Washington State Pharmacy and Therapeutics Committee
P&T Meeting Notes
December 21, 2016

Michael Johnson: Good morning. This is Michael Johnson and we're going to convene the Washington State Pharmacy and Therapeutics Committee at this time. I think first of all we'll start off with introduction starting here off to the left and then when we're done with that Ray Hanley is going to give some announcements here.

April Phillips: Medicaid.

Jodie Arneson: Medicaid.

Christy Pham: L&I.

Jaymie Mai: Labor and Industries.

Doug Tuman: L&I.

Dale Sanderson: Committee member.

Po Karczewski: Committee member.

Christine Klingel: Committee member.

Michael Johnson: Committee member.

Eric Harvey: Committee member.

Mason Bowman: Committee member.

Susan Rowe: Committee member.

Leta Evaskus: Health Care Authority.

Donna Sullivan: Health Care Authority.

Ryan Pistoresi: Health Care Authority.

Ray Hanley: Health Care Authority.

Thanks, Michael. I just had a couple of quick announcements. The first is that we have five committee members who will be leaving the committee and I wanted to thank them for their service. I guess we could say they are sort of graduating. And that's Mason Bowman, Susan Rowe, Christine Klingel, Eric Harvey and Christopher Smith who is not here today. But I really wanted to thank you for your service and it's going to be a different P&T Committee with five new members, as well, but thank you so much for that.

[applause]

Susan Rowe: Thank you for all your support through the years.

Ray Hanley: The other announcement I had was that we are going to be voting a new vice chair today who will take over the position on January 1st and the choices are Lisa Chew, who is not present but will accept in her absence. Amber Figueroa, Po and Dale are all eligible and in the batters box for vice chair. And then the last announcement is that Michael Johnson will remain chair of the committee for one more year. That's all I had besides to wish you all a very happy holiday and thank you again for your service.

Michael Johnson: Is Marian on the phone?

Woman: Wait, wait, wait. Let's voice.

Michael Johnson: I'd like to nominate Lisa for this. I think she's been here and she'd like to do it.

Dale Sanderson: I'd like to second.

Michael Johnson: Discussion? Any other nominals, too? I don't see any other nominations so we'll go ahead and vote on this. All in favor say aye.

Group: Aye.

Michael Johnson: All opposed same sign. All right. Lisa gets it. Thank you. So at this time I think we'll start off with the second generation antipsychotic update with Marian.

Marian McDonagh: Okay. Great. Thank you. I'm here. Yes. Can you hear me okay?

Michael Johnson: We can hear you.

Marian McDonagh: All right. So slide this is the fifth update of this report and it was finalized a couple of months ago. Let's go to slide 2.

There are seven key questions for this report and they are organized around the different populations in this report. So key question 1 is about patients with schizophrenia. Question 2 is patients with major depressive disorder. Question 3 is adults with bipolar disorder. Question 4 is children and teens with bipolar disorder. Go to slide 3.

Question 5 is about children and teens with autism spectrum disorder. Question 6, children and teens with disruptive, impulse control, and conduct disorders. And then question 7 is subgroups of the patients based on a variety of characteristics. And so if we go to slide 4.

This is the interventions that are included. A list of the interventions that are included in the report and there were four new products added to the report this time. Two oral drugs brexpiprazole and cariprazine and two injectable products. Aripiprazole has a second long-acting injection which is given every four to six weeks as opposed to the previously available product which was every four weeks. And paliperidone then has a new product that is three months – every three months and previously their other injectable is again monthly. Those are the new products. Let's go to slide 5.

It's just a list again of those populations and the evidence is presented in order of the populations. Any subgroup analyses or evidence that is available will be presented with the population that they belong to. And then slide 6.

This is just a reminder of the limits we put on the study designs. So we narrowed the scope of this to be primarily about head-to-head comparisons. So for all of the adult populations only head-to-head trials were included or in the cases where we would allow observational evidence. So let's say for serious harms or long-term harms, again, it would need to be head-to-head comparisons. But for pediatric patients we did not make that requirement. So placebo-controlled trials are still included given, you know, the idea that we still want to know whether they work versus placebo or not. Whereas an adult populations that's probably not the main issue.

Now on slide 7 we have the summary of the strength of evidence ratings and just a reminder that these are… these ratings are applied to a body of evidence and they looked at not just the individual trials and their quality, but also things like are their findings consistent across the trials and how precise are the resulting estimates? To slide 8.

So the results for this update. We included 54 new studies and additionally there are 24 secondary publications. So there are often subgroup analyses or additional outcomes that were not reported in the primary publication. You can see that just over half of those are trials and then we have a variety of other kinds of papers that were included and we did receive packets of information from a number of manufacturer's as well. Slide 9.

Starting in on the new evidence for schizophrenia and related psychoses. We added 22 unique studies to update 5. Slide 10.

I guess I should comment, you know, that what's in those 22 studies is really just very little evidence on the new drugs. So only one randomized controlled trial for cariprazine, one for brexpiprazole and one for the three-month injection of paliperidone palmitate. For the new aripiprazole injection we only had a network met… two network meta-analyses that were based on placebo-controlled trials. So not a lot of evidence for these newer products.

Sorry, back to slide 10 here with the quality of life. There was some new evidence, but it didn't change any of the previous findings. It was about the older drugs, you know, so nothing new there. Slide 11.

For functional outcomes again the same thing. We did have some new evidence, but it simply confirmed these previous findings.

Slide 12 is the outcomes of risk of hospitalization or rehospitalization and risk of relapse and those… there was no new evidence for those outcomes. Slide 13.

Drug discontinuation we do have some new evidence and this outcome is [inaudible] to reflect the patient's ability to stand treatment over time and withdrawals could be due to any reason – inadequate efficacy, adverse events, or other reasons. So we find moderate strength evidence from a network meta-analyses of 112 head-to-head trials that olanzapine and clozapine result in 24 to 55% lower rates of withdrawal from treatment than most of the other drugs. And the exceptions are that only clozapine had a lower risk compared to cariprazine and that it statistically is significant lower risk. And only olanzapine had a significantly lower risk than oral paliperidone. The long-acting injectable forms of risperidone, aripiprazole and paliperidone were not found significantly different to clozapine and olanzapine. And the only other statistically significant finding was that the extended release formulation of quetiapine and risperidone both had significantly lower risks compared with iloperidone. So the long-acting injectables do not have a lower risk than the orals for discontinuation. But if we go to the next slide…

This is looking at the evidence for the time to discontinuation and the only new evidence here was regarding the long-acting injectable form of risperidone where we had a single study that found that this product had a longer time to discontinuation than aripiprazole, clozapine, olanzapine, quetiapine or ziprasidone. Slide 15.

So looking at improvement in the chore psychiatric symptoms there's a published network meta-analysis that included only the oral drugs and mostly older drugs and found that clozapine had marginally or a moderately better improvement in psychiatric symptoms than the other

oral drugs and then behind clozapine was olanzapine risperidone, which had similar rates and then oral paliperidone. But there's no evidence in this network meta-analysis on cariprazine, brexpiprazole, and of course none of the injectables. So the comparative evidence on those drugs is not clear for the improvement in symptoms. For the risk for suicide or suicidal behavioral there is no new evidence other than incidental reports. Slide 16.

Looking at withdrawals due to adverse events, moderate strength evidence again from a network meta-analysis here we had 91 randomized head-to-head trials that we included. So we found that long-acting injecting risperidone had a significantly lower risk than many of the oral drugs and the odds ratio for example for the oral risperidone versus long-acting… the long-acting injecting risperidone was 2.33. There was no difference between the long-acting injectable drugs and no difference for the newest oral drugs. So cariprazine and brexpiprazole. Clozapine was also found to have a significantly greater risk than iloperidone with an odds ratio of 2.2. And then we have other evidence in the report on specific adverse events such as extrapyramidal symptoms, metabolic adverse events, weight gain and sexual side effects, but those are not reported here on the slides because it is very limited evidence. Much of the better evidence relates again to the old drugs and confirms the findings and evidence on new drugs is just very limited and too limited to really draw any conclusions.

The next slide is looking at patients experiencing their first episode of schizophrenia and then looking at patients by age group. And while we have some new evidence for patients with their first episode, it did not change any of these conclusions and we didn't have any new subgroups analyses or specific studies in differentiating by age. So the conclusions there don't change. Slide 18.

There were several either subgroup analyses of patients in studies… Asian patients or studies conducted entirely in Asian patients and the findings of those did not differ to the overall findings of the report. Next slide.

This slide is looking at some other additional subgroups that were in the previous report and there's no… the evidence… no new evidence here for these subgroups. Slide 20.

Going on to the evidence for major depressive disorder, and we had no new evidence for this update. So slide 21.

This is the summary of what we had for the evidence last time for major depressive disorder and that does not change. Slide 22.

This is looking at bipolar disorder in adults. Here we had only one new study, which was rated poor quality. So the findings of the report don't change. Haven't changed.

So slide 23 and 24 have the results from the previous report and those are not changed for this report.

So if we go to slide 25 this is the summary of the evidence for bipolar disorder in children and adolescents. So there's no new direct evidence, no head-to-head studies. We did have some new placebo-controlled trial evidence and this slide is actually incorrect. The slides of the… the studies of asenapine and risperidone were good in fair quality respectively and there were two additional studies that were rated poor quality. Next slide.

On this slide we have the evidence for asenapine is new. The study on risperidone simply confirmed the findings of previous placebo-controlled trials. So response with asenapine is similar to the other SGAs here that it is better than placebo and the rates were 42 to 54% response with asenapine depending on the dose or the study, and then versus 28% in the placebo group. And then at the bottom of the slide there's also information on weight gain. So this is looking at clinically important weight gain of 7% or more increase from baseline and the range there was 8 to 12% versus one with the asenapine versus 1.1% with placebo. So similar to the SGAs. Going to slide 27.

This is looking for subgroup evidence in children with bipolar disorder and there was no new evidence. So slide 28.

Looking at children with autism spectrum disorder or disruptive, impulse control, and conduct disorders. And here we had really the new evidence was one new head-to-head trial over risperidone compared with aripiprazole in children with autism spectrum disorder. Slide 29.

Symptom improvement from the head-to-head evidence. The new head-to-head study found no difference between aripiprazole and risperidone. Both did improve scores from baseline at two months. And then the response with aripiprazole was statistically significant among a subgroup… of a subgroup analysis of white children, but not statistically significant in a smaller subgroup analysis of non-white children. Again, those are subgroup analyses and they are quite small. So this may well be a statistical power issue that there just weren't enough children in either group, but particularly in the smaller non-white group. Slide 30.

There is no new evidence specifically for the children of disruptive impulse control and conduct disorders. Slide 31.

This is a slide on adverse events and it really applies to children with either autism spectrum disorder or these disruptive impulse control and conduct disorders. And the evidence that we actually have is from that new head-to-head trial, which is in children with autism. So the discontinuations due to adverse events, extrapyramidal symptoms and weight gain. There was no difference between the aripiprazole and risperidone for any of those outcomes.

Slide 32 is introducing the section we have on serious harms and if you're looking across populations with the exception that really most of this evidence applies to adults with schizophrenia or bipolar disorder.

Slide 33 then for mortality we have three new observational studies of mortality risks with the second generation antipsychotics. And differences were not found for any of the comparisons between the drugs and really this evidence applies only to the older drugs. So risperidone, olanzapine and quetiapine were all similar at one year after starting the drug and clozapine and quetiapine had a lower risk compared

with patients who had the diagnosis but were not taking an antipsychotic drug. Slide 34.

Looking at the risk for cardiovascular outcomes and cardiac harms. Here the observational evidence finds no difference in the risk of CV events again between the older drugs of risperidone, olanzapine and quetiapine are really what's represented here. Slide 35.

This is looking at the risk for new onset diabetes in adults and there is no new evidence for the incidence of diabetes. The bottom of the slide we also do include diabetic ketoacidosis. So here we didn't have new evidence on ketoacidosis alone, but a new study included a composite outcome that included ketoacidosis hyperglycemia and hyperglycemic osmolar state. So a much broader definition and there was no difference between risperidone and olanzapine regardless of age group, but quetiapine had a lower risk than risperidone in the older age group.

Moving to slide 36 then looking at this same issue, the risk of diabetes in children. Antipsychotic use was found to increase the risk of developing diabetes at least two-fold compared with either healthy controls or children with a similar diagnosis, but not taking an antipsychotic drug. Additionally, a single study found the risk of developing diabetes to be greater with aripiprazole than with risperidone, but it is a single study even though it was a large observational study we still need to have confirmation of that finding.

On slide 37 then looking at some other serious harms here we had no new evidence for tardive dyskinesia and other serious adverse events.

So the summary slides. These summary slides are just summarizing what we found in the new update and not what was in the previous reports. So for schizophrenia olanzapine and clozapine were found to have a lower risk of discontinuing treatment compared with eight other second generation antipsychotics. Specifically clozapine had a lower risk than cariprazine. Olanzapine had a lower risk than paliperidone extended risk. Quetiapine extended release and risperidone both had a lower risk than iloperidone. Secondly, clozapine moderately improved symptoms more than the other oral second generation antipsychotics followed by

olanzapine and risperidone and then paliperidone, but again the new drugs and long-acting injectables are not included in that analysis. Long-acting injection risperidone has a lower risk of withdrawal due to adverse events and I guess I should mention also… remind you that the long-acting injection risperidone also had a longer time to overall all cause withdrawals. Slide 39.

Mostly here for these major depressive disorder the adults with bipolar disorder there is no new evidence and as you know with children with bipolar disorder there was some new evidence on asenapine versus placebo that was very consistent with the other evidence for the other second generation versus placebo. Slide 40.

This is looking at new evidence for children with autism spectrum disorder. Aripiprazole and risperidone were not found different in symptom improvement or adverse events. Slide 41.

This is looking at serious harms. Just a quick summary in adults there were no differences in all-cause mortality, cardiovascular mortality or cardiovascular events among the older drugs. And in children and teens the second generation antipsychotics are associated with an increased risk of new onset diabetes when compared to healthy controls and there is a suggestion that aripiprazole is associated with higher risk for new onset diabetes than risperidone in children.

And that's it. The summary of our update report.

Michael Johnson: Thank you, Marian. Any questions from the committee?

Po Karczewski: I'm wondering if there was any address of elevated prolactin levels which is a big question for a lot of consumers, particularly due to all the commercials that are apparently out there looking for people having gynecomastia from prolactin elevation. It's a big point with trying to get people to start with Risperdal.

Marian McDonagh: Yeah, I see what you're saying. Unfortunately, many years ago… well, this report is so large that intermediate outcomes such as, you know, prolactin being a lab value and not the actual outcome of gynecomastia

that we didn't include that trying to focus more on the health outcomes. So it's not in this report, unfortunately.

Po Karczewski: Thank you.

Susan Rowe: Marian, all of the data on the decrease in suicidality is that only for schizophrenia or is it all indications?

Marian McDonagh: That's such a great question and the answer is really that the good evidence is only in schizophrenia and what we see in the rest of the studies is really incidental reports that are not, you know, the outcomes are not confirmed and there is very few of them. So it's really not… you can't really make a whole lot of sense of it. So it's really not… the only good evidence is from really one large really well done trial that was in patients… high risk patients with schizophrenia. So this really doesn't… not much of anything high quality in other populations.

Susan Rowe: Thank you.

Michael Johnson: Any other questions? All right. Thank you, Marian. At this time we're going to turn to the stakeholders. If you want to stay on the line, Marian, if you have time that would be great.

Marian McDonagh: Okay.

Michael Johnson: I'll just remind you that we'll limit comments to three minutes. The first person up will be Dr. Deborah Profant. And then the next one up with be Lyle Laird. We'll do this up at the podium and again just introduce yourself and tell us who you represent and we'll go ahead and get started.

Deborah Profant: So I'm Deborah Profant. I'm one of the medical science directors for Alkermes and I'm going to speaking to you today on Aristada, which is aripiprazole lauroxil. So Aristada is an atypical antipsychotic indicated for the treatment of schizophrenia and it is a prodrug of aripiprazole. Aripiprazole lauroxil's unique formulation provides controlled release after injection and it extends exposure to the active molecule. Following injection Aristada is converted to anti hydroxyzine methyl aripiprazole

which is then hydrolyzed to aripiprazole. Depending on the individual patient needs treatment with Aristada can be initiated with a dose of 441 mg, 662 mg or 882 mg monthly. You can also initiate treatment with the 882 mg dose every six weeks. With the first injection you need to administer oral aripiprazole for 21 consecutive dates. That study states all the approved dose and regimens for Aristada result in aripiprazole concentrations within the therapeutic range and that was determined to be 102 to 435 ng/ml. This range also overlapped with the oral aripiprazole concentrations that were determined. The availability of three dose strengths and two dosing intervals yields aripiprazole concentrations that span the oral aripiprazole dose range and the prolonged aripiprazole profile provides sustained therapeutic coverage in the event a dose is missed. There is no oral supplementation required when the time of the last injection is less than or equal to six weeks for the 441 mg dose or less than or equal to eight weeks for the 662 or 882 mg dose. Aristada was evaluated in a 12-week randomized double blind placebo-controlled study in adult patients with acute schizophrenia. This study showed improvement of psychotic symptoms based on the total [inaudible] scores and both dosages showed statistically significant and a clinically meaningful improvement compared to the placebo dose. In the one-year openly [inaudible] extension study 85.7% of Aristada treated patients achieved stabilization.

In terms of adverse events the most common adverse event was [inaudible]. The majority of the [inaudible] was reported before the second dose and most of it occurred during the time when there was an oral aripiprazole overlap. By having multiple dose strengths and the dosing interval options this allows providers the option to tailor treatment based on individual patient needs and therefore we respectfully request the committee to consider having Aristada as one of your preferred options on the PDL.

In terms of the other warnings and significant safety events I'm going to refer you to the prescribing information.

Michael Johnson: Thank you. Any questions? Okay. Next up will be Lyle Laird and following will be Kim Laubmeier.

Lyle Laird: Good morning. My name is Dr. Lyle Laird. I'm a PharmD director in MSL with Sunovion Pharmaceuticals. Thank you very much for allowing us to address you today on lurasidone and Latuda. I will briefly review the key clinical information on Latuda and then my colleague, Kim Laubmeier, will review new comparative health economic and outcomes data.

Lurasidone is indicated for the key treatment of both adult schizophrenia and bipolar depression. It's the only agent with an indication as both monotherapy and adjunctive therapy with lithium or [inaudible] for the treatment of bipolar depression. Lurasidone and clozapine are the only atypicals with pregnancy category B ratings. Lurasidone has no clinically relevant impact on QT interval and smoking is not expected to affect its pharmacokinetics. Lurasidone's safety and efficacy has been established in numerous clinical trials. Here patients on average did not have significant increases in weight or metabolic parameters and this is important given that patients with mental illnesses have increased risks of diabetes, obesity and cardiovascular diseases. In [inaudible] please see the lurasidone full PI for complete warnings, precautions and adverse events. Thank you.

Kim Laubmeier: Good morning everyone. My name is Kim Laubmeier and I'm a director of health economics and outcomes research with Sunovion Pharmaceuticals. In addition to the favorable clinical trial outcomes lurasidone has also consistently demonstrated favorable comparative health outcomes and cost effectiveness. Starting with hospitalization outcomes and real-world claims analyses from Medicaid and commercial databases lurasidone initiation was associated with a significant decrease in both all-cause and mental health related hospitalization for patients with schizophrenia and bipolar disorder in the six-month follow-up period. Similarly, in another analysis of Medicaid patients with schizophrenia hospital length of stay was significantly shorter for patients switching to lurasidone compared to those switching to quetiapine. Turning to adherence outcomes in real world claims analyses in Medicaid patients with schizophrenia and bipolar disorder patients on lurasidone experienced significantly higher adherence rates compared to patients on aripiprazole, olanzapine, quetiapine and risperidone.

Looking at number needed to treat outcomes and a comparison of the only three approved agents for bipolar depression lurasidone yielded a substantially more favorable relative number needed to treat and number needed to harm compared to quetiapine and the olanzapine plus [inaudible] combination.

Finally, in terms of economic outcomes in an independent [inaudible] claims database analysis patients on lurasidone had substantially lower total medical costs when compared with those on aripiprazole, quetiapine, risperidone, olanzapine and paliperidone. In conclusion lurasidone addresses the need for safe and cost-effective agents to manage adult patients with schizophrenia and bipolar depression and importantly in the most recently published Medicaid treatment guidelines, lurasidone's position as a first line treatment for both schizophrenia and bipolar depression with a specific footnote indicating that lurasidone has a better metabolic profile than quetiapine in treatment of bipolar depression.

Also on behalf of Sunovion Pharmaceuticals I respectfully request that lurasidone be retained on the preferred drug list for the Medicaid beneficiaries in the state of Washington. Again, we thank you for the opportunity to speak today and we're happy to address any questions.

Michael Johnson: Thank you. Any questions? All right. Thank you. Next up would be Dwayne Stone and following will be Lauren Simonds.

Dwayne Stone: Good morning. Thank you for considering this topic today for me. My name is Dwayne Stone. I'm a licensed mental health counselor in Washington and I'm also the divisional director for case management and substance use disorder services and vocational services at Community Psychiatric Clinic. I have like 30 years of experience working with clients with schizophrenia and psychosis. I'm here today to ask the committee to ensure that my clients have open access to all of the second generation antipsychotic therapies that you're discussing, especially the longer-acting ones like [inaudible]. These therapies help my clients tremendously. In my role as the director I work with 30 case managers, probably 15 chemical dependency professionals, and what we do is we provide all kinds of other supportive services to our clients, you know,

with serious mental illnesses. Services include housing, vocational services, substance abuse disorder services, symptom management kind of stuff, psychosocial rehabilitation, and various day programs. And one of the things that the long-acting injectables allow us to do is it actually allows us to have a different conversation with our clients. When somebody is coming in on maybe a weekly basis to do some kind of medication management or they are taking oral daily medication, a lot of times they will take medication holidays and we all know why. They are going to drink that weekend or they just don't like the side effect profile and so we see the side effect profile and the symptom management go up and down, up and down. As a result they fall out of those supportive services that I was talking about and those are the services that actually keep people employed, in their relationships, and so the longer acting medication experience for our clients really keeps them in those services.

There's lots of examples where we're working with somebody and they are on the daily or the oral medication or what have you and then they will fall of that and then they will lose their housing because of it. So persistency on medication is critical to maintain some of these supportive services. Things like the longer acting ones like Trinza, you know, there's no difference in cost and so I don't understand why we don't just make that available. My case managers have about 80 people on their case load and, you know, the services we're providing is already complicated in the mental health system and so we have to have, you know, my case manager is working with the administrative end of trying to figure out if somebody has some kind of funding source and their health plans can pay for Trinza or has the medication been tried prior to… there's just not going to do it because they're trying to work with them on their housing and their food stamps, etc. So we don't really have quality conversations as a result of that. I also understand that the state is trying to look for… working with those people [inaudible] get appropriate care and keep them out of the more expensive levels of care like the state hospital and the jails. Also these longer acting medications I think do that as well. So the bottom line is I'm asking the committee to really make these longer acting injectables conveniently available to people in private practice and certainly in the mental health program because then I know that the folks who we are working with are going to keep their jobs and…

Michael Johnson: I'm sorry, the time is up.

Dwayne Stone: Okay.

Michael Johnson: Next is Lauren Simonds and next up is Samantha Sweeney.

Lauren Simonds: Good morning and thank you for the opportunity to speak with you. My name is Lauren Simons and I'm the CEO of the National Alliance of Mental Illness for Washington State. NAMI Washington is part of the nation's largest grass roots mental health organization dedicated to building better lives for the millions of American's effected by mental illness. You'll have to pardon me. I have a migraine. I have a little problem seeing. NAMI Washington's concern that the Health Care Authority is seeking therapeutic interchange for second generation antipsychotics we would note that from the first P&T review the authority for therapeutic interchange has been denied. Historically, antipsychotics have earned a special recognition and as a result special coverage status within the PDL. All antipsychotics have been added to the PDL at the P&T meeting after DERP review. Statutory refill protection exists for antipsychotics. Therapeutic interchange has never been allowed in this class of medications. PDL decisions have been binding on the Medicaid managed care organizations and the reason for this unique recognition are many and are well documented.

Several studies attest to the reduced total treatment costs realized when patients are treated with second generation antipsychotics. While the cost savings data is most robust with long-acting injectable antipsychotics, similar but less significant savings have been calculated with an oral second generation antipsychotic. This is due to enhanced compliance as a second generation antipsychotics are much less toxic than the first generation products. The side effects of psycho pharmaceutical medications can be severe and debilitating which often leads a person with mental illness such as schizophrenia to stop taking their medications. Barriers to accessing these medications result in increased visits to treatment centers, emergency rooms, hospitalizations, encounters with law enforcement and at times suicide. All of which undermines the wellbeing and continued recovery of the patient and shifts costs to these other more expensive systems. Based on

independent data the daily cost of the most expensive antipsychotic without regard to required Medicaid rebates is $77 per day. In comparison the cost of King County jail mental health care only is $156 per day and according to the 2016/2017 summary of state hospital charge rates the average per day cost for routine inpatient treatment at Eastern State Hospital is $737 per day and for Western is $618 a day. The potential cost savings are obvious and we encourage the Health Care Authority to prioritize the use with the most clinically appropriate medication that will offer the best outcome for the person living with mental illness, which in the long run will save money by reducing costs associated with the other more expensive systems utilization noted previously and NAMI Washington urges the P&T and the DUR Board to continue to allow access to all second generation antipsychotics for both the fee-for-service and managed care patients without interference from the proposed therapeutic interchange. The National Institute of Mental Health notes a medication that works well for one person with schizophrenia often doesn't work for another and this is further evidence that health care providers with their patients not review committees or health plans are best suited to make treatment decisions. And while we understand the need for cost savings, such savings should not be made at the expense of the patient's health and safety. The priority should be to improve…

Michael Johnson: I'm sorry. Your time is up.

Lauren Simonds: …the outcomes. Thank you so much.

Michael Johnson: Next up is Samantha Sweeney. This will be followed by Paul Thompson.

Samantha Sweeney: Good morning. My name is Samantha Sweeney and I'm a managed [inaudible] liaison with Otsuka. Thank you for the opportunity to present information on Abilify Maintena and Rexulti. Before I begin I'd like to stress that serious mental illnesses or heterogeneous disorders with a wide range of potential genetic environmental and psycho social factors may impact their clinical course and there appears to be substantial interpatient variability in response to antipsychotic medications. Therefore Otsuka supports an open access policy to allow for

individualized and appropriate treatment of patients with serious mental illness.

Abilify Maintena is an atypical antipsychotic indicated for the treatment of schizophrenia. It's administered by a health care professional via deep intermuscular deltoid or gluteal injection for all available doses. Abilify Maintena is formulated to contain aripiprazole and no biotransformation is needed to derive to the active drug form. Based on the pharmacokinetic modeling data Abilify Maintena and oral aripiprazole tablets the estimated oral aripiprazole dose equivalence is approximately 16 mg with a 300 mg dose and 21 mg for the 400 mg dose. A [inaudible] filing and administration is four days with the deltoid and then five to seven days with the gluteal muscle.

The efficacy of Abilify Maintena for the treatment of schizophrenia was established in a 12-week trial in acutely relaxed adults and a 52-week maintenance trial as described in the prescribing information. Additionally, as highlighted in the DERP report, the efficacy and safety of Abilify Maintena versus paliperidone palmitate in patients with schizophrenia was evaluated in Qualify, which is a head-to-head randomized open label rated blinded study. It's the first to compare atypical [inaudible] treatment effectiveness on a measurement of health-related qualify of life and functioning. Abilify Maintena shows significant improvement compared to paliperidone palmitate on the [inaudible] Carpenter Quality of Life Scale from baseline to week 28. Please note that aside from [inaudible] there are currently no other comparative studies with Abilify Maintena and branded atypical LEIs.

Now switching over to Rexulti, Rexulti is an atypical antipsychotic indicated for use as an adjunctive therapy to antidepressants for the treatment of major depressive disorder or MDD and the treatment of schizophrenia. There are four registration and double blinded placebo controlled studies assessing the efficacy and safety of Rexulti in these indications and these are fully described for you in the prescribing information. In [inaudible] please take note of the boxed warnings for Abilify Maintena and Rexulti which include increased mortality in [inaudible] patients with dementia related psychosis and for Rexulti only

suicidal thoughts and behaviors in children, adolescents and young adults.

In closing, Otsuka respectfully asks that Abilify Maintena continue to remain available to patients in Washington with the same access that they have received to date. We also request that Rexulti be included on the preferred drug list in line with our support for open access. Thank you so much for your time.

Michael Johnson: Thank you. Any questions? All right. Thank you. Next up is Paul Thompson and then followed by Raymond Morrow.

Paul Thompson: Hello and thank you for letting me [inaudible] testimony today. My name is Paul Thompson, PharmD. I'm the director of pharmacy for Navos Mental Health. Navos Mental Health is a large behavioral health center in King County providing inpatient, outpatient, residential, as well as outreach programs for patients suffering from mental illnesses. We heavily rely on our effectiveness by the access this committee grants around second generation antipsychotics. I'm here to advocate, as well as request the committee to consider to maintain open access for these second generation antipsychotics. OHSU's review is unprecedented, gold standard and definitely applicable at the level of caring for our patients. However, we also do know that with any meta-analysis population-based data the limitation really hits the clinician at the point of care when you have an individual with a unique and complex set of symptoms that may have a pyridoxal effect regardless of the population data. I'm here to represent my entire medical staff, inpatient, outpatient, nursing, case management, and peer bridges in trying to keep all the dots connected with our patients, the cost of continuum of cares and barriers added to the second generation antipsychotics both oral and long-acting are going to be yet another barrier for us to be able to contribute our effective, compassionate, and quality care for our patients that we serve.

In closing it's really our patients that are ultimately going to get the consequences of these restrictions. Our providers are extremely maxed with going through the current restrictions that we are within the managed care environments that the formulary gets carried through and by adding more restrictions could ultimately result in five different

processes and methods that my providers have to walk through to continue access for our patients of these medications. And every patient is different. These long-acting injectables serve valuable but benefits each individually. Clinically aside even on the… whether it's a two-week, four-week, six-week, three-month patient visit sometimes those are the lifestyles that we have to consider with our patients and when we actually can see them pending that they actually make their appointments. I do want to just… just in closing I do want to reiterate that open access is extremely vital for us… for Navos Mental Health and what we do to continue delivering the effective and compassionate care and the quality of ensuring patients don't get rehospitalized and hit that ground zero and have to start all over again. Thank you.

Michael Johnson: Thank you. Next up is Raymond Morrow. This is our last stakeholder for this topic.

Raymond Marrow: I just want to say good morning to everyone and thank you for allowing me to speak. My name is Raymond Marrow. I'm the director of operations for the western region for Genua a QOL health care company. We are a pharmacist services company that specializes in behavioral health. All of our pharmacies across the country are located on the campuses of pay-for-health facilities. We have 340 pharmacies in 44 states. So behavioral health is what we do. I've been practicing pharmacy for 35 years. I've been in the trenches. I know about pharmacy services and I know and care about the patients and outcomes. Everything that we do has to be about outcomes. It's just that simple. And then behavioral health it all starts with adherence and compliance. When we have hurdles and barriers, we don't have uniformity in formularies it makes it difficult for us to do our jobs. When you have fee-for-service and you have five managed care plans and you don't have uniformity or simplicity we can't take care of our patients and that's what it is all about. We just want to take care of our patients. We want to keep them out of the hospitals. We want to keep them off the streets. We want to take care of them. It's a brittle group. When a patient comes into my pharmacy or into a doctor's office we don't want to ask, "What plan are you on," before we decide how we are going to approach treatment. We shouldn't have to ask what plan are you on before we decide how we are going to approach treatment. We have to have

uniformity. We have to have simplicity, access to a second generation. We have to have access to the long-term injectables. We have a client who walks in and they won't take their meds. They just won't take them. They won't take their pills. You have to do the long-term injectables. If we have a patient who is in the ACT program or PAC program, they are homeless, we have to go find them. We have to put them on a long-term injectable. We have to have access, guys. So when you look at this and you are talking about this formulary and you're talking about the decisions you want to make, we need uniformity. We need simplicity and we need access. This is all about outcomes. Thank you.

Michael Johnson: Thank you. Any questions? Marian, are you still there?

Marian McDonagh: Yes, I am.

Michael Johnson: Any comments on your part?

Marian McDonagh: I don't think so. I think everything sounded consistent with what we were presenting.

Michael Johnson: Exactly. All right. Thank you.

Dale Sanderson: I have a question on the report. A lot of my patients with the newer second generation antipsychotics have tolerability issues in terms of akathisia and restless and activation. A lot of the side effect profiles that are listed for these medications list those separately, but they are very similar symptoms and they create a significant problem for a number of my patients in terms of the tolerability. Was that something that you looked at or saw in your report at all?

Marian McDonagh: Well, yeah. Yes, and there's two ways we look at. One is certainly just looking at the reports of either EPS or akathisia separately. And then also sort of the over-arching, are they able to stay on the medication? Or do they withdraw due to an adverse event? So that was the purpose of that network meta-analysis to look at more globally. Can people stay on the medication? And so we didn't see a lot of differences there except for the long-acting injectable risperidone before being a little bit better. But for the individual reports it becomes very confusing in terms of how the

things are reported from study to study. If you look across the studies even with the newer medications you just don't see big differences. You don't see a winner and I think it's easy to show a difference when you're comparing the drug to placebo, but when they are compared to each other the difference is just sort of… it's one study might find a small difference and the next two find no difference at all. So it gets muddy very fast with the EPS adverse events in particular.

Dale Sanderson: Yeah, one of my concerns though is that these side effects, which are very, very similar, are divided into separate categories. So if you're looking at just akathisia, you know, you are comparing something compared to somebody who has activation, restlessness, akathisia, as well. It's difficult to compare these medications.

Marian McDonagh: Right. And that is because… in part because of the way that things are stratified differently from study to study. Is that what you're…

Dale Sanderson: Yes.

Marian McDonagh: Yeah, I agree completely and I think over time too we've been reviewing this class for over 10 years and I think the way people are reporting those side effects in particular has shifted over the years where now akathisia is separated out sometimes and sometimes it is lumped in with other things and you know, five or eight years ago it would have definitely not been separated out in this way. So it makes it very, very difficult to compare all the evidence even across the years. So the newer drugs, in particular, are hard to compare to the older drugs then. So, yes, I agree. It's very… not simple.

Dale Sanderson: And it does seem like, you know, some of the newer second generation products are… that are less metabolically at risk seem to have a greater emphasis like on the restlessness and akathisia.

Marian McDonagh: Uh huh. Some of them are. It does seem like that, yeah. And again we always… because the… it's one group second generation but they are actually two or three groups within that. Some of these other… it's very difficult then to try and group them and we try in the report to do that, but then we try to look at the over-arching issues about persistence. You

know? Which of the drugs are people able to make it and others they are not.

Dale Sanderson: Thank you.

Marian McDonagh: Yep.

Michael Johnson: Any other questions from the committee? Okay. Thank you, Marian.

Marian McDonagh: Okay. Thanks.

Michael Johnson: We'll start looking at the business at hand here.

Dale Sanderson: I have a question on the very end of this about pregnancy. We're moving away from category As, category Bs. Do we need that in there at all or is there some other way of framing that?

Susan Rowe: We've looked at this, you know, from a teaching standpoint. Yes, we are moving away from A and B. Um, it's fairly convenient right now. The new classification goes to look at the actual evidence and not having it right in front of me it's more evidence indicates compatible with pregnancy. You know more than me that with pregnancy, especially for bipolar, sometimes olanzapine is just sort of a lifesaver to get women through pregnancy safely. So I think it's a really good point. I just am not quite sure what to substitute it with.

Mason Bowman: Yeah, the stakeholders today discussing Latuda still list it and it's mentioned a category B. So I know some of these drugs are not… are phasing into that review and I don't know if those stakeholders want to comment on that if we can give them just a moment. Is that appropriate to do?

Lyle Laird: We retained the pregnancy category A, B, C, etc. only for the sake of the usage as it stands right now. But we realize it's going to change and it is changing as you said to this more descriptive format and more human-based format because the former categories included a lot of animal data too and I think the new categories will be more human based. But just for the sake of, you know, recognizing the pregnancy categories we kept

saying what it is and this drug, lurasidone, is a category B at this point. That was the only reason it is not… that we won't change it as we have to. With the new label it will be changed.

Donna Sullivan: Could you please state your name just for the record?

Lyle Laird: Lyle Laird.

Donna Sullivan: Thank you. I think what would be better because the A, B, C categories are going to be phased out of the labels. If you want a drug that is… where the evidence shows that it is likely to be safe for use in pregnancy than I suggest you say that. Because otherwise we, you know, we get pigeon-holed into what you tell us to do to try and find a B and might be picking a drug that, you know, only because it says it is B it is preferred where other drugs that are just as safe in pregnancy, but because they don't have a B on their label they're not held in that safe fashion. So I would just say that, you know, we make sure that we have a drug that is… where the evidence supports safe use in pregnant women.

Michael Johnson: Thank you.

Lyle Laird: You bet.

Susan Rowe: I think that's a great suggestion. I think we can use it going forward. Some companies have had pregnancy registries, some have not, and so that's, you know, I don't know if that goes into… I mean in my practice I flip open Briggs and look at the rating and then if I need to look further then I start calling for pregnancy registries.

Michael Johnson: I think with the new labeling it will soon be available in the new package inserts updated. So I think just saying safe in pregnancy is the best. Any other comments on that?

Man: I think just a generic comment about actually considering the implications like on the risk in pregnancy would be reasonable.

Amber Figueroa: I'd like to make a motion after considering the evidence of safety, efficacy and special populations for the treatment of schizophrenia and bipolar

disorder in adults and children, major depressive disorder in adults, and children and adolescents with autism spectrum disorder or disruptive behavior disorders, I move that all routes of administration for aripiprazole, asenapine, clozapine, iloperidone, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, ziprasidone, brexpiprazole, and cariprazine are efficacious for their approved FDA indications and should be preferred on the Washington preferred drug list. Second generation antipsychotics cannot be subject to therapeutic interchange in the Washington preferred drug list. The preferred drug list should include at least one medication that is considered safe in pregnancy.

Eric Harvey: I'll second.

Po Karczewski: We have an N in front of clozapine.

Michael Johnson: All right. We have a motion on the table. Any other comments?

Amber Figueroa: Can you take the last two lines off?

Donna Sullivan: I was just about to take out that sentence.

Amber Figueroa: Okay.

Michael Johnson: This is the motion pending. All in favor say aye.

Group: Aye.

Michael Johnson: All opposed same sign. All right. The motion carries.

Man: As someone who prescribes these drugs on a regular basis even though population studies find fewer differences between them, you know, individual differences is remarkable how patients with seemingly similar drugs can have very different like responses and tolerability issues.

Michael Johnson: Are we ahead of schedule?

Donna Sullivan: We are ahead of schedule. We're trying to reach the next speaker to see if he's able to join us early. So maybe take a five-minute break while Leta is reaching out.

Michael Johnson: Okay. Five minutes.

Ian Blazina: Hello. This is Ian Blazina with the Oregon EPC. I believe I'm the next speaker.

Donna Sullivan: Ian, are you on? Okay. We actually do have him.

Michael Johnson: Revoke that break. Ian, this is Michael Johnson. We are going to get your slides up.

Ian Blazina: Okay. I also have a question before we started. The request for the presentation asked for scan number 1 from 2015, but there is a more recent scan, number 2, from this month. So I just wanted to clarify which presentation you would like to hear?

Donna Sullivan: We should be… it looks like we have the one from 2015, unfortunately, in the binder, not the updated one.

Ian Blazina: Okay. So you'd like to hear the 2015 version?

Donna Sullivan: Hang on just a second. The committee… it looks like we kind of did a little snafu on which scan we included in the binder. We included an older scan accidentally. So do you want to hear the information on the newer scan knowing that you don't have the slides in front of you?

Michael Johnson: Yes.

Donna Sullivan: Okay. Ian, yes, let's please go with the 2016 scan, but just please remember we don't have those slides in front of us. So try to be explicit with your comments.

Ian Blazina: Okay. I have both slide sets in front of me so I will try to mirror information that is missing from what you see.

Woman: So would you like us to put up the slides from 2015 then?

Ian Blazina: Um…

Donna Sullivan: Okay. Ian, go ahead.

Ian Blazina: All right. Um, so this is the preliminary scan number 2 for the long-acting opioid analgesics in December 2016. The last report was update number 7 in September of 2015. Next slide.

As I said the last report was September 2015 with searches through March 2015 and the last scan was scan number 1 in December 2015. The current scan runs from searches for October 2015 through November 16, 2016. Next slide.

The included population was adults with chronic non-cancer pain and we excluded cancer patients and patients who are HIV positive. Next slide.

This is just a list of the included drugs, which I will not read. Next slide.

The current scan identified several new formulations. One of oxycodone and naltrexone, which the brand name is Troxyca ER. Oxycodone extended release Xtampza ER and buprenorphine Belbuca and the previous scan identified MorphaBond extended release, which is an extended release morphine sulfate. Next slide.

The current and previous scans did not identify any new serious harms or boxed warnings. The current scan identified one comparative effectiveness review from Catith(?) and the previous scan had identified an AHRQ/NIH review. Next slide.

So we have in this current scan we identified one potentially relevant head-to-head trial. There were none identified in the previous scan. The previous scan identified one active control trial and we identified no new active control trials in the current scan. The slide set does not have the information. The head-to-head trial that we identified is from 2015. It was a 12-week trial of 453 patients compared oxycodone naloxone to oxycodone and also two morphine. The active control trial was a long-

acting versus short-acting. So it was long-acting dihydrocodeine versus short-acting dihydrocodeine and it was an eight-week trial with 60 patients. Next slide.

So since the last full report we identified four new drug formulations, three in this scan. We identified two comparative effectiveness reviews. One new in this scan and there are a total of two trials, one head-to-head trial, which was identified in this scan and one active control long-acting versus short-acting trial, which was identified in the previous scan. And that's all I have. Are there any questions?

Michael Johnson: Any questions? It doesn't look like there are any questions. All right. Thank you.

Ian Blazina: You're welcome.

Michael Johnson: I guess you're free to go. There are no stakeholders signed up for this. We'll look at the motion. I make a motion that we accept this scan as adequate.

Mason Bowman: I second.

Michael Johnson: All in favor say aye.

Group: Aye.

Michael Johnson: All opposed same sign. All right.

Eric Harvey: I'd like to reiterate the prior motion.

Susan Rowe: I'll second.

Michael Johnson: All in favor say aye.

Group: Aye.

Michael Johnson: All opposed same sign. All right the motion carries.

Amber Figueroa: Since we were going on the 2016 and he included a couple other drugs, didn't he?

Donna Sullivan: This is a scan so even though there are new drugs identified they are not eligible to be preferred.

Amber Figueroa: Thank you.

Donna Sullivan: You're welcome.

Woman: Let's take the break now.

Michael Johnson: Okay. We're going to take a break at this time. We're ahead of schedule. What time do you want to… okay, a 15-minute break.

Welcome back from the break. Rebecca, we'll just take a second to get your slides up and then I'll let you know when we are ready.

Rebecca Holmes: Sounds good.

Michael Johnson: Okay. We're ready.

Rebecca Holmes: This long-acting insulin scan was finished in September 2016. Next slide.

The original report for this topic was finished in September 2015. The last… this is the first scan since that report and the searches for this scan went through August of 2016. There is also an update report underway with a draft due in April. Next slide.

These are the drugs included in this scan, the ones that are underlined are new since the 2015 report. Next slide.

We're included both adults and children with type 1 or type 2 diabetes. So type 2 in children, as well including both long-term health outcomes and glycemic control, hemoglobin A1c and fasting plasma glucose and harms include nocturnal hypoglycemia. Next slide.

Again, several new drugs since the last report. The two versions of insulin degludec, Tresiba and Ryzodeg combined with insulin as part were approved just after the last report was finished and then there's this follow on drug Lantus insulin glargine or Basaglar and that was approved at the end of last year. There was also one other drug in development that we had been following, [inaudible], which was discontinued in December 2015. Next slide.

We found no new populations, boxed warnings or reviews for this scan. Next slide.

But we did find a fair number of trials. There were 21 head-to-head trials and 20 publications and almost all of those were of the drugs, just one included only the old drugs. And there were also 7 secondary publications, again, almost all of those were in the new drugs. Next slide.

So this is just some detail on those head-to-head trials. This is in type 1 diabetes, comparisons of degludec to detemir, degludec to glargine. Next slide.

Type 1 and type 2… there is one trial on here that we wouldn't now be including; at the bottom Dual V includes a fixed dose combination of degludec/liraglutide which DERP participants asked us to exclude the combinations with GLP1 agonists. Next slide.

And just the end of those 20 trials. Next slide.

So in summary three new drugs approved since the September 2015 report, two versions of degludec, and the glargine [inaudible], 20 head-to-head trials of the drugs, one of the old drugs, and 6 secondary publications of the new drugs, one of the older drugs. So that's what I have for the scan. I'd be glad to take any questions.

Michael Johnson: Any questions from the committee? One question.

Dale Sanderson: Is there any issue in terms of the stability of the insulin since a lot of these are carried in travel settings. Was there any difference between

the long-acting insulins in terms of their stability and need to be refrigerated?

Rebecca Holmes: I don't have that information from just looking at the scan. I'm not sure it is something that we looked at in the reports as well. I could find out if that is something that the participants might be interested in knowing about.

Dale Sanderson: Thank you.

Susan Rowe: Dale, I think they are all considered stable for a month at room temperature although the degludec is a little bit longer than 28 days. I think it's just… in travel it's just for patients to keep them away from extremes.

Michael Johnson: Any other questions for Rebecca? Thank you Rebecca. There are no stakeholders for this class. Oh there was? You didn't sign up. Okay. When you come up to the front I'll just have you state your name and who you represent.

Anthony Hoovler: My name is Anthony Hoovler. I'm a medical doctor and I'm representing Novo Nordisk. I'd be happy to address the question first about stability. There is a difference among the insulins. The longest is 56 days, which is Tresiba, Levemir and Toujeo are 42 days, and the others are much less.

Today I'd like to share some highlights with you regarding Tresiba. Tresiba is a long-acting basal insulin analogue and was first approved in September of 2015 to improve glycemic control in adults with diabetes. However, this week the FDA approved an expanded label for Tresiba and it's now indicated to improve glycemic control in patients with type 1 and type 2 diabetes from age one year to adulthood and that's the only basal insulin approved for both type 1 and type 2 diabetes from that age category.

As with other insulins hypoglycemia is the most common adverse reaction of Tresiba. For other safety information I would refer you to the PI. In regards to efficacy there are 10 head-to-head clinical trials in the PI. Tresiba is compared to Lantus in 7 of those trials, Levemir in 2, and

Januvia in 1 and all of the head-to-head studies comparing Tresiba to other insulin analogues, Tresiba met the primary objective of non-inferiority in regard to A1c reduction. In addition, a statistically similar percentage of adult patients on Tresiba versus comparator was achieved in A1c of less than 7%. So in addition to the expanded indications I mentioned there are many characteristics that make Tresiba unique among the basal class. It has a half-life of 25 hours, a duration of action of at least 42 hours, and both of those are the longest within the basal class. It's administered once a day, but unlike other once daily basal insulin analogues, which by label must be administered at the same time every day, Tresiba can be administered at any time of the day. It comes in U100 and U200 formulations, both in a flex touch pen, which looks like this. The flex touch pen U100 can give 1 to 80 units in a single injections. The U200 pen can provide 2 to 160 units in a single injection and that option to provide up to 160 units is unique for Tresiba. The U100 and U200 formulations are bioequivalent so there is no requirement to do dose conversions between the pens.

As far as starting doses for insulin naïve patients is outlined in the PI, but for patients already on insulin, adult patients, it's a simple one-to-one basal conversion. For pediatric patients it's recommended to start Tresiba 80% of the total long or intermediate acting daily dose to minimize the risk of hypoglycemia. After being opened, as I mentioned before, it's good for 56 days, which is two weeks longer than any other insulin.

So with this data that I've presented including several of the characteristics that set Tresiba apart, including this new label indication just this week, I would respectfully request that you add Tresiba as an option on our preferred drug list. I'd be happy to entertain any other questions you have.

Dale Sanderson: What steps did you take to safeguard people confusing the U100 and U200? It seems like that would be a significant concern.

Anthony Hoovler: It is and that's a very good question. If you look at the pens, and I have a U100 and U200 demo pen here [inaudible – stepped away from the microphone] is the dose that you get. This is the U200 and this is the

U100 [inaudible – stepped away from the microphone] and you'll find that a lot of the newer insulins are coming in pen only.

Mason Bowman: I had a couple questions. So just to clarify, so if someone is going from Lantus to Tresiba, I want to make sure I heard correctly, you reduce the dose by 20%? Is that true? Or just go straight across?

Anthony Hoovler: In adult patients the label says one to one basal conversation.

Mason Bowman: Okay. But for kids you go…

Anthony Hoovler: For kids it is 80%.

Mason Bowman: Okay. And then secondly there's quite a few patients who, for instance may have been on a Lantus SoloStar pen and so they have all these needles and when we make a switch are those needles compatible?

Anthony Hoovler: Generally they are, yes. Yes.

Mason Bowman: Okay.

Michael Johnson: Thank you.

Anthony Hoovler: Thank you.

Michael Johnson: Do we need Rebecca on the line? You're free to go, Rebecca. Thank you.

Rebecca Holmes: Thanks a lot.

Eric Harvey: I will move to accept the scan.

Michael Johnson: All those in favor say aye.

Group: Aye.

Michael Johnson: All opposed same sign. Great.

Susan Rowe: I do have a question though. Looking at… the drugs we're not able to include… so the Basaglar and the degludec.

Donna Sullivan: We looked at the approval process for Basaglar and it's not… it went through a system similar to a generic, but it's not considered a generic for Lantus, so for our purposes the Basaglar insulin glargine has already been reviewed. It is the Tresiba and the Ryzodeg that are… because this is a scan the insulin degludec has not been included in a full update.

Christine Klingel: I move to reiterate the prior motion.

Michael Johnson: We did the scan.

Susan Rowe: Sorry.

Mason Bowman: I second.

Michael Johnson: I think we have to read this first. Do we have to read it?

Donna Sullivan: You don't have to read it.

Michael Johnson: Okay. All in favor say aye.

Group: Aye.

Michael Johnson: All opposed same sign. All right. It carries.

Woman: Brittany?

Brittany Holzhammer: Hello. This is Brittany. Can you hear me?

Woman: Yes.

Brittany Holzhammer: Great. Thank you so much. So I'll be presenting the sixth preliminary update scan report on Alzheimer's drugs. This was completed in October of this year. Next slide, please.

So to provide a little bit of history the last update report was update 1, which was completed in June of 2006 with searches through December of 2005. The last scan was scan 5, which was done in August 2014 and the date of searches for the current scan spanned June 2014 through September of this year. Next slide, please.

So this slide illustrates the interventions that were included in this scan. If you take a look you can see the stated drug is one we identified in this scan and we'll revisit this in just a second. Next slide, please.

So we included patients with Alzheimer's disease and for comparators we included any other Alzheimer medication that was listed on the previous slide, any combination of Alzheimer medications listed on the previous slide and also placebo. For study designs we included RTCs only with a sample size greater than or equal to 100 and then study duration greater than or equal to 12 weeks. Next slide, please.

So in this current scan we identified one new drug, which was a combination of the memantine/donepezil. This was approved in December 2014. In previous scans we identified one new drug and two new doses or formulations of existing drugs. The new drug was tacrine which was approved in May of 2012 and we found a new dose of rivastigmine and memantine also. Next slide, please.

So in this scan we identified no new populations, but in a previous scan we identified one new population for rivastigmine. This is the treatment of mild to moderate dementia associated with Parkinson's disease. Next slide, please.

So we've identified no new serious harms in this scan or previous scans, as well as no new comparative effectiveness reviews in this scan or previous scans. Next slide, please.

In terms of new evidence we've identified a total of six new potentially relevant head-to-head trials since the last report; two of which were identified in this scan. We've also identified 28 new potentially relevant placebo-controlled trials and 34 publications. Two of which in one publication were identified in this scan and since the last report we've

identified one new secondary analysis of trials that were previously included in the last report, but this was identified in the last scan. Next slide, please.

So this slide illustrates the new head-to-head trials that we've identified since the last report. You can see the two shaded trials are the two that we identified in this scan. One is a comparison of memantine and donepezil, rivastigmine and galantamine and the other comparing rivastigmine add-on to memantine add-on. Next slide, please.

So since the last update report we've identified one new drug combination in this scan and two new drug doses or formulations for rivastigmine and memantine. We've identified one new population for rivastigmine, six new head-to-head trials, two in this scan, and 28 placebo-controlled trials, two of which were in this scan as well. Any questions?

Michael Johnson: I don't see any questions. And there are no stakeholders signed up for this topic. Thank you.

Brittany Holzhammer: All right. Thank you.

Michael Johnson: Thank you.

Amber Figueroa: I'd like to move that we accept the scan as adequate.

Michael Johnson: I second that. All in favor say aye.

Group: Aye.

Michael Johnson: All not in favor same sign. All right. It passes. Okay.

Christine Klingel: I move to reiterate the prior motion.

Eric Harvey: I'll second.

Michael Johnson: All in favor say aye.

Group: Aye.

Michael Johnson: All not in favor same sign. Great. The motion passes. I think we have one more motion on the table?

Donna Sullivan: Yes. So the Alzheimer's drug class we're going to propose to archive meaning it hasn't been updated since 2010 and it doesn't look like it's going to be updated anytime soon. So Leta is pulling up the motion for archiving this class.

Susan Rowe: As combinations come alone with better composed of previously approved components are they included, not included?

Donna Sullivan: They'll be included, but they are not likely to become preferred because once they get a combination it's usually a branded product and the cost of it, unless the cost of the combination product was cheaper than taking both of the generic products in combination, it probably would not elevate to being a preferred drug.

Mason Bowman: So just to clarify, do we need to read this off or just…

Donna Sullivan: Yes, please read it.

Mason Bowman: All right. After considering the scan presented today I move to archive the following drug class from further regular review by the P&T Committee: Alzheimer's drugs dated 12/21/2016. 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 this drug class without additional committee approval so long as any resulting changes in the preferred status of a drug remain consistent with the committee's last motion for that drug class. The committee may review the archive status of a drug class upon its own initiative, or by request of the participating agencies at any time.

Susan Rowe: I'll second.

Michael Johnson: All in favor say aye.

Group: Aye.

Michael Johnson: All opposed same sign. Great. Okay. The motion passes.

So at this time we're going to adjourn the P&T Committee and then if we're ready we will convene the Drug Utilization Review Committee at this time.

Donna Sullivan: I'm just going to go over the current limitations that we have on the drug classes that we reviewed and provide recommendations for any changes that we are asking for. So the second generation antipsychotics is the first drug class and this just… this slide just lists all of the drugs that were reviewed and what their status was prior to today's motion. So based on the motion what will happen is the new products Aristada, Rexulti, will become reviewed. Versacloz was still not included in the OHSU review so it won't be considered eligible for preferred status, but the other two products will get changed once we announce the results from this meeting.

Here's just the rest of those medications. So also Invega Trinza will be added to the drug class review as preferred.

Second generation antipsychotics – the current limitations are we require continuation of therapy meaning that if a patient is already on one of the antipsychotics we can't… we will not require them to switch to a preferred antipsychotic. There's no therapeutic interchange. Previously and again reiterated by the committee today. We do require generics first so that they must try at least one preferred generic before they can try a preferred brand or a non-preferred brand. Antipsychotic duplication for patients under 18 years of age requires a second opinion. In the oral antipsychotics under 18 years requires a second opinion if they are outside of our current dose limits. With the injectable antipsychotics all injectables for kids under the age of 18 require a second opinion. We also require a prior authorization if the patient is 65 years or older just to make sure that the antipsychotic is not being used for sedation or dementia-related psychosis. And then we limit those… the injectable antipsychotics to their FDA maximum doses. And at this point in time patients must step through one preferred product before a non-

preferred product will be authorized. There is an exception to the second opinion process if the child is in crisis. So if the doctor writes on the prescription the child is in crisis or if the pharmacist feels that the prescription needs to be… or the medication needs to be dispensed immediately then it is approved for up to three months while we go through the second opinion process. So we won't stop… it's in the judgment of the… either the clinician or the dispensing pharmacist to make that judgment.

So here are the age dose limits. I'll just let you look at them for a few seconds. I'm not going to read through them all. They haven't changed since the last time that you have reviewed them.

Mason Bowman: Could you clarify or elaborate more about what the second opinion network entails and who is involved?

Donna Sullivan: We call it a second opinion network which is kind of a misnomer. At this point in time our second opinion provider is Seattle Children's. Their Department of Adolescent and Child Psychiatry, Dr. Hilt is the chair of that department and the child and adolescent psychiatrists that are within that department are kind of our network of providers that provide the case reviews. So what would happen is if a medication is flagged needing a second opinion we will request the chart notes and justification from the prescriber. The agency gathers that information and forwards it on to Seattle Children's and then Seattle Children's, one of their providers will review all of that information, and then set up an actual phone call with a prescribing provider. And once… on that phone call they will come to a consensus typically of what the treatment plan should be going forward and then once that phone call is completed then Seattle Children's will send the Health Care Authority back like a consultation note describing what was discussed and what was agreed upon and then we will make sure that the health plans enter that information into their systems or if the child is still on fee-for-service we'll make sure that it gets properly coded so that they can get those medications filled.

Mason Bowman: Thank you. What's the turnaround time typically for that process?

Donna Sullivan: It really depends on the provider's response back to Seattle Children's. Once they have the information from the provider, you know, Seattle Children's is trying to reach out to the doctor's office and the goal is within 48 hours, but often times the doctor is non-responsive or they don't ever respond and so some of these, you know, linger because the doctor… I don't know if they just choose not to participate in the second opinion and they change their prescribing to within our limits. So a lot of them just never get reviewed and we think it is because the prescriber's change their limits.

Mason Bowman: Thank you.

Christine Klingel: Do you have a sense, since this has been in effect since like 2013, right? The second opinion network or longer?

Donna Sullivan: It's actually been… the antipsychotics wasn't our first drug class, but I think it's been since 2006.

Christine Klingel: Do you have a sense of how many second opinions they have had to perform with this? Is this really common?

Donna Sullivan: Unfortunately, there are a lot. I don't know the number off the top of my head. I mean it was probably over 1,000. It's probably several thousand that they have reviewed in the course of the 10 years that we have been performing it. Because we have second opinions for antipsychotics, the ADHD medications, duplicate antidepressants. So it is polypharmacy like more than five psychotropic drugs. So they do all those second opinions. Specific to antipsychotics I don't know what that number would be.

So moving on our recommendation is really to continue the current age dose limits for children under 18 years of age, as well as the prior authorization requirements for injectable medications. We are recommending that… this is kind of a standardized recommendation that we are making for all drug classes. You are welcome to change it, but they must try all preferred drugs with the same indication before a non-preferred drug will be authorization unless the preferred drugs are contraindicated or not clinically appropriate. This doesn't have a significant impact with the antipsychotic class because you just made

them all preferred. So it will only be those drugs that are considered not reviewed that we'll have to step through the preferred products before the not reviewed drug would be approved. Unless, of course, it had a unique indication or it was contraindicated or not appropriate for that particular patient. And so we're recommending therapeutic interchange based on your motion which you did not allow therapeutic interchange so that will continue as directed in your motion.

Man: So you included in this list both long-acting routinely given antipsychotics, as well as more of the emergency ones, the intermuscular short-acting that would be used in the emergency room. Is there a… should these be in a different category?

Donna Sullivan: The traditional antipsychotics like haloperidol and things like that that you would use are not included in the second generation antipsychotic class. If a drug is administered in an emergency room it is bundled in the emergency room payment. It doesn't go through the pharmacy claims processing system. So there would be no impact on those medications.

Man: It's in the list here as, you know, ziprasidone IM, the Geodon IM, and the Zyprexa IM both would be just a single dose basically.

Donna Sullivan: And they are on the PDL just because we include the entire kind of product family on the PDL. So they are included as, you know, whatever their preferred status is, is what we mark them as.

So we did have stakeholders.

Michael Johnson: Yes, we have stakeholders for this. Again, when you get up to the microphone please introduce yourself. There is a three-minute limit. The first person is Bill Strayr.

Donna Sullivan: Bill is not here.

Michael Johnson: Okay. Next up is Lauren Simonds.

Donna Sullivan: Nope.

Michael Johnson: Okay. Paul Thompson. And then following him will be Kim Laubmeier.

Paul Thompson: Hello again. My name is Paul Thompson, director of pharmacy at Navos Mental Health out of King County. I did want to give our feedback from my perspective and my role regarding the bullet number two recommendation which was that all preferred drugs must be tried before a new agent could be considered. I feel that that's a very all-encompassing language that would consider a potential… I realize the purpose and the intent, but that purpose and intent gets flipped five different ways when this gets to the managed market place. Each one of those managed care companies that orchestrate the program will interpret that guidance, apply their unique variables and execute different processes that providers will have to go through to follow… to try to get the patient on the right medication.

In the end it is an extreme example, but with that language essentially a potential managed care company would make the patient try and fail 12 to 14 medications before a potentially newer, potentially novel mechanism or innovative new drug that came to the market that might have a potential value to a patient.

This language also would include that the patient would have to try and fail agents like clozapine, as well as olanzapine pamoate before they could go to a newer agent. I definitely want to thank the committee today for giving all current SGAs approved preferred status, but this does really impact down the road as new items and new opportunities and new things enter our marketplace that might prove value to our patients. Thank you.

Michael Johnson: Any questions? Thank you. Next up is Kim Laubmeier.

[inaudible]

Michael Johnson: Okay. Then the last up would be Raymond Morrow.

Raymond Morrow: Again, thank you. Again, I'm Raymond Morrow. I'm with Genova [inaudible] Health Care Company. I'm the director of operations for the western region. I'm just piggy backing Paul's comments. The wording to

try all of the preferred; I think it opens the door for these managed care plans to set… there's too many barriers for a prescriber and a pharmacist to deal with. When we're dealing with these five managed care plans, if you open up any door I'm telling you, these guys jump through it and they put barriers out there that you can't believe. Paul and I have been working closely with Donna in trying to police these plans a little bit. We have to spank them because they are going to try and put barriers in front of us that will not allow us to use the meds that we need to help our patients. So that wording needs to be brought down and addressed. The word "preferred" and "trial all" you can't have it. It's just… it's not going to allow us to practice. It's not going to allow us to really take care of our patients. The prescriber doesn't have the time to jump through all the different barriers to… to have a patient try five or six different meds, the side effects that can occur, we affect their lives dramatically. You know, they try one med, they have a side effect. They have to recover from that side effect. They try another med, it didn't work. They try another med, it doesn't work. We can't do that. That's not healthy and safe for the client. So we have to look at how we word things. We have to close the door to make sure these five managed care plans don't put all these barriers in place.

With these five plans I'm hoping that we are going to do a better job of holding them to try to stay close to what we are talking about today in this PDL. Again, we're constantly having to police these guys because they are all over the board. This plan won't cover this med. This month that plan won't cover this med or they want us to do a prior auth on this med. So when a patient comes into my pharmacy or into a doctor's office we don't have to want to be concerned about what plan they are on. We want to make sure that we have the freedom to take care of these clients. The long-acting injectables we have to have true access to that. And [inaudible], that opens the door for a lot of patients. We have patients who are in PAC(?) programs or homeless patients. Trying to track them down. If we could get them on Trinza and we would only have to give them a shot every 90 days. That's great.

Some of you guys, if you haven't studied Trinza and looked at it, look at what it does and how it changes the energy, a patient could miss his injection for 30 or 60 days and he'll still be stable on Trinza. So it allows

us to take care of a population or group that was a troubled group. People that we don't have access to, people that are homeless. We have to find them. So we got to make sure that with these five managed care plans that we can use that drug. And with these five plans some of them we can use Trinza and some of them we can't. Some of them you have to do prior auth after prior auth after prior auth to get it done. We're delaying health care for these clients. So let's just make sure when we word these things that we be careful and we don't open the doors for these five plans to do whatever they want to do.

Michael Johnson: Thank you. Questions from the committee?

Susan Rowe: I have a question for Donna. As we reviewed it we looked at current limitations and it says must step through one preferred product before a non-preferred will be authorized. And then as we look at the recommendation continue current limitations. But then the next one says all. So can you clarify?

Donna Sullivan: I think the recommendation to continue the current limitations was around the age dose limits and the prior authorization for the injectables for those 65 and older and those under 18, not the try one preferred before you try… I mean there are so many antipsychotics now. They are all preferred. Occasionally we get the new drug… the issue with the antipsychotics, which has always been kind of the discussion around these, is you don't know what drug is going to work. You don't know which side effects that they are going to get until you try it. And so the idea is to try, you know, the generics first was to try the cheapest one. The generics first legislation only allows us to require them to try one generic drug. It doesn't say, "Okay, if you start with risperidone then you need to go olanzapine or quetiapine or one of those." So it's really, you know, we don't know. There's no magic bullet to know which drug is going to work. There might be some indications based on its mechanism of action, but having a preferred drug list, what's the point of having a preferred drug list if you don't require them to try the preferred drugs before they get the non-preferred drugs. So that's kind of where we are moving. And just to remember there is always an exception process that, you know, if they can't take the preferred drugs there is a case-by-case

evaluation or consideration for those patients. That's kind of what the rationale is for the recommendation that we're going through.

Mason Bowman: So regarding these gentlemen's remarks, could you clarify a little bit… based on if we go forward with this wording how that is going to trickle down to those other managed care plans? Are they each going to have their own preferred?

Donna Sullivan: No. The managed care plans are required to follow our preferred drug list. It is contractually required. It can be challenging. The new injectable drugs, when they came out, because they weren't on our PDL, the long-acting injectables at first they put in prior authorization requirements. We, you know, then instructed them that they could not require prior authorization for those drugs. They could not require them to be filled only at specialty pharmacies. They had to allow retail fills and they had to have them allowed in the medical and the pharmacy benefit. I think the biggest challenge that we have with managed care plans is it's, you know, they have the pharmacy benefit manager, which is a separate entity from the managed care plan, and what we find is that the pharmacy benefit manager might make global changes to their PDL that are not supposed to impact the state managed care plan, but there is a problem and it does. It just causing all this cascading things until Raymond calls me and tells me that something is happening that shouldn't be happening and then we call the health plans and have them fix it. But it is an ongoing process to get the managed care plan, you know, to correctly program and administer this class of drugs. But once we do fix it… once we do identify it we work very hard to get it fixed. We have monthly meetings with the managed care plans and medical providers like Raymond and Paul and some of the other psychiatrists around the state so that we can talk about, you know, what's happening versus what's supposed to happen and how to best handle those situations.

Amber Figueroa: If the… I have to say that I don't agree with the recommendation of trying all preferred drugs because looking at what's preferred there are 10 that I circled. You know, a lot of these drugs are being prescribed by psychiatrists, which they may get some extra time with the patient, but in community health we're prescribing some of these drugs and we get 15 minutes with the patient. I don't have time to… I know that there are

channels, but kind of like you said about the second opinion thing, when you're at the end of the day and you want to go home to your family you choose the path of least resistance and so you will adjust your prescribing so that you can go home that night, instead of maybe what's best for the patient. So I think we do need to weigh… I agree that the purpose of a formulary is to watch cost and to at least try generics or preferreds, but I think having to work through, you know, five or six meds to be able to get… to try something is a bit much.

Donna Sullivan: And I do want to clarify that it would be… it's not formulation of each drug. So if they were… tried olanzapine they don't have to try all formulations of olanzapine. So it's really the active ingredient, not necessarily the different formulations. I just want to throw that out there that it is based on the ingredient. Dale, you had a question?

Dale Sanderson: To give you an example of a potential issue with this, so if you have someone who has significant metabolic issues, diabetes, lipids, weight issues, if you're asking us to put them on Zyprexa/olanzapine prior to one of the other more metabolically conservative drugs I mean that potentially is going to be harmful to the patient.

Donna Sullivan: Right now they are all going to be preferred. So we wouldn't be asking you to put them on Zyprexa or olanzapine before aripiprazole. I mean they are both generics. So generics first you get one or the other. Generics first is for the preferred brands. You have to try one of the preferred generics. For all of the brands then are preferred that were currently reviewed. So really the only ones that we're talking about are those few drugs that were not included in the OHSU review, which would be the new plazid(?) and the Versacloz, which is the clozapine solution. So those are the only two that would… you would have to use the preferred products before you go to the non-preferred product. So it's not that we're trying to make you do all preferred generics before you get to a preferred brand. It's you try one generic, that's generics first and then you can have a preferred brand. But for those non-preferred drugs you have to try the preferred generics and the preferred brands unless there's a contraindication or a clinical reason why those drugs wouldn't work. And it might be that if you've tried, you know, that clinical reason could be that you've tried that mechanism of action and you don't think

it will work. But that would just require a case-by-case review for those drugs that are not covered.

Dale Sanderson: Thanks for clarifying.

Po Karczewski: I share the concern about this requirement. I mean right now we're just locking out [inaudible] but we don't know what's going to be happening in the next couple of years in terms of other antipsychotics coming along. I agree with Dale that there are… olanzapine is so well known for weight gain as is quetiapine and quetiapine is considerably less antipsychotic action many of us feel. I understand generics first requires only one generic and so we can't alter that to like two or…

Donna Sullivan: The way that the statute reads, and it can be up to interpretation, it reads that for a patient's first course of therapy you can require a generic drug. So it's been interpreted by the state, meaning Health Care Authority, that the first… that the direction of a first course of therapy means the first course of therapy with an antipsychotic. Meaning that if they have already… if they try like risperidone then that's their first course of therapy and so the next course they can go right to a brand. You can question whether or not it's their first course of therapy with that drug that you're wanting to prescribe or with the class of drugs. So at this point in time we've had a broader policy that says it is only one. So that is how we have been implementing that.

Po Karczewski: So they couldn't go to a non-preferred brand. They would have to go to a preferred brand.

Donna Sullivan: Correct.

Po Karczewski: Right. Which kind of locks out…

Donna Sullivan: Chuck isn't here today but to be honest with you I might have misspoke on if they have had a generic they might be able to go to a non-preferred brand. Let me double check that. I don't know off the… I thought that they had to try a preferred, but I'm not 100% sure after I said that out loud.

Po Karczewski: It's so important that once you find something that actually works for a client and they will be adherent to it, it would be a shame if we didn't have the full spectrum to work with.

Donna Sullivan: And after they've already been on the drug, even the non-preferred drugs or non-covered drugs… or not reviewed drugs I should say, not covered, that was a mistake. But the not reviewed drugs if they have already been established on it, other than samples then we would continue that medication. Our policy on samples is Medicaid has no copay so there is absolutely no reason to give somebody samples.

[inaudible]

Donna Sullivan: It's the first… their first course of therapy with the second generation antipsychotic.

We're open for recommendations. You've said that you don't like trial all. Is it one? Is it five? Is it two? Is it three? That's up to you guys to make that decision.

Eric Harvey: I think because almost of them are preferred and we have so little information about who is going to respond to which drug I guess I don't feel as strongly that the wording in this last bullet here is really going to impact most people's decisions. I guess there is no crystal ball. You don't know what drug is going to work for a patient. So to say that it is going to be that one or two that's not preferred, it seems quite a stretch to me to sit here and say that.

Susan Rowe: I agree. Other disease states – if I have 10 drugs to choose from I'm really happy. I think given that there are so many choices in that first… that first choice and then… how likely is it that out of the… your clients… out of the 14 drugs that are available and then just 2 would require a prior authorization. Are you going to choose those?

Amber Figueroa: I'm just thinking of what that prior authorization would look like if you had to have tried all the preferred drugs. I'm going to have to sit down, look through their history, write down the dates of each one of those 10 drugs that they've used. If they're not totally psychotic in the moment

and can actually tell me when they've been on those meds, you know, it's going to require some research to actually prove that they've been on them. I'm just thinking of the time aspect that's involved if we do need one of those two drugs. I would go to some wording like two or three is my thought as a clinician. What do other people think?

Christine Klingel: So my only hesitate is clozapine. If we can somehow maybe single that one out because I know that one, you know, like there's no pharmacy in Wenatchee that actually dispenses clozapine. And so if they had to potentially step through and clozapine is not appropriate for a lot of patients that would be one I would maybe single out just for the monitoring and the availability of it. It is for resistant patients typically and so they probably are stepping through many of these before they get there, but if they had to step through clozapine before they got to Vraylar or one of the newer agents that might be an issue.

Po Karczewski: I'm just thinking that if somebody for instance tried Risperdal and they had some akathisia or EPS you certainly wouldn't want to try Latuda or one of the ones that more prone toward that. So that would be… I mean that would be a clinical reason not to do that, but it has been pointed out that the HMOs don't always make as much sense as the HCAs. I think… I'd be in favor of two or three as being a requirement because they are far from equal in their action. I mean quetiapine is good for sleep, but not really good for a lot of other psychotic processes. There's a lot of clinical decision making that goes along here and I think the idea of… I mean putting Clozaril to the side is kind of a no brainer. You certainly wouldn't be trying that with everybody, but I think there are some others that are just, you know, olanzapine on somebody who is overweight, as Dale pointed out, would certainly be contraindicated, but some of that is pretty hard to get across in a PA particularly to the HMOs.

Dale Sanderson: Just to… I know that it is difficult to use clozapine and the monitoring and all of that, but it is by far the drug of choice for treatment-resistant schizophrenia. I don't know how that fits into this scheme here, but there is… there is clozapine and then there is everything else when it comes to efficacy.

Donna Sullivan: I would suggest that we reserve that discussion to… if and when we ever talk about taking two or more antipsychotics at the same time.

Michael Johnson: Kind of what I see, you know, we have like 14 medications and this is kind of a for-instance. Let's say I had someone on three different medications and I've tried, you know, there are seven or eight more left, but if I had reasoning, you know, if I said, "Okay, they need this drug," and if I get this PA report I could say we've tried and failed these three preferred brands and here's why I'm choosing one that's not preferred. Would that be like an appropriate response? But it would only be if we didn't say "all".

Donna Sullivan: I'm hearing you guys talk about like if risperidone and they have akathisia. I don't know the mechanisms off the top of my head, but you wouldn't want to use Latuda. Would it be better to say that they have to try one of each category so that if they are in their… they have all their little subclasses that they try one of each subclass that you don't make them try, you know, three in the same subclass that you would expect to have maybe similar adverse effects versus…

Michael Johnson: Kind of what I've been sitting here thinking, if you look at that last sentence it says must try all preferred drugs with the same indication unless there are contraindications or intolerable adverse effects from previous similar medications. I would say something to that effect because then I would have a way out of choosing one of the other ones that I think is better from a clinical standpoint.

Amber Figueroa: But you're going to have to take the time to write that down.

Michael Johnson: Yeah, but if prescribe three I know what happened to those people on those three drugs. You know what I'm saying? I mean at least I wouldn't have to, you know, I could say here's why I'm going this route. They had effects with this, they had weight gain with that, you know what I'm saying? But just how to word that is what I'm struggling with.

Dale Sanderson: In terms of picking a number I know that for the clozapine it is recommended that you fail two antipsychotics before you go to clozapine. So perhaps that number has some [inaudible] to it.

Mason Bowman: I do want to put my two cents in, I guess. As we were talking initially, even before the discussion really began I was tripping up on this "try all" as well and I do know we have quite a few options. But I did kind of think, too like a two or three alternative would be a nice approach and give people some alternatives. At least it would satisfy in my opinion the HCAs recommendation and the statutes there, but also give providers the flexibility to move forward with something else if they feel they need to.

Michael Johnson: I'll ask Po what his…

Po Karczewski: I would move that we accept the above except for the last bullet. And I would alter that to be two…

Mason Bowman: Now would we want to… and I don't know, Donna, maybe you could clarify. What would this wording mean if we were to say something like must try one generic and then try a preferred brand before going onto a non-preferred drug to be approved or does it really… are we getting too deep into the weeds there? Or would this satisfy HCAs process?

Donna Sullivan: Based on the generics first you… like let's say I'm a brand new patient. I've never had any antipsychotic before and you want to try to prescribe Latuda. We would require you to step through a generic first. If you tried that generic and it wasn't working or you had an adverse event and then you wanted to go back to Latuda then Latuda would be covered. So that would be two. Then you would be able to get your not preferred or not reviewed drug after that. So that would be your two. So if you wanted to say, you know, you have to try at least one generic and then two others then that is three. So then you would have to say you need to try three.

Mason Bowman: I kind of like the last proposal trying to do a preferred generic and then stepping forward to preferred brands before authorizing a non-preferred drug or at least stepping forward to that [inaudible] process for that. For me I think it satisfies both ends of the spectrum of concern, in my opinion.

Donna Sullivan: So would you say that they need to try at least one generic and two preferred brands before getting a not preferred drug? Because we don't want to say, you know, they might want to try all the different generics.

Mason Bowman: In my thought process if… let's say the provider's intent is to try this non-preferred drug. I think for me that would be a proper step therapy process. Not necessarily pigeon-holing a provider to say they have to do this. They could easily go to a different generic if they wanted. Does that make sense?

Donna Sullivan: So are you saying… I think what you're trying… what the eventuality would be is that you want them to try three and one of those three has to be a generic. Because what you don't want to say… you really don't want to say that they have to try at least one generic and at least two brands because, you know, what if they've already tried three generics and you want to go to the not preferred drug? So you're kind of pigeon-holing into going to a brand as opposed to you've tried three of the generics and you really don't think the brands are going to work because of whatever and so you want to get this new drug or this not preferred drug. So I think what you're trying to say is that you must try three preferred drugs, one of which must be a generic.

Michael Johnson: We'd have to change that to three on that last…

Dale Sanderson: We also need to think about the fact that if we are having these different trials of drugs we're talking about weeks and months of someone who is not being controlled. You know? I think we have to think about the quality of life of the patient, as well.

Donna Sullivan: Isn't that what you do anyway? You try a drug. You put them on it for a few weeks. You see if it works. You switch to another one.

Dale Sanderson: If we're having all these different trials, you know, whatever we can do to help create stability as quick as possible is the goal.

Donna Sullivan: I mean if you think in your mind that this drug is the only drug that is going to work and you have a clinical rationale that you can support that you need the not preferred drug then you submit an authorization request and you plead your case. You don't, you know, start and just march through knowing that something's not going to work. I think that is where the disconnect is, is that the process is set up for a case-by-case

for you to try to justify clinically why these other ones can't work and if you can't justify that then you need to try the other ones. I think that's how, you know, medicine is practiced anyway because you don't know which one is going to work. So you have to pick one and you start them on that and you keep them on that until they start… they either get better, they start having adverse reactions, or it's clear it's not working. Then you pick another one. There is no crystal ball on which one is going to work.

Po Karczewski: Particularly given the number of medications that are preferred I think it's reasonable to phrase it this way.

Amber Figueroa: So I like the product so far. I'm thinking about the patient who just got discharged from Eastern, because I'm on that side of the state, or I had a patient a few months ago who was in jail so he lost his insurance because he was in jail for three months for doing something when he was psychotic. So he had been on meds while in jail and then he came out. So what would that look like to get him back on his previous meds? Is that considered continuation of therapy?

Donna Sullivan: Yes. So that would be considered continuation of therapy.

Amber Figueroa: Even though he didn't have insurance.

Donna Sullivan: Yes. If he's on it. That is one of the challenges that we have is the hospitals have their own preferred drug list and it was… like they will start a patient on an injectable and that has been a challenge, but we are working on it. If they are going to be discharged on an injectable, but we do require continuation of therapy.

Michael Johnson: Any further discussion on this? Are we satisfied with this? I'm going to make a proposal that we approve what we see on the screen at this time. Do I need to read this?

Donna Sullivan: Yeah. Sorry.

Michael Johnson: So I move that Medicaid Fee-for-Service Program implement the limitations for the second generation antipsychotics listed below.

Continuation of therapy required [inaudible] protected class RCW 69.41.190. Therapeutic interchange program based on the most recent P&T Committee motion. Antipsychotic duplication for under 18 years of age requires second opinion network review. Oral antipsychotics…

Donna Sullivan: These are supposed to be sub-bulleted.

Michael Johnson: Okay. So sub-bullet. Under 18 years of age require SON review if outside dose limits. Limitation recommendation by pediatric mental health work group and approved DUR Board. For injectable antipsychotics under 18 years of age require SON review. Over age 65 require a prior authorization to verify not being used for the treatment of dementia-related psychosis. Limited to FDA labeled maximum doses, generic first, and must try three preferred drugs, one of which must be a preferred generic with the same indication before a non-preferred drug will be authorized unless contraindicated or not clinically appropriate.

Amber Figueroa: The second bullet point should be say no therapeutic interchange based on what we said earlier today? Or do you want to leave it generic?

Donna Sullivan: That's to your…

Michael Johnson: So no therapeutic interchange program based on the most recent P&T Committee motion. Okay. Thanks for catching that.

Eric Harvey: I'll second.

Michael Johnson: All in favor say aye.

Group: Aye.

Michael Johnson: All opposed same sign. All right. Thank you.

Donna Sullivan: Whew! I really do appreciate your feedback in a discussion like this. I don't want anybody to think that we're just asking for a rubber stamp approval. So great discussion.

So long-acting insulin products. The Tresiba has not been reviewed. The Levemir is not preferred. We have insulin glargine, Lantus is our preferred product and then Basaglar and Toujeo although their insulin glargine prior to today's meeting they had not been considered reviewed, but they are now considered reviewed. So for the long-acting insulins the current limitations, which we just approved several meetings ago was… there's an expedited authorization code that allows patients that have type 1 diabetes to not have to go through an authorization process to get a long-acting insulin. So if the pharmacist enters that code when they process the claim then the insulin would pay as prescribed. For patients with type 2 diabetes that we… they have uncontrolled insulin… or uncontrolled glucose using another basal insulin such as a combination with regular or MPH then they have to try that combination for three months before we would approve a long-acting insulin. So we are moving toward… that is what was approved several months ago. And then for patients that have gestational diabetes they have to try that combination for at least one month before a long-acting insulin would be approved. They won't be approved if a patient is using exenatide or liraglutide or rosiglitazone or if there is another contraindication or hypersensitivity to the insulin products or one of their excipients. We do limit the doses, the amounts to 100 units per day except for Lantus because there's Toujeo which is insulin glargine, which is the not preferred product. It is 300 units per ml. So allow Latus to be used up to 300 units per day as well. And then again they must step through the preferred insulin product before a non-insulin product would be… or a non-preferred insulin product would be authorized. At this time Lantus is the only preferred long-acting insulin.

So our recommendation was to continue the current limitations which is to try the one preferred product before they can get a not preferred product and I don't remember what you guys said about therapeutic interchange off the top of my head.

[inaudible]

Donna Sullivan: Okay. So we'll move to the Word document that has… here's the motion.

Michael Johnson: I think we have one stakeholder.

Donna Sullivan: Oops. Sorry!

Michael Johnson: Dr. Anthony Hoovler?

Anthony Hoovler: Again, my name is Anthony Hoovler. I'm a medical doctor. I'm actually a board certified endocrinologist. I am licensed in Washington. I live on Bainbridge Island, but I work full-time for Nova Nordisk although I do see patients pro bono here in Washington as well. I just wanted to make a comments on the slide regarding long-acting insulin products. Your preferred product is not… does not have FDA label approval for type 2 diabetes in children. The only two that do are Levemir and Tresiba. And also the comments for long-acting insulins, the current limitations under the clause must not have concomitant use of exenatide by [inaudible] on liraglutide, [inaudible] or rosiglitazone. Liraglutide is also available as Victoza and there is a label indication to use Victoza and long-acting insulin. So I wanted to make sure that's clear. There is not an indication for [inaudible] so that is correct. That's all I had. Any questions?

Michael Johnson: Thank you.

Christine Klingel: I missed the meeting where this was originally enacted with the long-acting insulins and the limitations that they have to… it was only approved first for type 1 diabetics. I was looking at the reasoning why and I know in practice we have a lot of type 2 diabetics on the basal long-acting with their [inaudible] amino-acting and one thing that we've seen for patients who are kind of bouncing between managed care Medicaid and fee-for-service they've been on the long-acting and then get switched for a couple of months temporarily to the fee-for-service and then we've had to change their insulin regimens over to NPH and then all of a sudden they get put back on their managed care plan and then they're having to bounce around. So I've seen it for two or three patients since we've made that change. So it asks maybe we could put in an EA code that they've already been established on the long-acting just so they're not having to… because we've seen they've had to come in for extra appointments, for dosage estimates to try to… when they are switching to say to NPH injections versus the one long-acting. I think it

would help with their continuity so they're not being bounced depending on if they're fee-for-service for…

Donna Sullivan: That should not be happening. If that is happening then I'll make sure that it's not. We'll fix that. We had made the decision to grandfather people that were already on a long-acting insulin. So if they are being rejected then, you know, the conversation… if there's a prior authorization it should just be they are already on it. So we would just continue that care. So that shouldn't… they shouldn't have to… once you've established on it you shouldn't have to bounce back and try NPH. If that is happening I will make sure that we get it fixed.

Christine Klingel: Thank you for that.

Amber Figueroa: Do we need to include in the recommendation something about continuation of therapy since there's not anything in there?

Michael Johnson: I just have one question on continuation of therapy. We recently had an 18-year-old that was admitted to the hospital for DKA in the ICU. He was discharged on Lantus insulin. I guess they covered it for months. So now she's in the office and I have to switch her to NPH? I got this prior auth saying Lantus was covered for one month because she was in the hospital.

Donna Sullivan: Is that from fee-for-service or was that from the managed care plan? Because the managed care plans have their own criteria for long-acting insulins. This is just with the Fee-for-Service Program.

Michael Johnson: That might have been in the managed care. I'd have to look. If you're placed… that's technically type 1 diabetes. An 18-year-old who is DKA. So this should be covered then, right? Because looking at the expedited authorization that still should have been covered.

Donna Sullivan: If they were in fee-for-service, yes.

Michael Johnson: Okay.

Amber Figueroa: I do think the point brought up by the speaker we need to address that as far as Lantus is not FDA approved for children with type 1 diabetes.

Donna Sullivan: Just because it's not FDA approved for children doesn't mean that there's not evidence showing its use and support. I actually looked up on Micromedics and it might be type 1 diabetes, but it down to the age of 6 for type 1 diabetes. I don't know if there would be… Lantus is now off patent. There is no impetus for the manufacturer to go out and do, you know, try to get an FDA indication for that, but there is data out there supporting its use in kids just as there is a plethora of data of all of these long-acting insulins as being safe and efficacious in pregnant women.

Michael Johnson: At one point this was all we had and it was used this way off label.

Amber Figueroa: Just playing the devil's advocate do we want to encourage people to use things that are off label or not FDA approved for that? I'm not saying in this arena…

Donna Sullivan: If it is supported in the compendia then our… the realm of evidence that you are supported to be using is FDA labeled indication or supported in the compendia as safe and efficacious. So they are supported in the compendia.

Amber Figueroa: So what are we doing for the 3-year-olds?

Donna Sullivan: I would have to go back and look to see what… I was looking at the FDA indication, not the off label data supported. There's an FDA indication for type 1 down to age 6. I don't have the data down for… off the top of my head for younger than that.

Michael Johnson: Any other discussion on this? There's only one product so I would… I think what is on the screen is fairly reasonable. Do we need to read this again or does someone else want to read this?

Donna Sullivan: I'm sorry to interrupt. I know the stakeholder said something about deliriglutide in the [inaudible] that we might have that mislabeled. I will double check to make sure… double check the labeling on these and we'll put in the appropriate. If Victoza now has a label that it can be used with

long-acting insulin then we will allow it and I think there is a comma missing potentially there. We'll correct that according to what the actual drug interactions and contraindications are.

Mason Bowman: I don't have that reference in front of me to check, but I want to say that Victoza is for diabetes and I think [inaudible] was something to do with weight loss or something like that. I could be wrong. Off the top of my head I'm just trying to remember that.

Amber Figueroa: How do you guys feel about the dose limitation? 300 units? Is that… I mean I don't… I don't know the clinicians how much bad diabetes you guys managed. We have a nurse practitioner that does a lot of our really recalcitrant diabetes management. So I don't have any patients above that. As far as what you guys filling in pharmacies. Are you running into issues?

Donna Sullivan: I want to go back to why we did this. I mean the long-acting insulins, the argument for the long-acting insulins is that you could have once-a-day dosing. What was happening is we were seeing a lot of patients were using the long-acting insulins and doing twice-a-day dosing. So if the argument is the convenience and adherence of once-a-day dosing is why the long-acting insulins should be used, once you're doing more than one injection per day, you know, you could use the other insulins as well. The units per day was really to try to cut out that BID dosing.

Mason Bowman: I do manage diabetic patients in conjunction with providers at… in the setting at multi-care where I work. Some of the issues that patients run into with… and the reason why they have to go sometimes to twice a day is sometimes it's a volume issue. When they start getting… I've had frequent patients anywhere above 70 or so they start having tolerability issues. So some providers have then separated that just for a matter of convenience and then one other thing too is about the Lantus SoloStar pen is it only goes up to 80 units anyway. So if a patient has a higher dose they have to do a second injection anyway. So I think in some cases I think a 300 unit per day might help just reducing the volume per injection in those type of things.

Michael Johnson: I think we typically… they have to be on greater than 60. If they can't tolerate it then we divide it. Any other comments? So I think there is a proposal on the table to approve the motion that's on the screen. Does someone want to make that motion?

Susan Rowe: I'll second it. Or has it not been made? Let me read it. Let me get the classes on. I, Susan Rowe, move the medical Fee-for-Service Program implement the limitations for the long-acting insulin class listed below. An expedited authorization code for the diagnosis of type 1 diabetes mellitus continuation therapy for patients already using long-acting insulin. Uncontrolled as in hemoglobin A1c greater than 8 on another basal insulin regimen such as a combination of NPH with mealtime [inaudible] as a fast-acting insulin. Must try three months for a diagnosis of type 2 diabetes mellitus. Must try one for a diagnosis of gestational diabetes and may not have subject to research, concomitant use of exanatide or liraglutide or rosiglitazone or other contraindications that are hypersensitivity to insulin products or one of their excipients. Dosing limitations of 100 units per day except Lantus 300 units per day. Must step through all preferred long-acting insulin product before a non-preferred will be authorized. Therapeutic substitution is allowed based on the most recent P&T Committee motion, whatever that was.

Michael Johnson: Thank you for reading that. All in favor say aye.

Amber Figueroa: I second the motion.

Michael Johnson: I we didn't…

Amber Figueroa: I did now.

Michael Johnson: All in favor say aye.

Group: Aye.

Michael Johnson: All opposed same sign. All right. Thank you.

Donna Sullivan: We have the Alzheimer's. It's ten to 12. I don't know if you want to stop now and do lunch. The agenda has lunch scheduled for 12:20. Do we

want to continue with the Alzheimer's class and then do lunch after that? Okay. I see shaking heads. We'll move on.

Okay. Alzheimer's products. In the Alzheimer's products at this point in time the generics are all preferred and I think that's… just the generics are preferred on this particular class. Limitations – no therapeutic interchange based on your motion that you reiterated today. We require a prior authorization for kids 18 years and younger. These medications were being used in children for some autism and other behavioral problems that it popped up. So that's why we put that prior authorization on there. And then they must step through one preferred product before a non-preferred product will be authorized. We are recommending that we continue the PA for kids. That they try all preferred drugs with the same indication before a non-preferred drug will be authorized and then therapeutic interchange – no therapeutic interchange based on what you did earlier this morning. So, I move to our motion.

Mason Bowman: I move that the Medicaid Fee-for-Service Program implement the limitations for the Alzheimer's class listed below including no therapeutic interchange according to the most recent P&T Committee motion, to continue to require a prior authorization for children under 18 years of age, and that the patient's must try all preferred drugs with the same indication before a non-preferred drug will be authorized unless contraindicated or not clinically appropriate.

Michael Johnson: I second that motion. All in favor say aye.

Group: Aye.

Michael Johnson: All opposed same sign. Okay.

Donna Sullivan: Now I do want to break for lunch because there might be stakeholders for Vivitrol that are thinking that it's going to be after lunch. So I would like to be cognizant of that. Michael, we need to adjourn for lunch and reconvene at 1:00.

Michael Johnson: Okay. We are adjourned until 1:00.

Okay. I'd like to reconvene the Drug Utilization Review Board and we're going to start with the long-acting opioids. We're a little bit out of order.

Ryan Pistoresi: Thank you for the introduction. So we'll go ahead and get started with the long-acting opioid policy.

So as you remember from our October meeting we had previously talked about the short-acting opioids. I did not have the long-acting opioid criteria ready for you then. It is ready for you today. So you may recognize some similarities between this criteria and the previous criteria that was presented in October. So first, a bit of background. So as you all are probably very well aware of that Washington state and the rest of the United States is facing an opioid epidemic and one of the statistics from the DOH that I wanted to present to you is that there are approximately 700 deaths annually and it's been about this level for the past four or five years. So it has no longer continued to increase, but it has remained steady throughout this time and this is both prescription opioids and heroin overdoses, as well.

So on October 7th of this year Governor Jay Inslee signed executive order 1609 for state agencies to address the opioid crisis and one of the directives of this, or one of the goals of this executive order is to help prevent inappropriate opioid prescribing and to reduce opioid misuse and abuse in our state. This is one of the areas where we are trying to take our policy to address what's going on within Washington State. So the primary goal of this opioid criteria is to align our Health Care Authority opioid policies to be consistent with the 2015 AMDG guidelines and 2016 CDC opioid guidelines to reduce the amount of unnecessary opioids in the community. So that's what our focus is.

So the sources for this clinical policy are derived from a number of different clinical guidelines and other resources including the aforementioned CDC guidelines and AMDG guidelines. We also used criteria from the Canadian guidelines due to its high level of evidence and its supplementation to some of the areas that are not as complete in the CDC and AMDG guidelines. And we also used the American Pain Society

opioid guidelines for chronic, non-cancer pain, and also information from the Dr. Robert Bree Collaborative.

So just a quick overview of this presentation. We'll go over briefly what these guidelines actually said about initiating long-acting opioids. Then we'll transition into the expedited authorization for long-acting opioid for chronic pain conditions. And then lastly moving onto the prior authorization criteria for the long-acting opioids.

So to start the CDC, outlined in recommendation number 4, that one initiating opioid therapy for chronic pain. Clinicians should prescribe immediate release opioids instead of extended release opioids. Now one of the factors for this recommendation is that there was fair quality evidence that initiating with an extended release or long-acting opioid had a higher risk of overdose than when initiating with an immediate release opioid. And they also continued to say that there was not enough evidence to evaluate the safety of using immediate release opioids for breakthrough pain with extended release or long acting opioids for chronic pain and that they recommended avoiding the use of immediate release opioids in combination with extended release or long acting.

The AMDG guidelines have a similar recommendation in that they found that patients that were receiving long-acting opioids had a 2.5 fold increase on the risk of overdose when compared to those receiving short-acting for the unintentional overdose. And that's after adjusting for age, sex, opioid dose, and other characteristics. And that they recommended that when initiating long-acting opioids that the patient has been opioid tolerate and has been taking at least 60 MEDs daily for a week or longer. The Canadian recommendations recommend that for an opioid trial to select the most appropriate opioid trial and using a stepped approach and to consider safety. While it doesn't have it explicitly recommended here they were recommending immediate release and low abuse potential opioids to start.

Although this was not one of the guidelines, this was also a founder in the evidence review that the FDA had released an announcement on the safety labeling changes and post market study requirements for extended release and long-acting opioids back in 2013. One of the changes that

they were making is that for the daily around-the-clock long-term opioid treatment for which alternative treatment options are inadequate. So we can step ahead to slide 10.

This is the background for the expedited authorization criteria and these are for patients that have chronic medical conditions that will require daily, around-the-clock, long-term opioid treatment. And that they may receive these long-acting opioids without needing to go through a prior authorization. Two of the conditions that we identified here are those patients going active cancer treatment or they are at a hospice, palliative care, or end-of-life care.

With that we are on to the prior authorization criteria. This slide is actually a bit outdated. We've been continuing with our work on the short-acting opioids and would like to say that some of this information may not be the direction that we're continuing to move on forward with what we will be discussing at our January DUR meeting. We are looking at having the authorization criteria be for patients who have been on an immediate release opioid for at least seven days, but we are looking to step away from having the prior authorization for immediate release opioids at this time so that second bullet you can remove. The third bullet is also probably not applicable at this time. So you could likely remove the third bullet, as well. But the first and fourth bullets, the one that says that we are recommending that patients not be opioid naïve before starting a long-acting opioid, and that the prior authorization is to ensure that it is medically necessary are accurate for this slide. Thank you!

So the prior authorization on this slide we are also looking to change it from rather than simply being trial and failure of non-opioid medications and/or non-pharmacologic therapy to also include immediate release opioid therapies. So that way if patients have been on immediate release opioid therapies and do require daily around-the-clock long-term opioid treatment that they have tried non-opioid and opioid combinations to manage their pain prior.

The next slide is the in combination with appropriate non-opioid and non-pharmacologic therapies. And to have a baseline assessment of

measurement objective pain scores and function scores for which to demonstrate clinically meaningful benefit or opioid therapy.

The next slide is to have a complete screening for mental health, substance use disorder and naloxone use. And to inform the patient of urine drug screens in the future for the presence of opioid in the absence of other drugs pending the continuation of the long-acting opioid therapy.

On slide 16 is the requirement of checking the PDMP for current use of benzodiazepines and for reporting previous and new MEDs to ensure that they are within the MED guidelines recommended by the CDC.

On slide 17 is to have a comprehensive documentation of the pain condition and the patient's medical history and to evaluate the patient for history of diagnosis of or risk of abuse, addiction, or overdose for adverse events such as respiratory or cardiac distress or the use of sedatives or stimulants or other drug-drug interactions or contraindications and for use in special populations in case they have chronic kidney disease, COPD, or elderly or have sleep apnea as these conditions have shown to have more adverse events than the general population.

On slide 18 is to discuss with the patient realistic goals of pain management such as what is a reasonable and attainable goals for pain, function, adverse events and the general ups and downs of managing chronic, non-cancer pain. And to discuss the discontinuation as an option either if the medication is not producing positive health outcomes or if the patient can transition to non-opioid therapies or potentially immediate-release opioid therapy. Or if the patient is showing signs of substance abuse disorder.

After a signed pain contract that encompasses these requirements to ensure that the provider and patient understand the goals and expectations of this chronic, non-cancer pain therapy.

This slide… the justification for the extended release we've mentioned it previously that they've tried and failed an immediate release opioid so

this links back to what was shown on a previous slide, but to have that justification for why to step into an extended release rather than another immediate release. And then this we may not be looking at limiting it long-acting opioids to a seven-day supply or a three-day supply. But we will be looking at specific quantity level limits. So we anticipate that if prior authorization is approved that it would be for a month at a time or whatever the provider intends to do before follow-up.

So this slide is just a summary of all the different criteria that were mentioned on the previous slides. So it's here on one slide if you want to go back and review multiple criteria at a time. As I mentioned, some of these are a bit outdated since we have been evolving this policy in conjunction with our short-acting policy. So some of these may be outdated.

Moving on to slide 24 is a bit of a summary of an update of what has changed between the previous criteria that we just reviewed and what's more specific for the long-acting opioids and so this is just to document an inadequate response to the immediate release opioid therapy. The expected duration of treatment for both an IR and/or ER opioids and information on how the strength, dose and frequency of the immediate-release opioid would change, including what a new anticipated MED would be for that patient based on the anticipated use if they are going to continue with immediate release opioids for breakthrough pain.

As you probably are aware for this class we are looking for trial and failure of all preferred products prior to the approval of a non-preferred product and we are looking at a maximum of one unit per day for 24-hour formulations and a maximum of two units per day for all other oral formulations.

Slide 26 are various citations.

And on slide 27 is the end. I'm open for questions. Yes?

Dale Sanderson: Is there an established template for the pain contract that you recommend?

Ryan Pistoresi: Yeah. So the AMDG guidelines has a template that they can provide and we're looking at… if that would be reasonable for our patient population and for our providers, but if not we are looking at using that as a basis to develop a template that we can supply.

Dale Sanderson: You are developing?

Ryan Pistoresi: We can develop one. I know other health organizations have their own that they… okay… so we may point to the AMDG guidelines, but we won't be developing a template to provide, but we can point to one.

Dale Sanderson: Okay.

Amber Figueroa: On the units can you clarify what a unit is and maybe given me an example of what falls in those classes?

Ryan Pistoresi: Sure. What slide was that on?

Amber Figueroa: 25.

Ryan Pistoresi: Oh yeah, so a unit in this example is like a tablet or a capsule. So…

Amber Figueroa: So OxyContin tablets for the whole day? It doesn't matter the dose? Or the milligram?

Ryan Pistoresi: No.

Amber Figueroa: Just two a day?

Ryan Pistoresi: Yeah. Just two a day. Yes.

Susan Rowe: Would it be though, preferably within the CDC guidelines of not more than 90 MEDs?

Ryan Pistoresi: So that's a good point. That's what the guidelines are recommending, but for patients that have severe chronic pain that would require above 90 we do recommend a pain specialist consult, but we don't actually have that in the criteria here for that initiation of a long-acting opioid.

Amber Figueroa: I feel like something needs to be put in there because we hear the numbers thrown around all over the place with both Washington State legislation and then CDC and other organizations. Are we going to require that if it goes above a certain MED that they have a prior authorization or we're just going to assume that everyone is following the law and getting a pain consult or how does this document fit into the numbers that are being thrown away? Does my question make sense?

Donna Sullivan: At this point in time for the long-acting opioids we haven't really set a threshold of, you know, after this milligram you have to get a prior authorization. Not to say that we won't go there based on what the CDC and what the AMDG guidelines say, there's a big question about is it 90, is it 50, is it 120? So at this point in time we haven't put, you know, we're thinking quantity limits will help with that issue where if you, you know, if it's FDA approved for twice-a-day dosing you can have twice-a-day dosing. If it's supposed to be a once-a-day dose you can have a once-a-day dose. If you need… for like OxyContin if you need more than two per day then, you know, maybe you need to step up to the next higher strength to control your pain. I think that's how we are trying to manage that at this point in time.

Amber Figueroa: I think, as a prescriber, it's really nice to make you guys the bad guy and be able to say, "Well, I'm sorry. That's all that's covered." I mean potentially I could do a prior auth but at that point I would say, you know, I'm not willing to do a prior auth. I think you're good where you're at. I appreciate that you want to stay generic at this point, but at some point we may need to… because there's so many different doses and strengths of things that… and MED is the most widely accepted, I think.

Donna Sullivan: One of the challenges… and we looked at this when we were doing the immediate-release policy, it's nice to say 50 MEDs of opioids should be the maximum. The problem is that, you know, that means it's two pills for oxycodone, five pills for hydrocodone, one pill for this, one pill… it's not the same. So you would have to know which drug, what its conversion factor is in order to say what… how many pills you could prescribe. So we thought…

Amber Figueroa: We'd know that as prescribers.

Donna Sullivan: Okay. So we were thinking that that would be overly complicated to try to figure out on each particular medication… on oxycodone how many can I prescribe? On hydrocodone how many can I prescribe? So we were just trying to say, it's two. If it's a BID dose you can have two. For immediate release we're going with the five pills per day regardless of what that MED might be on a daily basis.

Ryan Pistoresi: So we did receive feedback previously, as you remember, in October we had that MED limit of 50, but we did receive feedback from others that they did not like that different limit of saying this is five of this or two of that or one of that. So that's why we were stepping away from that. It was based on feedback that we received between the October meeting and this meeting.

Amber Figueroa: We're all cognizant. I mean it's our licenses on the line. As far as I… speaking for myself, but I think most of my colleagues we're very aware of, you know, there's dosing calculators if you can't figure it out. I think the pill limit is fine, but I can already see the patients. As soon as they find out that their limit is five they are going to ask for the max dose or they are going to try and pay cash for anything above that. It's fine. I'm not nay-saying. I'm just giving some feedback.

Mason Bowman: On slide 14 what's the non-pharmacologic modalities that you guys are looking for? The criteria that you're going to be using?

Donna Sullivan: Physical therapy, occupational therapy, anything that would help improve the function of the patient that might not be drug related. And we do know, you know, we have some challenges and we admit we might not cover enough physical therapy appointments to make this ideal, but we are working on trying to change some of those other limitations that we have like acupuncture or more physical and things like that. That is something that we're trying to address and trying to kind of keep in line as we put more restrictions on the opioids.

Mason Bowman: We advocate too for patients to try exercise and those types of things. Is there any type of coverage for, aside from physical therapy, some type of

fitness type of things, you know, to allow the patient to have access to those facilities or programs that might be out there in the community?

Donna Sullivan: At this point in time, no, there's not. Not any assistance. I mean unless it is a privately-insured patient that has… there's possibly if they have a health savings account and the doctor writes a justification for like Weight Watchers, as an example. If you have a condition and weight loss is one of the treatments, the doctor can justify it and say, you know, they need to lose weight and then they can use their health savings account to pay for Weight Watchers. I'm not sure if there… I think there's something about health plans, but it has to be really where they can use their health savings account, but it is not something that is a covered benefit from the health plan itself.

Susan Rowe: Our physicians will write a letter so that patients can get… be considered for a reduced premium at the YMCA for things like the therapy pool for fibromyalgia and things like that. There's ways to get these things.

Christine Klingel: So from a clarification standpoint operationally, so if a patient now… if we approve this criteria would present at a pharmacy for a long-acting opioid. It would automatically have a prior authorization. No?

Donna Sullivan: We tried this in the past when we tried to put quantity limits on OxyContin after it had been on the market and we have lots of patients that are getting two, four, six pills per day. We have to make sure that we can handle that volume of disruption. So I think what we would do is make this for new starts on a long-acting opioid that we would look back, you know, so many days and if they haven't been on a long-acting opioid then this criteria would apply. Somebody who has already been on a long-acting opioid chronically would just get grandfathered in.

Christine Klingel: Thanks. So any new start then… going forward… so if they presented, had not had any previous supply in less than… or the seven-day supply in the previous 28 days, they would have a stop here, the physician or the provider prescriber would have to go through fill out all of the prior authorization with all of this information, then it would be approved, but only for the one for 24 hours, or two units for… okay. Got it. If they are a cancer patient or a hospice patient then there would be an EA code.

Donna Sullivan: Right. And then they can continue to get the immediate release filled if it takes, you know, several days or whatever to get all of that information for the doctor. They can continue on their immediate release. We're not going to stop that, but this is just for the long-acting that they have to go through this prior authorization process.

Christine Klingel: Thank you.

Mason Bowman: Let's say a medication like Norco that's gonna be considered in your view an immediate release formulation, right?

Ryan Pistoresi: That is correct.

Donna Sullivan: If you… we have it on the PDL the long-acting opioids, the class that we just reviewed. It only pertains to those medications. So all of the oxycodone immediate release, morphine immediate release, those are short-acting and they can get those.

Amber Figueroa: Again, trying to be real world. So if someone goes to Christine and wants to fill their prescription and you're going to kick back a form that we fill out or all of this should be documented in our note or… what are…

Donna Sullivan: The traditional prior authorization now is there is a form that will have check boxes off of it, but if we… the question is do we require supporting documentation? Do we require a copy of the pain contract? Do we require a copy of the pain and function evaluation? At this point in time I don't think we've gone that far to say, "Yes, you have to submit all this documentation versus fill out the form, check the boxes." Yeah. I mean part of this, you know, part of this is we are trying to establish best practice and then the question is, if we agree that this is the best practice then the question is, is it clinically important enough for us to stop the claim and ensure best practice is being followed versus just trying to be educational and assuming that providers are always doing this. That's kind of where we are at right now, but I think we will stop these claims and require at least the form to be filled out.

Amber Figueroa: I'm again just going back to that 15 minutes I get with the patient. I would say that all of this stuff is gone over with my patient, although probably not in one visit. I'm just kind of thinking how that would play out clinically, you know, obviously we don't ever start people on opioids expecting them to have chronic pain. Right? It's an acute issue and then it morphs into chronic.

Donna Sullivan: It doesn't necessarily mean that you would do all this in one visit. You have somebody that comes in and they have an acute pain issue and 30 days later they are still having pain, you would think that there are certain times where you've brought them back in, you've done more evaluation. So it's an iterative process for you even to decide, okay now this is going long-term that, you know, if you did an evaluation on the first day then it would be considered completed. It's not like anything that you did before you started prescribing the long-acting opioid wouldn't apply if you had already done a psychological evaluation or a pain and function test then that would all go towards that PA.

Ryan Pistoresi: Just lining up what the guidelines are saying that, you know, you don't want to start opioid naïve patients. They need to be at a certain MED level for a certain number of days. We're hoping that a lot of this can be taken care of prior to the initiation of the long-acting opioid so that way when you're saying, "Yes, this patient should be on a long-acting opioid because previously we've done this. I have the baseline assessment. I've done this screening before." So that way when you're at that step hopefully all of these things would have been taken care of. That's kind of our idea. We don't want this to be any type of major administrative burden. We're hoping that these have already been taken care of through the prior evaluations and through prior opioid therapy.

Amber Figueroa: I'm thinking of the time constraints. How long it takes to get into physical therapy and to… I mean do they need to have exhausted their visits or been through six weeks of physical therapy? I think that's probably at the discretion of the provider. But again it's like this continuum where, you know, when do you call it chronic pain? If they are using their five pills a day and it's not controlling their pain is that when you… I'm just talking out loud trying to help people who aren't in the room with the patient get a feel for… how overwhelming it is for a patient to deal with

everything and then the provider to kind of… it's not like you have acute pain and then you flip a switch and it's chronic pain. It's this long continuum of trying this, trying that. That doesn't work… where are we going to go with this? So it's the ongoing conversation with the patient. I appreciate what you're saying, Donna, that hopefully some of this stuff is already happening. If they are on an immediate release and they are continuing to fill I'm pulling the PMP, you know, making sure they're not getting it somewhere else. I probably wouldn't at the beginning be doing a urine drug screen although I know that's recommended.

Donna Sullivan: I'm not sure that we would require one, but again that's kind of like a best practice. You are doing one and we're not going to require the results. And to your point about the physical therapy, it's in combination with physical therapy. Maybe they need pain medication so they can go to physical therapy and actually do the work that they need to do because, you know, it hurts. That's part of what this is too. It's really trying to get that educational message out there that there are all of these other modalities that we need to use and that long-acting opioids, you know, were sold as the solution several years ago when they first started coming out and we kind of moved away from, you know, it's a lot easier to pop a pill than go to physical therapy. So we're just trying to make sure that those things that really show to improve function and reduce pain are being used to the extent that, you know, they are effective.

Amber Figueroa: I think there is probably not a way to do this, but I think it would be more productive to have it on the front end as a checklist that it hasn't to be attached to the prescription or something like that, because the patient is already gone by the time I get a kickback saying, "Oh, you're gonna need a prior auth. Have you talked to them about?" You know?

Donna Sullivan: There will be an educational component to the extent that we can, you know, if providers will read it. Dan and I… Dr. Lessler and I were kicking around ideas on opioids in general and is it… to… there's feedback from, you know, some of the professional associations that they don't like the concept of prior authorization and do we have community management versus prior authorization? We're in ongoing discussions with them as well. We don't have to agree on… we're not expecting you to approve

this this month if you don't feel comfortable doing it. That's why we have the special January session so we can keep talking about how to manage this problem that we're having with opioid-related overdoses. But Dan and I were kicking around, you know, should it be like the pharmacist? Maybe the pharmacist when they get the prescription they can go check the PDMP and make sure that they aren't taking other opioids or whatever and then the pharmacists… we are all rolling our eyes. Everybody is like make them do it. Is it becoming the standard of practice when you receive a prescription for an opioid that you are checking the PDMP before you dispense the new one to see if they're, you know, did they just pay cash for it across the street two days ago versus now they are getting a prescription filled and what happens when you do see that they are getting opioid prescriptions from two different providers? Maybe they are paying cash or not paying cash. That was part of the question we were saying is, you know, do we have the pharmacist attest that, you know, that the doctor said this? Our problem is that we don't get the form when the pharmacist submits the claim they can't submit a form with the claim. That's why we have some of those expedited authorization codes but then the pharmacist would have to be the one making sure that the form is filled out and checked. Who do you require to provide the information if we're going to go down this route? We're thinking about it and any recommendations or suggestions you have would be welcome.

Mason Bowman: I would advocate for more pharmacists to be in medical clinics to do that, but that's a different topic. I have been out of the dispensing arena for quite some time, but I do occasional fill-in work every once in a while. To put that, you know, it's not a standard of practice. Now if I have somebody come in and say, "Hey, I just want to pay cash for this," and it's a new patient to our pharmacy. We've never filled for them before. That's gonna raise some red flags. I'm gonna check. But if it is somebody routine, unless it is something out of the ordinary like a new dosing or something kind of different then maybe we would, but there's… the volumes are too high. I think that goes for the providers as well. One barrier on the pharmacist side is… so the provider is on the PMP. They have a multiple quarry search. They can put multiple patients in. Pharmacists are only allowed one search at a time. And so that is a hold up, especially if you have a few prescriptions you need to fill and you'd

like to check on everybody at once. It would make it a lot more streamlined, but until that happens that's going to be pretty difficult and pretty time-consuming and labor intensive. It does need to be done though.

Donna Sullivan: Are there any recommendations or changes or… I think we need to think about it, sit on, talk about it some more. Or do you think you're ready to move forward? It's up to you guys as the committee to make the decision on how we're going to move forward with this. Would you like… one thing we could try to do is package it all up into one—this is short-acting, this is long-acting, and this is how they interact with each other. We've treated them now like it's two separate policies just because it's trying to develop one and then the other. But there is a continuum. It starts with the short-acting that we're allowing and then kind of morphs into chronic. Maybe to your point, Amber, of when, you know, what constitutes chronic pain and when do you start considering that?

Amber Figueroa: I'm still thinking from a time aspect. When I've already spent my 15 or 30 minutes with a patient and then I get the kick back and have to fill this out; I just feel like if there was some way on the front to have the checklist, you know, something simple like if you're prescribing immediate release opioids more than five pills a day you must fill this out for every patient. You know? If you give this the doctor is not going to read it. If you give them two forms and say starting such and such a date if your patient… if you're prescribing more than five or these or more than two of these you have to fill this out. I think it's much easier than trying to fit it into your already packed lunch hour when you're trying to chart on all the other patients. What do you guys think? What are your thoughts on that? I just feel like… it's a huge education piece, like you said. I don't know how we get the word out so that everybody knows that starting this date you're going to need this. But I think the more we can do that ahead of time and before the prescription is written, the smoother the process is going to be.

Ryan Pistoresi: I'm not sure what everyone's electronic medical records systems are like, but an idea could be, you know, with alerts that come up that if you start prescribing this and before you send it, it prompts you with an alert and says have you done this? Have you done this? Have you done this? So

that way if you do get this type of authorization request you have made sure that you have already done it.

Susan Rowe: What you have laid out here is very consistent with the law the physicians have already… like you say you do these things along the way. The electronic medical record has a phenomenon called alert fatigue where people start ignoring them. And so I think, you know, I think if you implement it, it will not take long to learn to fill out the PA especially if it's an easy check box PA. Now what does happen, what can happen that I think actually prescribers do pay attention to is now we're starting to get PDLs, formularies loaded into the electronic medical record. And if it said on the long-acting PA I think people would pay attention to that a little bit more because that's happening at the time of prescribing and so then you know something is coming down the way.

Christine Klingel: Amber and I work in the same practice for full disclosure, but I don't know how many new starts I've seen in the past six months to a year, again, because you'd have to be a prescriber living under a rock to not know that there are definitely new guidelines, there's new evidence that support the evidence against using long-acting opioids. And so I think most prescribers are savvy enough and really I'm hoping are having these hard conversations with their patients that they are considering to put them on long-acting opioids in the first place. So I think the number of new starts is decreasing already and if these current patients are, who are on opioids, are not going to have to go through this prior authorization hopefully the paperwork burden will be less because there's not so many people starting on these. At least I hope. I see it in our practice and I hope it's occurring statewide, as well. So maybe that will help with some of that paperwork burden.

Eric Harvey: I do have to support completely what Amber said about trying to get those kind of questions upfront into the workflow instead of coming back around later and saying you have to answer all these other questions now that you wrote that prescription.

Donna Sullivan: Part of that problem is that you guys control your workflow. So I can give you a form for you to print out, but I can't change your workflow. You guys have to change your behavior to incorporate that into the workflow.

We can just say, you know, if you're going to prescribe this, this is what you need to provide. But I can't make you provide that information. I mean if you were to request authorization before you prescribed it, you know, it would be the same process, but you have to know that it needs prior authorization. Often times you don't know until it gets kicked back. It's kind of a cart and a horse, you know, which comes first? So I mean it would be great if, you know, we tell you this is going to require prior authorization and if you could get it proactively that would be great. I mean it's too bad that the medical records don't, you know, communicate better with the pharmacy claims processing system so that it does say, you know, stops and says this needs PA. You need to do this, this and this, you fill it out and submit the claim and it all happens at once. I mean maybe in 20 years we'll be there. It's a shame to say that, but that would be nice if that could happen that way. But I can't, you know, implement a business practice for you. It has to be your workflow and your practice standards.

Amber Figueroa: I think just sharing… being providers we like to be in control and I feel like this is one of the biggest areas where we feel like the victim because we have chosen… not specifically opioids, but when we're talking about pharmacy coverage because… partially because we don't know and things chance frequently in plans. So… yeah. I just would advocate for the education piece as best as we can. I mean how can we share that with other people? Are there newsletters? Are there… I mean because the only way I know, besides coming to these meetings, is trying to prescribe something and having it kicked back. I mean is there proactive…

Donna Sullivan: Part of the problem that I think from a communication… from us being a plan is when we try to communicate with physicians regarding changes. It doesn't go to the doctors. It goes to the office manager who then reads it and tosses it or maybe it doesn't even get read. When we send stuff to physicians or providers I don't know where it goes. I know where I send it. But I don't know what happens to it when it gets there and who actually it gets disseminated to. I mean like even with the chair pharmacies I think often time, you know, the fax goes to the corporate and does it go out to each individual store? I don't know unless each one of those individual stores has independently signed up for our list serve

to get those communications directly. So sometimes it's really difficult. We're doing the best we can to let you know, but it's your office practice setup that, you know, it's not getting to the prescriber. It's going to somebody else that's not sharing it or it gets stuck in your inbox where you are busy and you don't read it because you're seeing patients. I don't know what's the best thing to do, you know, to have an infomercial on television or something.

Amber Figueroa: Patient's watch TV, the doctors don't have time.

Susan Rowe: No, but it is kind of interesting as we think about infomercials is, you know, again, you know, we have reporters recording our conversations six years ago on methadone and certainly the public has read through the newspapers of the opioids epidemic. I don't know that this, you know, new mandate to decrease it has been in the newspaper and that would be something very positive about what insurances and Medicaid are doing and what changes could be coming down the pike so everyone kind of reads it, the patients read it, we read newspapers, mostly, and so that's an option because certainly this epidemic has been in the news. It's just that our solutions are not yet. They might be.

Amber Figueroa: Do you have access to provider's email addresses through the Department of Health?

Woman: No.

Amber Figueroa: I think that would be the best way. If you put in the subject line like, "New changes for opioid prescribers," in capital letters…

Donna Sullivan: I mean if the providers that have signed up to receive the communications from the state list serve they will get the email because whenever we have a communication, you know, we send it out on our provider alert list serves. We post it online and stuff nowadays I don't think is getting mailed as much as it did, but we can potentially… we're meeting with WHISHA(?) and WISMA(?) and we will meet with the pharmacy association, as well and, you know, maybe try to get them to help on the educational piece as we move forward with this.

Michael Johnson: I think the WSMA newsletter… I think most of the docs see that where I'm at. Other things our office manager screens stuff. I don't always see my mail until the nurse is bringing it in, but the WSMA newsletter, if it's a medical related material like that we see that. Just a thought.

Amber Figueroa: I'm a member of OMA the Osteopathic Medical Association and they have over 300 members so that would probably be good too.

Donna Sullivan: So…

[inaudible]

Donna Sullivan: Try to make sure that we send notification out to all of the professional prescribing prescriber associations.

Michael Johnson: I will say one thing, I think a hard stop is the way to go and like you were saying whether you're filling out paperwork in advance or not, I mean this is one of those safety things and we are trying to prevent premature death. So out of all the things we've talked about today this probably has the highest importance of impacting public safety from a medical standpoint. What I tell patients is that it's not their pain that is causing them to die earlier, it's the medicines that we give them and we have to do it safely and this is one area where our medical judgment needs to outweigh our empathy and if they have to wait it's not like they didn't get their insulin, they will be back in the hospital in DKA(?). This is well, you know, you're just going to have to wait longer. You're just going to have to deal with it and maybe you'll make that physical therapy appointment after all. You know what I'm saying? I think you're right on track here.

Donna Sullivan: To that point they still can get the immediate release. So it's not like they aren't getting any pain medication at all. It's just that the long-acting opioid we're just going to be a little bit more diligent in making sure that the I's are dotted. So it's up to you guys if you want to read the motion or approve this criteria or if you want to wait until the January meeting and look at it all at one time or both of them together. It's up to you.

Michael Johnson: We postponed it previously.

Ryan Pistoresi: The previous one was just a draft. So it wasn't in its final state. We are still going through feedback and we're engaging other groups to see what they think. What we can find as a workable solution since the short-acting opioids are a little bit more complicated, a little bit more complex. This one is a little bit more defined and easier and that's why we figured we could bring this to you today and then focus on the short-acting ones in January. But, as Donna mentioned, if you would like to have them both together in January we can certainly do that, but this one was finished today in case you wanted to approve it.

Michael Johnson: From what I see on the screen I think this is what we talked about and it meets the safety parameters. I think I would be happy doing this.

Susan Rowe: I'm happy to vote with you. Yes.

Donna Sullivan: We need any stakeholder input before…

Michael Johnson: No stakeholder input. Sorry.

Donna Sullivan: No stakeholders?

Michael Johnson: No stakeholders.

Donna Sullivan: Okay.

Michael Johnson: So I'll make a motion then. I move that the Medicaid Fee-for-Service Program implement the limitations for the long-acting opioids listed below. (1) Is prior authorization to ensure consistency with AMDG and CDC opioid guideline recommendations. (2) Is step through all preferred long-acting opioids before a non-preferred, long-acting opioids will be authorized. (3) Maximum of one unit, i.e. tablet or capsule per 24-hour formulations and maximum of two units per day for the other oral formulations and EA code for active cancer pain in Hospice.

Amber Figueroa: Another thought just hit me. What happens to the people who are grandfathered in and then they want to increase their dose?

Donna Sullivan: They would have to get an authorization to increase their dose.

Amber Figueroa: Do we want to put something in there that says continuation of therapy or something like that?

Donna Sullivan: You can.

Michael Johnson: Do you want to continue therapy if they are above guidelines or are excessive or…

Donna Sullivan: What we don't… we have thousands, probably tens of thousands of patients on long-acting opioids that exceed these guidelines. We don't want to put somebody into withdrawal by stopping it and I don't want 10,000 phone calls because the phones won't be working and you won't be happy with me. There's two things that we're trying to address and this is to prevent new people from getting to be on long-acting chronic opioid therapy and high dose, but there's a completely different mechanism and approach that will have to be taken to get patients that are on those extremely high doses or on chronic opioid therapy to start, you know, ratcheting down or stopping. So I think that this is just the first whack at it to try to prevent new chronic use.

Michael Johnson: Potentially adding one extra line that says something to the effect of no increased dosages in grandfathered patients without authorization or something like that.

[inaudible]

Michael Johnson: Continuation of therapy for current or lower level of MEDs.

Man: Is that appropriate?

Michael Johnson: Yeah, perfect.

Susan Rowe: I'll second the motion.

Michael Johnson: All in favor say aye.

Group: Aye.

Michael Johnson: All opposed same sign. Okay. It passes. So now we'll move on to Vivitrol.

Amber Figueroa: I have a comment. One of the recommendations from, I think it is the CDC, is that these patients have Narcan. Patients that are on long-acting opioids have Narcan handy and that their significant other is taught how to use it for a possible overdose. Is that covered?

Donna Sullivan: Yes. So Narcan is covered. They… patients can get one per… one Narcan without prior authorization. We do allow health plans to do a prior authorization on the second fill and a lot of that is to try to figure out, you know, did they have an overdose event that we need to communicate with the provider about or, you know, is it expired or they lost it. But the plans can't deny that request for the second one. It's just more of a kind of information gathering piece. But, yes, it is covered and I believe the Narcan nasal spray has two inhalers in one package. We're considering actually letting them get two packages, but we're in the process of just trying to figure out what that would look like.

So speaking of then opioid use disorder so those patients that are on chronic opioids that want to get off of chronic opioids we're going to talk about Vivitrol. So Vivitrol is a long-acting naltrexone injection and previously we had put it on prior authorization for trial and failure of the oral naltrexone preparations or inability to, you know, for whatever reason they can't take oral naltrexone either due to compliance or other issues. We had some feedback from providers, some pharmacies that were working closely with providers around this, and our health plans were having difficulty getting the prior authorization approved timely in some circumstances and then some of the health plans were also, you know, requiring a specialty pharmacy dispensing the medication. So we had asked the plans to… or instructed the plans that they had to allow the first dose at retail, but they could still have the prior authorization on it and the more we've discussed this we really don't feel Vivitrol is going to be misused too much because of the route of administration. So our current limitations, where they have to have this diagnosis of moderate to severe opioid use disorder, you know, the unsuccessful treatment attempts with oral naltrexone and the three or more ER visits, the

abstinence, we're not going to stop Vivitrol anymore and require prior authorization. So our recommendation is we're going to remove those PA attempts. We have providers that are treating patients that are coming out of jail so they are already abstinent. They want to keep them from, you know, either going back to their old habits and they are missing the opportunity if they have to go through the prior authorization process or, you know, if there is a delay in getting a specialty pharmacy to deliver the medication. So we appreciate that feedback from providers and we're recommending to remove the PA requirements and to require the health plans to allow retail dispensing of Vivitrol so that we don't have missed opportunity and then potential, you know, fatal overdoses for patients that left because they're… by the time that we got the Vivitrol to the provider to administer it the patient has already relapsed. So that is our recommendation.

Michael Johnson: Okay. At this time we have three stakeholders. The first one will be Deborah Profant followed by Terree Whelan. We'll ask you to state your name and who you represent and you have three minutes.

Deborah Profant: I'm Deborah Profant, medical science director for Alkermes. I spoke to you this morning. I'm not going to take the whole three minutes, I don't think, but I just wanted to say that Alkermes is pleased to see that you're moving towards removing the PA requirements for Vivitrol because we recognize that all patients, you know, are not going to be introduced in Vivitrol based on the need for it to be completed detoxed from opioids before starting the medication. We do recognize that when clinicians are making this decision with the patients it's really based on patient preference, their past treatment history and the treatment setting when they decide between the different medication assisted therapies.

Also, in number of the guidelines really say, you know, to consider the different [inaudible] options. It should be a shared decision-making process between the clinician and the patient and Vivitrol is unique in that it is the long-acting naltrexone and it is an antagonist. So it does really require the patient to make that commitment to be opioid free and to be completely detoxed before they go on Vivitrol and also they have to go through the serious warnings about reduced tolerance to opioids and

as she was saying, that risk of overdose if they did consider challenging the blockade due to Vivitrol.

So in conclusion Alkermes is pleased to see that you're considering removing those criteria, the PA criteria, so that patients, if they do decide to… with their clinician, to go on Vivitrol they have access to the medication and there is no interruption in getting their second or third shot of Vivitrol so they can continue with the therapy.

Michael Johnson: Any questions? Thank you. So Terree Schmidt Whelan and then Bill Struyk.

Terree Schmidt Whelan: Thank you. Good afternoon Mr. Chairman and members of the committee. My name is Dr. Terree Schmidt Whelan. I'm the executive director of Pierce County Alliance in Tacoma. With me today is Jamie Benobo(?) who is the treatment director for the medication assisted treatment track of the therapeutic drug court for felony offenders in Pierce County. I'm here to ask you to do what I think you're already going to do. We sent a letter last week, which I believe you have in your binders. If not, I have multiple copies for you. But I wanted to come here to urge you to do exactly what you've discussed, which is to ease the requirements to better allow for physicians to treat people with no time restrictions or delays. As we all know heroin addiction on a good day is very difficult. On a bad day it is very, very difficult and any kind of interruption in time delay does serve as a potential for people to go out who may relapse and nobody wants that. Vivitrol may not work for everybody. It works for the majority of people that we see. On a personal note I should say that I have been in the field of chemical dependency for about 40 years. There is a rare time when I can stand up and tell all of you with all sincerity that this has had a significant impact in the drug addicted population that is in the justice system that you referred to a few minutes ago and it is making a remarkable difference. Jamie is the director of a treatment track for medication assisted treatment and the drug that she primary refers people to is Vivitrol because of the enormous success. People have a great deal of difficulty dropping by a clinic or taking medication on a daily basis sometimes, but a once-a-month shot is hard to not be able to chorale them to come in. So I just want to thank you for the time. Jamie is here to answer any

questions. I can answer any questions, but to thank you for your consideration in doing what I consider the right thing with Vivitrol. Thank you.

Michael Johnson: All right. Thank you. Questions? Thank you. Bill Struyk?

[inaudible]

Man: Sorry I wasn't able to sign in. Thank you for giving me time. My name is Dr. [inaudible] and we have a clinic in Tacoma that we treat patients with substance abuse disorder with medication-assisted treatment including Vivitrol, suboxone, subutex, etc. I wanted to essentially talk in favor of the recommendations. I think most of the comments that were mentioned I strongly second them. I also… we also treat patients who are from the Kitsap court system and I can just remember patients that I was not able to give the shot because of this preauthorization. Our office manager currently has to spend about a week at least. She has to fax multiple forms, call multiple times. It takes days to get these approved and then we have to wait for the medication to be shipped to us. We have to keep it in the refrigerator for the patient to show up and then give them the shot. There's multiple times that patients that were appropriate I would have given them the shot and they would have definitely been in recovery right now and we have lost a follow-up. At this point what I do is I give them a naltrexone tablet so that at least during that timeframe where they are going through detox and going over the difficult part at least they will be compliant and I think success of that has not been as good as we would like, but that's the only option that we have at this point. I would strongly encourage everybody to give this a favorable recommendation. Any questions I can answer?

Michael Johnson: Thank you.

Man: Thank you.

Donna Sullivan: I think we're ready for the motion if you're ready to give one.

Susan Rowe: I, Susan Rowe, move the Medicaid Fee-for-Service Program implement the limitations for Vivitrol listed below by removing all of the prior

authorization requirements. Vivitrol must be allowed to be dispensed from retail pharmacies.

Eric Harvey: I'll second.

Michael Johnson: All in favor say aye.

Group: Aye.

Michael Johnson: All opposed same sign. All right. Thank you.

Mason Bowman: I'm not opposing this in any way, I just wanted to get a matter of clarification as far as when we can expect this to be enacted, I guess.

Donna Sullivan: Thanks, Mason. I was going to say… the contracts of the managed care plans I believe requires… it's either 60 days or 90 days for implementation once we've notified them of the change. So it's not going to be immediate, but it will be out there as quickly as we can get it changed for them.

Susan Rowe: I have a… these are patients that also would be good candidates for Narcan. Is it covered for them?

Donna Sullivan: Yes. So the managed care plans also cover Narcan the same as the Fee-for-Service Program. So they are required to cover that. One last class before we go. I forgot also that methadone is… also has limits. So we just want to look at the current methadone limits. The limitations that Ryan went over previously does not include methadone. So methadone, right now, we put on prior authorization in October of last year. We grandfathered all patients that were on 40 mg or higher of methadone and we required that any patient that wanted to start on methadone had to try and fail all generic long-acting opiates before we would consider it. The maximum dose approved would be 40 mg and then… this actually says 20, but I think it was 40 is where we ended up drawing the line.

Susan Rowe: The line above it says max 40.

Donna Sullivan: Right. But where we allow continuation of treatment if taking greater than 20 mg. I think that's actually 40 mg of methadone. And then we created an expedited authorization for patients who had active cancer pain or were in hospice. So we're recommending that we just continue these limitations moving forward. And any patient that is approved for methadone, the ones that were grandfathered in were grandfathered in at their current dose. So any dose escalation, if it's less than… or above 40 mg would require prior authorization. So that is currently in place. We get very few requests for methadone. We had a few in the very beginning, but it's been really quiet and really no pushback at this point. So… motion?

Susan Rowe: I'll move…

Michael Johnson: I think we have stakeholders on this one.

Susan Rowe: Do we have stakeholders?

Man: No.

Michael Johnson: Oh, no stakeholders on this. I think the 40 mg I think that's the recommended and I think we just did this in October. I don't think there are any changes so I can go ahead and do this motion.

I move that the Medicaid Fee-for-Service Program implement the limitations for methadone as listed below. (1) Does not apply to methadone dispensed from an opiate treatment program. (2) Step through all other generic long-acting opioids before methadone will be authorized. (3) Maximum dosed 40 mg per day. (4) EA code for active cancer and hospice. (5) Continuation of therapy allowed for patients currently taking greater than 40 mg.

Amber Figueroa: I second that.

Michael Johnson: All in favor say aye.

Group: Aye.

Michael Johnson: All opposed same sign. All right. It passes. Thanks. Is that it?

Donna Sullivan: Yes, that is it. We are done.

Michael Johnson: All right. We are adjourned as the DUR Board. Thank you!