criteria as presented.

Amber Figueroa: I second that.

Susan Rowe: All in favor say aye.

Group: Aye.

Susan Rowe: All opposed, same sign. Okay. So we have some coverage criteria for antiplatelets.

Donna Sullivan: Okay. So over-active bladder products, again, I have them all listed here with their brand names. The underlined products are the short-acting products. Basically, the preferred products are the generics for Ditropan, so oxybutynin, long and short-acting, as well as the tolterodine and trospium long and short-acting are our preferred agents.

Our current limitations for both long and short-acting is that they must try and fail one preferred long-acting or short-acting preferred agent, depending on which is prescribed. So if the short-acting is prescribed they have to try a preferred short-acting. If a long-acting is pre… if a non-preferred long-acting is prescribed they have to try a preferred long-acting. And before a non-preferred drug would be authorized unless signed by DAW by the endorsing practitioner. Our recommendation is to implement generics first according to the formulation prescribed. So again, long for long, short for short-acting. So we would require that the patient step through one preferred product for one month before a preferred brand or non-preferred generic is authorized. DAW by an endorsing practitioner in this instance shall not override this requirement without authorization. So this is the generics first requirement and endorsing providers must comply with it as well. In addition to that, the patients must step through all the preferred generics at the highest tolerated label dose for one month each before a preferred brand is

authorized unless signed DAW by an endorsing practitioner. And the patient must step through all preferred brands at the highest tolerated dose for one month each before a non-preferred brand is authorized. Again, unless signed DAW by a non-endorsing provider. So the intent is to try to, you know, if there's multiple generics have them try the generic products that are available. If there's then multiple preferred brands have them try the preferred brands that are available and then… before they try the non-preferred products.

Chuck Agte: On the second bullet I would suggest that we maybe want to change the word brand to just drug because in the event that we have non-generics that turn out to be non-preferred we would want them subject to that as well, I believe. So yeah, the second and third bullets.

Susan Rowe: I think… I'm seeing contradiction here. So the first bullet points is one preferred product and then the second one says all preferred generics.

Chuck Agte: I can explain. That's the kind of convoluted nature of the generics first program, which we haven't done a direct update for a little while with you guys. Generics first we use that term a little bit too short-handed once we're talking… technically it is generics first for new starts and… or treatment-naïve patients. So as soon as you have tried a single product you are no longer a new start. We have law in Washington that says that when we implement generics first in a class that… or the board decides to basically. If the board decides that we can have generics first in a class it means for that truly treatment-naïve patient. We don't allow the DAW that we would normally allow for an endorsing physician, because implementing generics first means that the board has decided that for a treatment-naïve patient there is absolutely no reason to assume something other than… to assume any particular product is better than another for the patient. So that's why the first one says [inaudible] preferred because once they have tried one preferred then they are no longer a new start and generics first doesn't apply. And that would be the point at which an endorser DAW wasn't working previously. Now they are no longer treatment-naïve and an endorsing DAW would work. So that's the difference between the first bullet and then the following bullets. I don't know if that was clear or not, but…

Susan Rowe: That's clear. So let me kind of march this out. So a patient fails oxybutynin in generic short or long-acting and then they… the physician could sign DAW and it does not mean that then they have to march through the tolterodine and the trospium?

Donna Sullivan: Correct.

Susan Rowe: Okay.

Donna Sullivan: As long as it is an endorsing practitioner that signs it.

Susan Rowe: All right.

Donna Sullivan: And I did clarify… I did have a missing word on the first bullet. It should have said, "Must step through one preferred generic product," not just "one preferred product".

Susan Rowe: Are there any other questions?

Eric Harvey: I would move to accept the recommendation.

Michael Johnson: I would second that.

Susan Rowe: All in favor say aye.

Group: Aye.

Susan Rowe: All opposed, same sign. Okay. The motion carries.

Donna Sullivan: Okay. So the next class is the statin class. In the statin class we have, I believe, all of the products. I believe all of the generic products are preferred in this particular class. Our current limitations, we do have generics first in this class, but they must try one preferred generic before any brand is authorized. Crestor requires trial of the highest tolerated dose of atorvastatin and we have dose limitations on simvastatin and atorvastatin. We approve up to, but not 80 mg per day. So unless you've been on atorvastatin or simvastatin already for a year, the labeling has a maximum dose of… is not to exceed 80 mg, I believe. We don't approved

80 mg doses at this point in time unless they've already been taking it for more than a year. And then we have rosuvastatin limited at 40 mg per day. So the recommendation is to continue the current dose limits on atorvastatin, rosuvastatin and simvastatin. Continue generics first where a patient must step through one preferred generic for one month before a non-preferred generic… before a non-preferred brand or generic is authorized and then DAW does not apply for endorsing practitioners. And for other patients they must step through atorvastatin at the highest tolerated label dose for one month before a non-preferred brand or generic is authorized unless signed DAW by an endorsing practitioner. And so we're not making the patients, in this case, take… if they were already on simvastatin at a high dose I wouldn't ask them to go back and take simvastatin… I'm sorry. If they are already on atorvastatin at the highest dose it would be inappropriate to say go back and take pravastatin, simvastatin, all the other generics, because the next highest… the next product is another probably high potent statin. So we are just asking that, in addition to the generics first they have to have… they have to try atorvastatin at the highest tolerated dose before one of the non-preferred brands would be approved.

Amber Figueroa: So in clarification, would that be 60 mg is the highest then that you… I mean otherwise you'd be popping seven 10 mg pills of atorvastatin.

Donna Sullivan: Or 1-1/2 of the 20s. You could take… you can take three… you could take a half tablet. We don't actually have specific… I don't know how it's coded in the system, Chuck. I don't think it's coded at the quantity… the number of pills.

Chuck Agte: So for, let's see, so for atorvastatin we don't actually have limits on atorvastatin at this point. So there's nothing coded in the system.

Donna Sullivan: Okay. That's my error then.

Chuck Agte: We do have the limits on simvastatin and rosuvastatin, but we don't have a limit right now on atorvastatin. We would be implementing a new one if a dosed limit on atorvastatin with that first bullet. But how we could or would code it in the system I think that… actually, that wouldn't be coding in the system. It would come out through the PA process when

someone was trying to get rosuvastatin. So we would check what they've been on prior either in our system or by attestation by the pharmacist or patient. So we wouldn't really be looking at number of pills. We'd just be asking, you know, what dose have they been on? Or we would see that dose ourselves in the system.

Donna Sullivan: How are we checking the simvastatin limit as it is now? Is that coded to stop?

Chuck Agte: Right now the simvastatin… yeah, simvastatin is coded to stop. We have generic atorvastatin is preferred so it pays without limitations currently.

Donna Sullivan: Okay.

Susan Rowe: Isn't that okay?

Donna Sullivan: It's fine. It was my understanding, when we were doing this, there was already a limit on atorvastatin at 80 mg. So apparently that is not correct, but we do have a dose limit on simvastatin, but we do not approve an 80 mg dose of simvastatin unless they've already been on it for one year. And so that's the question I'm asking, how do we tell that they're… do we just not allow an 80 mg dose? There must be some sort of quantity limit on those products.

Chuck Agte: So for simvastatin and I'm sorry, I didn't catch that previously, the atorvastatin there. For simvastatin it is the number of pills based and it is just basic math, which includes some ridiculous possibilities, you the system would let you have a prescription for 15, 5 mg per day. It's coded to whatever the maximum number of tablets to get to not 80 mg.

Donna Sullivan: We could, for sake of clarity, change the limit on simvastatin to be 80 mg or less so that people aren't taking 5 mg tablets to get up to a 75 mg dose. We could, if you feel like, add atorvastatin limits, if you want to. The FDA doesn't… the maximum dose is 80 mg. So I don't know if you want to make it a hard stop at 80 mg or just let it go. So that's up to you.

Susan Rowe: I would say, you know, all of them have hard sort of maximum limits. And unless one of them has… like simvastatin, like rosuvastatin has been

shown to be harmful above a certain dose, I just don't think we should incorporate it, because I think the prescribers will just look at the maximum dose and limit it there. There is, you know, sometimes because simvastatin was once allowed to be routinely 80 and rosuvastatin, when it was first marketed, did go a little bit higher. I think those are good safety measures. I think the rest of them sort of take care of themselves.

Amber Figueroa: I would think that a hard 80 mg… I just think as a clinician less than 80 mg is really vague. I just don't know… as a prescriber how far do you want me to push it? Is it 60? Is it 70? You know? I just think maybe if we put it at a hard 80 mg that it would be clearer.

Donna Sullivan: So just limit it to 80 mg… oops, wrong slide.

Amber Figueroa: Or change it to 70 or change it to a specific number instead of just less than something.

Donna Sullivan: The simvastatin is limited to 80 mg per day, periods.

Christine Klingel: I think, in practice even, they recommend simvastatin at 40 mg. So you could say limit to 40 mg a day unless already taking greater than 40 for a year. I don't think I've ever seen in practice anyone write anything other than 40 or 80. I don't know if I've ever seen a prescriber write 60 just because there's not a tablet size available. Yeah, so if they took 40 and then… if you have already taken the 80 that's fine.

Donna Sullivan: Any comment atorvastatin limits or just leave… what Dr. Rowe said, just leave it as it is? Okay. So let me… Hang on. I'm going to get rid of atorvastatin down here. There we go. Are we good? Then motion.

Amber Figueroa: Oh… I just see that it is mentioned as Crestor and rosuvastatin. I don't know if you want to keep both of the names on that slide.

Donna Sullivan: Oh, I can change it. Thank you.

Susan Rowe: Would someone like to make a motion?

Michael Johnson: I make a motion that we accept this.

Susan Rowe: Second? I'll second Michael's motion. All in favor say aye.

Group: Aye.

Susan Rowe: All opposed, same sign. Okay. The motion is approved. Thank you.

Donna Sullivan: So next we are going to look at the antidepressants. I'm not going to try to pick out which ones are preferred because it's a complicated slide. Most of the generics are preferred. The grade out products are not… they are in the class, but they have not been reviewed by the Drug Effectiveness Review Project. So currently in this second generation antidepressant class we have generics first. So they must step through one preferred generic before any… I should say non-preferred product, not just the brand will be authorized. Continuation of therapy is required by statute. So if a patient is already on an antidepressant then we have… we are required to allow them to continue on that product until the prescriber makes the change. For non-preferred products the criteria is that they must try and fail two preferred products. We have dose limitations on citalopram of 40 mg per day and duloxetine of 60 mg per day. And then we have expedited authorization for duloxetine for diabetic peripheral neuropathy, fibromyalgia, and chronic musculoskeletal pain. And then for bupropion we have an expedited code to confirm that the product is being prescribed not for smoking cessation and that is an accurate statement. So we do stop the bupropion if they don't have that expedited code because we have, you know, it's complex. We have to bill it differently for CMS or report it differently for CMS depending on smoking cessation versus depression. So without going into all of the complicated explanation, that's why there is an expedited authorization code to confirm that they are not using it for smoking cessation. So our recommendation is to continue generics first, continue the dose limits and expedited authorizations as stated above, continue the generics first where they must try one preferred generic before… for one month before a preferred brand or a non-preferred generic is authorized and DAW does not apply.

This is where we'll have a little bit of discussion. Then the question is, you know, we would recommend that the patient then step through all the preferred generics at the highest tolerated doses for one month before a preferred brand is authorized and we should put… add here non-preferred generic is authorized unless signed DAW by the endorsing practitioner. And that they must step through all the preferred brands at the highest tolerated dose for one month before any non-preferred brand or generic is authorized unless signed DAW by an endorsing practitioner.

So I'm going to just scroll back up to the list of the drugs so that you can consider in this; would you feel it appropriate to make them try all generic products prior to going to a non-preferred product or a preferred brand? An example is they would have to try bupropion, citalopram, escitalopram, fluoxetine, fluvoxamine, mirtazapine, paroxetine, sertraline, venlafaxine before they would get one of the brands that would be… and I think the only brand that does not have a generic… the brands without generics are Luvox CR, Fetzima, Vibryd and Brintellix.

Dale Sanderson: One quick comment also like on citalopram. In the elderly, however you define that, citalopram is now limited to 20 mg. So does that need to be included in this?

Chuck Agte: If the board would like to implement that limit it would need to be included.

Dale Sanderson: It's an FDA guideline. The definition of elderly is a bit vague.

Chuck Agte: Would the board like to define elderly?

Susan Rowe: So Dale, how do you feel about the number of trials of a generic?

Dale Sanderson: The issue is these medications are quite different in their side effect profiles and stuff. I mean Wellbutrin or bupropion versus citalopram, mirtazapine, I mean these drugs have very different side effect profiles and it seems… it seems unrealistic for me to have someone who is like on an SSRI and then ask that they go through both mirtazapine and

bupropion before they go to another SSRI in the non-preferred class. That seems unrealistic to me.

Mason Bowman: I kind of have the same concern too because we're talking about, you know, a group of medications that we classified as SSRIs and then another group SNRIs and so sometimes the recommendations, too, are to… if a patient is going to be on an SSRI to try and fail one of those and then moving in within the same class is ideal before moving into a separate class. So I guess the concern would be is, are we going to be forcing patients to have to move into a different class when maybe the provider isn't quite ready for that or the patient as well?

Dale Sanderson: Again, I don't know if you want to move this into an SSRI, SNRI and more of an atypical like antidepressant. But again I mean if you have a class of atypical antidepressants the difference between mirtazapine and bupropion are very different—they are very different drugs, even though they are kind of both atypical antidepressants.

Donna Sullivan: We could… where I kind of see you going is saying that they would… would it be appropriate that they try and fail a preferred generic in each subclass before they go to a brand?

Susan Rowe: I actually… if you try and fail, you know, you're two months down the road with treatment of depression and… so then you're trying and failing or two and I'm not sure… some subclasses are just not appropriate to go to for every patient. So I guess I would rather limit trying and failing maybe one, possibly two, generics. As I look at this list, you know, most of our therapeutic options are generic and are on this list and so I think we could treat the patient with maybe… I mean I don't think we have to try that many medications to adequately treat the patient. I think we could… I guess I would say maybe try and fail one, but bring us back the evidence to show that that causes an explosion in some of the use of the brand name drugs. I'm not sure it will.

Donna Sullivan: That is the current criteria that they try and fail. They must step through one preferred generic already before any non-preferred medication brand or generic or preferred brand would be approved.

Chuck Agte: Two.

Dale Sanderson: It was reasonable, but staying through the entire list is… seems unrealistic. I think Susan's point is well taken. We're dealing with people like with depression and, you know, potential issues of their quality of life that we are trying to address.

Donna Sullivan: Then I guess the recommendation would be just to leave the current limits as they are? Okay.

Dale Sanderson: This is a brief question and I know that we addressed this briefly before, but nefazodone, do we have many people on nefazodone with its liver hepatic issues? Is that… I mean why is that even on the list?

Donna Sullivan: It's on the list only because it is… it has been reviewed by the committee… by the Drug Effectiveness Review Project. It's included in the report and the committee has not explicitly not included it.

Mason Bowman: I recall within a few months or a few meetings that we specifically stated that nefazodone was going to be excluded because of the hepatic toxicity issues. I recall that distinctly. I can't exactly say when, but I'm pretty sure that's the case.

Donna Sullivan: I will go back and check. I don't know if it was that you excluded it or just made it not preferred because…

Christine Klingel: I think we made it not preferred just like what we did with ticlopidine. It was reviewed, but it was not… and it looks like that is not preferred.

Donna Sullivan: It's definitely not preferred, but I will go back and check and make that…

Man: There may be a small number of people that have continued on this drug and it's the only one that works and they tolerate it side effect wise. But the hepatic issues are of huge concern.

Donna Sullivan: So when we review the antidepressant class as the P&T Committee I will try to ask… or remind you to keep that in mind when we review them,

because at this point in time this is the state of the antidepressant class. So we can't say it's no longer included in the class as the DUR Board.

Chuck Agte: However, the board, in their role as the DUR Board for Medicaid does have the option to say, you know, besides what we are recommending you can say nefazodone should require full prior authorization and tell us what you think the criteria should be because as our DUR Board you have that right. If you think that nobody should be on nefazodone without it being reviewed first that's something you can instruct us to do.

Susan Rowe: What do you think? Can we leave it non-preferred? All right. Would anyone like to make a motion to accept this criteria? The generics first?

Dale Sanderson: I move.

Susan Rowe: Second?

Lisa Chew: I second.

Susan Rowe: Okay. All in favor say aye.

Group: Aye.

Susan Rowe: All opposed, same sign. The motion carries.

Donna Sullivan: The next class that we're looking at is the estrogen products. For the estrogen products they are listed here. The preferred products are generic estradiol and we have the vaginal product of Estring as preferred. And then estropipate and ethinyl estradiol norethindrone combinations are preferred. So with the current limitations there's an expedited authorization for a diagnosis of gender dysphoria and then also labial adhesions for children 0 to 5 years old. The patients must step through a preferred brand or generic before a non-preferred brand or generic is authorized. So we don't have generics first in this particular class at this time.

So what our recommendations are is that we continue expedited authorizations listed above, that we implement generics first according to

the formulation prescribed. So if they are prescribing a patch that they have to try a generic patch before they can get a branded patch. If it's a pill, an oral tap product then oral products and that DAW should not apply. And they must step through, again, all preferred generic estrogens or preferred estrogen combination products at their highest tolerated doses according to formulation for one month before a preferred brand is authorized unless DAW by an endorsing practitioner. And they must step through all preferred brands at the highest tolerated dose for one month each before a non-preferred product is authorized unless signed DAW. And again I would make the caveat that that's by formulation.

Susan Rowe: Any questions for Donna?

Eric Harvey: One clarification I think for the labial adhesions usually they use a cream and… is there a cream available that is a preferred?

Donna Sullivan: No. But if it has the expedited authorization code it doesn't stop as non-preferred. Correct?

Chuck Agte: That code actually… that one actually isn't a code yet that is specific direction for our PA staff that the PDL doesn't apply and they approve if that's the diagnosis. So that one is not expedited yet, but we could potentially expedite it.

Donna Sullivan: Okay. So in this case what happens if a cream is prescribed for a child for labial adhesions it would, if it's not preferred, reject for not preferred. The pharmacy would actually have to make a phone call and give the diagnoses, but it would authorized when they make that phone call. I don't think that we see these that often. I would recommend that we create a code for it. That way it saves the pharmacist a phone call.

Amber Figueroa: So this is implying that if a patient wants to do local vaginal estrogen, since there's no generics, they would need to try either a transdermal or an oral, which are systemic before they could get the vaginal?

Donna Sullivan: I think… what I didn't put in here is that it would be by formulation. So they would have to try the Estring before they tried one of the non-preferred vaginal products.

Christine Klingel: Just for clarification, so say in Amber's case they wanted a local vaginal product, they would just need to use the Estring first, did not tolerate, and then could get the prior auth for say a cream?

Donna Sullivan: Correct.

Christine Klingel: Okay. That's better.

Susan Rowe: Any questions? Changes? Okay. So I, Susan Rowe, move to accept this criteria as now presented.

Mason Bowman: I second.

Susan Rowe: All in favor say aye.

Group: Aye.

Susan Rowe: The motion carries. Nasal steroid products.

Donna Sullivan: The next class are the nasal steroids. They are listed here and it does include the OTC products. Our current limitations, we do have generics first. They must step through one preferred generic prior to any brand as authorized. And then Rhinocort is approved for women who are pregnant or breast feeding. Our recommendation is to continue the approval of Rhinocort for pregnancy and breast feeding and I will caveat that to say Rhinocort or its generic equivalent, if there is one. Again, basically it's the same premise here. It is step through one preferred generic or one preferred OTC product for one month before a preferred brand is authorized and dispensed-as-written by an endorsing practitioner would not override this requirement without authorization. I threw in there the OTC product because sometimes the OTC products are cheaper than the generics. So we don't want to have them take a more expensive [inaudible] generic than an OTC product.

They also must then step through all preferred generics and all preferred OTC products at the highest tolerated dose for one month before a preferred brand is authorized unless DAW is signed by an endorsing

practitioner and then must step through all brands at the highest tolerated dose for one month before a non-preferred and I'll change this to non-preferred product is authorized unless signed DAW by an endorsing provider.

I'm trying to make it so we can see all of the words on the screen.

Eric Harvey: I will move to approve the recommendations as stated.

Susan Rowe: Thank you, Eric. Do I have a second?

Dale Sanderson: Second.

Susan Rowe: All approved say aye.

Group: Aye.

Susan Rowe: All opposed, same sign. The motion carries.

Donna Sullivan: And we're done.

Susan Rowe: Okay.

Donna Sullivan: Lunch is not here yet. It's 11:30.

Susan Rowe: So for those here let me first ceremoniously pass the three-minute egg timers to Michael Johnson. Thank you so much for serving. And, Eric, thank you. We will adjourn the Drug Utilization Review Board for this month and see each other in June. Donna and crew will be busy this afternoon.

There is a bleeding disorder collaborative meeting starting at 1:00. It is like this one, an open meeting, and you are welcome to stay if you are interested and attend. Anything else?

Donna Sullivan: Nope.

Susan Rowe: Okay.

Donna Sullivan: If you don't want… you're welcome to stay. If they bring your lunch you can take your lunch and leave or if you want to sit here and eat here in the room you can stay here and eat in the room. We just ask that we get out of here by 12:30 so we can set up for the next meeting. But you're welcome to stick around and hang out in the room if you'd like.