

Drug Utilization Review Board

August 16, 2017

- Michael Johnson: It is 9 a.m. and we will go ahead and get started. First, I'd like to welcome you to the Drug Utilization Review Board here at Washington State. This is a recorded meeting so before speaking, please identify yourself. I will let stakeholders know time is limited to three minutes and we'll try to abide by that. I think we'll have a full agenda today. There's a lot of people speaking. At this time we'll go ahead and introduce yourselves. Starting to my left, state your name and what your position is.
- Michael [inaudible]: Michael [inaudible] I'm a Pharmacy Intern at Community Health Plan of Washington.
- Frances McGaugh: [inaudible], Clinical Pharmacist from CHPW.
- Julie Hartford: Julie Hartford, Health Care Authority.
- April Phillips: April Phillips, Health Care Authority.
- Charity Harris: Charity Harris, Health Care Authority.
- Catherine Brown: Catherine Brown, committee member.
- Susan Flatebo: Susan Flatebo, committee member.
- Nancy Lee: Nancy Lee, committee member.
- Po Karczewski: Po Karczewski, committee member.
- Diane Schwilke: Diane Schwilke, committee member.
- Michael Johnson: Michael Johnson, committee member.
- Lisa Chew: Lisa Chew, committee member.
- Jordan Storhaug: Jordan Storhaug, committee member.

Dale Sanderson: Dale Sanderson, committee member.

Amber Figueroa: Amber Figueroa, committee member.

Donna Sullivan: Donna Sullivan, Health Care Authority.

Leta Evaskus: Leta Evaskus, Health Care Authority.

Ray Hanley: Ray Hanley, Health Care Authority.

Piao Ching: Piao Ching, Pharmacy Director, Coordinated Care.

Dave Johnson: Dave Johnson, Molina Healthcare.

Petra Eichelsdoerfer: Petra Eichelsdoerfer, United Healthcare.

Michael Johnson: So today I think we're... we have a full agenda. I'm going to turn this over to Donna Sullivan.

Donna Sullivan: Thank you. So I just want to make a few announcements about the agenda. So we will not be reviewing the progestin class or the two oncology classes that were scheduled for this afternoon. We just didn't have time to get those criteria for ready. So I apologize if you're here for those. I want to go through and give some background on why we're here and what we're doing. Some of this will be a repeat of the special meeting that we had in July. So I apologize for duplication, but I thought it would be helpful for everybody to hear it again and for those that were unable to attend last month. And then we'll give you kind of an update of where we are and what we're doing and then after that we'll get to product... reviewing the drug classes.

The legislature passed a budget proviso and within the budget proviso they directed the Health Care Authority to develop and implement a single standard Medicaid preferred drug list to be used by all managed care plans in addition to the fee-for-service program on or before January 1, 2018. We are supposed to do that in consultation with the Medicaid Managed Healthcare systems and the P&T Committee or the DUR Board. So you'll notice that we will now have our managed care plans here

around the table with us so you can ask them questions about their programs, as well as the Health Care Authority.

You will notice that we are here convened today as the Drug Utilization Review Board so the Medicaid PDL decisions will be made with you convened as the DUR Board and not the P&T Committee. So I just wanted to let you know.

We are also to ensure that access to clinically-effective and appropriate drug therapies in each class while we maximize federal and supplemental rebates. 340B entities will continue to operate under their current pricing agreement.

The budget proviso did provide us some funding to use consultants. To contract with an evidence-based drug class vendor, a supplemental rebate vendor, and gave us some additional staff resources as well. All MCOs must use the PDL and they are not allowed to negotiate their own rebates for drugs that are within the... what we're calling the Apple Health preferred drug list. If there are drug classes that don't make it onto the preferred drug list we will allow plans to negotiate rebates for those products. Managed Care Plans also will need to provide the Health Care Authority with their drug-specific financial information on a frequency determined by Health Care Authority.

And that information... in... through the budget proviso is to be held proprietary, confidential, and not to be subject to public disclosure. The Health Care Authority was also directed to provide an annual report to the governor and the legislature in November 2018 and in 2019 comparing the cost of purchasing drugs through this new system compared to previous years. The budget originally included a savings expectation of 10%, which is about \$144 million over the biennium.

So again I want to reiterate what our priorities are with the Health Care Authority. The priorities are patient care and access to necessary medications come first. We want to make sure that there is as little disruption as we can avoid or avoid as much disruption as possible. We want to make sure that patients, prescribers and pharmacies have easy access to the right information and that they know who to call and when

to call if there are questions about a prescription claim. And then again minimize both patient and provider disruption.

So we developed a work plan and this is just a brief overview. So we did some data analytics leading up to this meeting and you'll see some of the results of that as we go through the drug classes. So that has been completed. We are currently developing the preferred drug list and we hope to have the first iteration completed by October 1st, 2017. So I want to take this time to say we're going to have two implementation phases. One will be January 1st, 2018. The second will be March 1st, 2018. The reason why is that when we were doing our analysis of how best to create the PDL and share it with the health plans we want to do that electronically and so in order to do it electronically we need to change our claims processing system and configure it so that we can export a file that the managed care plans can use. Our vendor, through our process to test that and build that, it won't be available until mid-February. So what we will be doing is taking these drug classes that are on the agenda today and we'll be implementing these January of 2018. The other drug classes... we will continue to have our monthly meetings and then other drug classes will be implemented on March 1st of 2018. So we will do the best we can to have a comprehensive formulary... or I'm sorry, preferred drug list by March of 2018.

So that NCPDP formulary file is the file that I was just mentioning and so that is the March 2018 date. We are also trying to build or purchase a tool so that providers and patients can look up what the preferred drugs are online with an interactive tool. So not a static document. That is to be determined. We are working on a communication plan that is ongoing, as well as changing to our technology. We're looking at finance. We have to figure out how this will impact rates to the managed care plans and then we are in the process of negotiating a contract with a supplemental rebate vendor and a clinical evidence provider. Any questions?

Before we go onto that what I want to do is kind of talk about the process now. So what... we're not going to go through clinical reviews of each drug class. All of the drug classes and the drugs that are on here have been reviewed by each of the plans' P&T Committees already. So what I

have is a slide that will first present what we're going to recommend to be the preferred drugs within the class. Then I will go to a spreadsheet that will show... display those drugs and then the formulary status, the current formulary status, for each of the health plans and the Fee-For-Service Program so that you can see that many of these drugs classes their plans are already very similar. Then we will look at the limitations, if any. So if there are prior authorization requirements or quantity limits we will look at those and after that we will request or ask the stakeholders if there is any input from stakeholders that they want to provide. And then we'll go ahead and have a motion... or you'll discuss, decide if you agree with the recommendations and then make a motion on what you wish should be preferred.

Amber Figueroa: Can you explain kind of how the PDL will work as opposed to... or maybe within the same system as like different tiers in the managed care organizations as far as coverage? Like if we set certain meds on the PDL then is that going to be... would that have the potential to end up on the tiered list in the managed care overview?

Donna Sullivan: The preferred drug list, the managed care plans will have to follow it. So if there is a drug that becomes preferred then the managed care plans have to make that preferred. If we decide that there is going to be a prior authorization on a drug then every plan will have the same prior authorization criteria and we will, to the extent possible, have the same form to try to streamline and ease the doctor's burdens on requesting prior authorization for certain drugs. So there shouldn't be any tiering. The plans have to cover the drugs as they are determined to be preferred with the restrictions that are allowed by the DUR Board. Any other questions before we start about the process?

So I think I chose some easy ones to start out with so that we can kind of get our... ease into it. So we'll go ahead and get started.

The first class is the epinephrine, self-injected products. In those are... there's AUVI-Q, adrenacllick, there's the generic for adrenacllick, EpiPen, EpiPen junior and the generics for EpiPen junior. We are recommending that the generic for EpiPen junior and EpiPen be the preferred products. So this is my spreadsheet and I apologize. I put it... it is not in the same

order as the slides. As we look at it, the EpiPen is at the bottom and I'm going to make this bigger. I'm going to have to scroll back and forth. We only had utilization in the adrenalin, epinephrine, auto injector and the EpiPens. The plans had... the numbers in this spreadsheet if there is a five in one of these cells over here and I might have to pull up my other spreadsheet which has these locked, so these are the health plans. So we have the first box is what I call the PDL concordance. The other box is what I've done is I've assigned unique numbers to the status. So if a drug is not preferred then there is a 700 in the file and these are just random numbers that I pulled out of my head so that they would add up in a way that I could figure out who was doing what. So 700 is not preferred. Five means it is preferred without... that it is preferred. When you look across all of the plans this PDL concordance what I did is I basically just added it up and averaged it. So if you see a 15 as the last two digits that means three of the plans had the drug preferred. If there's a 30 then there are 6, 20, 4, 25, 5, etc. So this is my way of... if there's a 35 it meant... well you'll say 35 divided by 5 is 7. So it's the five managed care plans, the Fee-For-Service Program and our supplemental rebate vendor would make 35. Where there are 35s everybody is already the same. So this is partly how I went through to see how close we already are in many of these classes and then also looking to see, okay, if we're not very close what is the utilization for the plan? So what is the potential disruption if we are to make a change? Going back down to the EpiPen... so four of the plans... six of the plans already have the generic EpiPen as preferred and this is not a supplemental rebate that we're getting so this is just the federal rebating is driving the decision in this particular class and the utilization is... there is 10,000 claims... 10,000 clients, 1,100 roughly were fee-for-service. About 9,500 in managed care. About 13,000 total claims in EpiPen. So this is a class for me changing from epinephrine to generic epinephrine. They are exactly the same product made by the same manufacturer. They are just packaged... one is the brand and one is the generic. So we don't feel there is much disruption going in this particular class, which is why we recommended switching to the generic. Any questions so far?

Michael Johnson: I know that occasionally there are drug shortages. Is there anything in this... I mean obviously if the generic was all of a sudden unavailable for some reason is that taken into account?

Donna Sullivan: Yes. That happens all the time where a generic becomes... if there's a shortage of a product and we find out that pharmacies are just unable to get it on a broad basis then we do have to make adjustments. But we make those pretty much on a case-by-case basis.

The policies, or the limitations, for the epinephrine auto injectors is that they have to try the generic preferred drug or have a contraindication to it, but if they have a contraindication to it, then they probably can't take any of the others. And we're suggesting right now most of the plans have a limit of two per month, which I believe is one package. So we're proposing a quantity limit of... a quantity of two per month.

Amber Figueroa: Does that come in a single package? Because thinking of all of them that I prescribe I would say that probably 90% of them are never used and they expire out. So if it's cheaper to do a single pack, if that exists, then I would recommend that.

Donna Sullivan: I don't think they come in a single pack. Diane is shaking her head, no.

Are there any stakeholders in this class?

Michael Johnson: There are no stakeholders.

Donna Sullivan: Okay. I tried to whip up some motions and why am I not displaying here? Maybe we won't have a motion. I'll just read what the motion says. It's really complicated. It says I move to accept the recommended preferred drugs and limitations in the epinephrine auto injector class. But I can't make the motion so one of you have to.

Amber Figueroa: I move to accept the recommended preferred drugs and limitations in the epinephrine auto injector class.

Lisa Chew: I second.

Michael Johnson: All in favor say aye.

Group: Aye.

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

Donna Sullivan: It appears...

Michael Johnson: I think the next class is opioid antagonists?

Donna Sullivan: We are going to move along and we're going to go to our backup paper. So it is on slide 10 in your packets. The opioid dependence treatments, and I apologize because we won't be able to display the utilization, the buprenorphine... the products within this class are buprenorphine/naloxone combination products that are generic. There is naltrexone, suboxone film, Vivitrol, Bunavail, there's the buprenorphine mono product, Zubsolv and Subutex. There we go.

Within this class we are recommending that the preferred products are the buprenorphine/naloxone tablet, the naltrexone, the suboxone film and Vivitrol and that the other products are non-preferred.

So here are the products and again the buprenorphine/naloxone is preferred with all of the plans and it is covered without prior authorization. So all of these medications right now, except for the buprenorphine mono products are covered without prior authorization. Buprenorphine monotherapy is covered only in pregnant women or if you have an allergy to naloxone. So we are recommending that the suboxone, because of its supplemental rebate potential the generic buprenorphine tablets and naltrexone, and I'm going to have to switch. Unfortunately the buprenorphine products are partial opiate agonists where the others are opioid antagonists and they are in a different class here.

So here are the opioid antagonists. So we have evzio... actually that's a rescue agent. So we have the naltrexone and the Vivitrol. So we're recommending that those are also preferred and it's... already the plans have those pretty much covered and I don't know why this isn't 80. This isn't 80 because that's a 50 and it should be a 50 and it should be a 5. Let me go back. Skip to our limits. There are no limits in this particular class other than the buprenorphine is limited to monotherapy, which I

mentioned. Going back to our slide... so if your drug is not listed in the preferred column then it's not preferred. I just realized that not all of the products are listed on this particular slide in the non-preferred agent. So if they aren't in the preferred column they are not preferred. Are there any stakeholders?

Michael Johnson: Yes. We have four stakeholders for this. Reminder there is a three-minute limit when you get up to the microphone up here. Just introduce yourself. The first person is Dr. Nick Casale. After him will be Michael Boskello.

Woman: There is one stakeholder who did not sign up who wants to speak at the end.

Michael Johnson: Okay.

Nick Casale: My name is Nick Casale. I'm the manage market medical science liaison for Indivior, the manufacturer of suboxone, sublingual film. I'm going to defer my testimony back to the committee unless you have any questions about the [inaudible] or our product in particular.

Michael Johnson: Thank you. So Michael Boskello. After him will be Mark Murphy.

Michael Boskello: Good morning everyone. Mike Boskello. I'm a medical science director with Alkermes Pharmaceuticals. I'm here today and supporting the decision that was made and if there are any questions I'd be happy to answer them at this time for Vivitrol.

Michael Johnson: Thank you. So Dr. Mark Murphy and following him will be Robert Hamilton.

Mark Murphy: So Dr. Sullivan, thank you for the opportunity to address the committee. Robert, would you kindly give those to Dr. Sullivan? Before today I wasn't certain of the status of the committee. If you had already decided on therapeutic agents. I'm very pleased to learn that some important medications for opioid use disorder have been considered and are still on formulary. The document that Dr. Sullivan has is the surgeon general's report that came out last year describing the situation we're currently

facing with the opioid crisis. I'm sorry, that's an over-used word, but it is a crisis. So in the future if there is a call to roll back some of these medications I would suggest to go to that document because it provides the scientific basis for the use of these medications, as well as some of the economic analysis. Investment up front in treatment yields great dividends down the road and the surgeon general's report calls that out very well. So I will yield the balance of my time to Robert Hamilton. Robert is the manager of our substance abuse disorder—a program at Multi-Care and I'm the medical director for addiction services there, as well as the president of Washington Society of Addiction Medicine.

Robert Hamilton: I just want to express my pleasure of hearing this news this morning and also just say that as a provider of the boots on the ground behavioral health services to the individuals with substance use disorders. I can tell you that what Mark said about the dividends they are there. This adjunct therapy really helps to stabilize people up front the greater engagement, retention in services and better outcomes at the end.

Michael Johnson: Thank you. I think there's one more? No? Okay. That's all of the stakeholders.

Donna Sullivan: Okay. So we're going to move to the motion.

Lisa Chew: I just had a quick question. For the buprenorphine monotherapy for pregnant women, what would the work flow be for that provider to order that? Would that be a prior authorization?

Donna Sullivan: It is a prior authorization, yes. It seems that there's... my computer or the projector doesn't like non-projection mode. I'm just going to copy and paste this into a new slide. All right. There's the motion.

Jordan Storhaug: I move to accept the recommended preferred drugs and limitations for the drugs to treat opioid dependence.

Catherine Brown: I second.

Michael Johnson: All in favor say aye.

Group: Aye.

Michael Johnson: All opposed same sign. Great. The motion carries. Thank you.

Donna Sullivan: Okay. So now opioid antagonists. This particular class is looking at naloxone injectable. I apologize, naltrexone is on here again. So we're recommending naloxone injectable, as well as Narcan nasal spray to be preferred and the Evzio to be non-preferred. And so we're on slide 11 in your packets if you need it. There are no limits on these products at this point in time. And we have already looked at the utilization. So most... the health plans now, including fee-for-service are required to cover the Narcan nasal spray. We allow the first one without prior authorization, but we are allowing managed care plans to put a prior authorization on the refill and they are not allowed to deny the request for refill, but it's really trying to find out, did the patient use the medication? Did they have an opioid-related overdose event? And potentially... that allows the plans to, you know, have the opportunity to notify the provider and also check to see if that patient... if they did use it are they still being prescribed opioids and try to do some intervention there. So Narcan nasal spray is currently preferred by all the plans, as well as the naloxone injectable, the vials and Evzio currently... the plans I'm pretty sure they all have it on prior authorization. Any questions from the committee? Any stakeholders?

Michael Johnson: I didn't see any stakeholders.

Donna Sullivan: Okay. I'll go ahead and copy this one. It likes the PowerPoint and doesn't like the other one.

Michael Johnson: I propose that... I move to accept the... or that we move to accept the recommended preferred drugs and limitations for the drugs to treat opioid overdose.

Lisa Chew: I second.

Michael Johnson: All in favor say aye.

Group: Aye.

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

Donna Sullivan: So the next class are the drugs to treat attention deficit and hyper activity disorder. So the preferred products that are being recommended for amphetamines are the long- and short-acting amphetamine salt combos, the long- and short-acting dextroamphetamine product, Vyvanse. For the methylphenidates it is dexmethylphenidate, the short- and long-acting products, methylphenidate, the generic short- and long-acting products, and for non-stimulants we are recommending atomoxetine, clonidine extended release and guanfacine extended release. And you'll remember that this class, we just reviewed this in April, so the product selection does reflect the motion that the P&T Committee made back in April putting both the clonidine and guanfacine in a preferred position. Strattera has gone generic, I believe, and so the atomoxetine is preferred as a generic at this time. There are... within this class the reason why some of these drugs are bolded is that there is opportunities for the program to prefer the brand drug over its generic equivalent because after the federal rebates the brands are actually cheaper than the generic equivalent. So in those instances if the agency chooses to go down that path that's still being discussed internally. Then there is possibility that these particular brands would be preferred instead of their generic products. And for limitations on these... I'm not sure if we can see.

So for the children I don't have all of the age dose limits populated, but if you recall that we do have age dose limits on the stimulants and the other ADHD products for children 0 to 17 years of age and those go to a second opinion review if they exceed those age and dose limits. Other than the age dose limits, we're recommending that they have to try two preferred products before they can get a non-preferred product.

For ADHD in adults it's... we're prescribing for greater than 18 years of age and again just trying and failed two products for getting the non-preferred drug and the same with narcolepsy, mental fatigue. Binge eating disorder is slightly different. We're limiting it to being prescribed by a psychiatrist. That they have tried and failed two preferred stimulants, in addition to topiramate and one of the... and an SSRI such as

citalopram, sertraline, or escitalopram and that they are also getting cognitive behavioral therapy.

Amber Figueroa: So this is the first time we're seeing the tried and failed. So what will happen to the people who are on a branded drug now on January 1st?

Donna Sullivan: That's a good question and I didn't think about that to put it in the motion. One of the things that I also want to look at is the utilization to figure out what the disruption is. So we want to consider grandfathering some drugs and we can look through here and look at what the impact would be if some drugs became non-preferred. So let me show you what the utilization looks like in this particular class. With this particular class the clonidine, most of the plans already have it preferred, as well as the guanfacine extended release. All of the plans already have the generic product preferred for the amphetamine combinations, as well as the extended release combinations. Methylphenidate, the generics are already preferred by most of the plans here. So at this point in time most of the plans are already aligned and I'm just going to slide over to the utilization. You can see this is the first... this is how many claims there are. So most of the products... most of the patients are already in the products that are preferred. So my recommendation is that people that are also on a non-preferred drug, most likely have already gone through a prior authorization request or a non-formulary exception request and so I would recommend in this class that we grandfather the current users that are on the medication and then just new starts will have to go through an exception request with the tried and failed if they want a non-preferred drug. Any questions or comments? Stakeholders?

Michael Johnson: There are no stakeholders for this class.

Donna Sullivan: Okay. Can you guys read that?

Amber Figueroa: I move to accept the recommended preferred drugs and limitations for the drugs to treat ADHD. Current users of non-preferred drugs within the class should be grandfathered, i.e. allowed to continue with the non-preferred drug.

Jordan Storhaug: I second the motion.

Michael Johnson: All in favor say aye.

Group: Aye.

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

Donna Sullivan: The next class that we'll be looking at are the bronchodilators and the beta agonists. In that class for recommended we are looking at... the preferred products are the generic albuterol nebulizer solutions, albuterol extended release tablets, albuterol syrup, and regular albuterol tablets. The inhalers are Proair HFA, Proventil HFA and serevent and if... the non-preferred products are listed in the column on the right and I'm not going to read them all. If your product is not listed in the preferred column it is not preferred, even if it is not listed in the left column. I just want to make sure there's no confusion over that in case we accidentally missed a product that is on the market.

So for the utilization in this class and the formulary status five of the plans have Proair as preferred already, three of the plans have Proventil already preferred. The oral albuterol products most of the generics are already preferred in most of the plans. So we are pretty... the recommendation is pretty concordant with the current status in these drugs and the... if you follow the fives across you can see that the utilization is already the majority in these products. My recommendation as part as grandfathering with the albuterol inhalers would be not to grandfather the albuterol inhalers due to the cost difference. It really doesn't make much clinical sense to me. That is your decision to make and let's go to see what the limits look like.

So the... it's just a tried and failed class. So you have to try and fail two preferred within the same dosage form. So two inhalers before they could get the non-preferred inhaler in this particular class.

Amber Figueroa: So we don't have any of the RespiClick or Respimat ones as preferred. So can a pharmacist explain to me, would there be some kind of a mechanical reason that the Respimat would need to be... formulation would need to be used instead of just a regular HFA?

Nancy Lee: No.

Donna Sullivan: Thank you. Because we can't hear you shaking your head.

When we say tried and failed it also... that includes contraindications or some clinically meaningful reason why they couldn't try a preferred. We would never require somebody to try a medication that, you know, they were allergic to or had a contraindication to. So just keep that in mind. When we say try and fail that includes, you know, adverse reactions or reasons why you wouldn't... the medication would be clinically inappropriate.

Michael Johnson: One questions – just kind of for clarification. So we have the preferred list on the left, but there's nothing that would prevent one of the managed care plans from having Respimat preferred if that's their choice. Right?

Donna Sullivan: No. They are prohibited from adding anything to the preferred list.

Amber Figueroa: Can you scroll over and show me the usage of the albuterol tablets? I've been practicing in this state for almost 15 years and I thought you could only get oral formulations of albuterol from Mexico. I didn't even know it was...

Donna Sullivan: I believe it's these ones here. I could be wrong, though. This is the extended release tablet right here. So very few. If I need to I can pull up the spread sheet that has the formulation in it.

Amber Figueroa: Is there a benefit of having it as a preferred if there are nine people in the whole state on it? Or is there... does it matter either way?

Donna Sullivan: I don't think it matters either way. It's already... five of the plans already have it as preferred or just open. It's just not used. Any questions?

Michael Johnson: There are no stakeholders.

Lisa Chew: I move to accept the recommended preferred drugs and limitations in the bronchodilator beta agonist class. Non-preferred drugs should not be grandfathered.

Catherine Brown: I second.

Michael Johnson: All in favor say aye.

Group: Aye.

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

Donna Sullivan: Michael, I want to call an audible here and go back and have the committee make a decision on grandfathering for the first couple of classes where we forgot to consider that. So with the auto... epinephrine auto injectors I do not recommend grandfathering. So for Robert's rules of order I think we have to redo the motion and revote just to be safe.

Amber Figueroa: I move to accept the recommended preferred drugs and limitations in the epinephrine auto injector class. Non-preferred drugs should not be grandfathered.

Lisa Chew: I second.

Michael Johnson: All in favor say aye.

Group: Aye.

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

Donna Sullivan: So for the opioid dependence class I actually do recommend non-preferred drugs should be grandfathered.

Jordan Storhaug: I move to accept the recommended preferred drugs and limitations for the drugs to treat opioid dependence. Non-preferred drugs should be grandfathered.

Catherine Brown: I second.

Michael Johnson: All in favor say aye.

Group: Aye.

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

Donna Sullivan: And then... so now we're back to the COPD agents. Thank you. Sorry. I apologize for that. So for the COPD agents the preferred products recommended are the ipratropium/albuterol combination, the ipratropium nebulizer, the Spiriva handihaler, and the Stiolto Respimat. Non-preferred agents are on the right hand side and just to point out that the Spiriva Respimat would be not preferred in this particular class.

So for the utilization and the formulary status most of the classes already have... or most of the plans already have the ipratropium bromide preferred and I think that these are actually broken out into two different sections. So the combination product is in a different section. The atrovent is preferred in most of the plans. That would be a change. The incruze ellipta is preferred in five of the plans and tudorza in four. The utilization in this class is kind of all over the board. So the ipratropium and the Spiriva handihaler in the middle, and you can see that they have probably more than about half of the utilization... slightly less than half of the utilization. The rest being incruze and tudorza. And so it looks... so these two here are the ipratropium and the Spiriva and then these are the... the other two are up here, the other classes. There would be several thousand people that would be impacted by this particular change. What we are recommending is that they try and fail all preferred for... before they can get a non-preferred drug.

Diane Schwilke: To say that they have tried and failed all... I know that we have some populations of patients that are homeless and a nebulizer is not really practical so to have them required to try a nebulizer before they could have a different inhaler might be a little unreasonable.

Donna Sullivan: Right. It would be within the dosage form. So if they are wanting a non-preferred nebulizer they would have to try the preferred nebulizers. If they wanted a non-preferred inhaler they would have to try the preferred inhalers. So it would be within its route of administration.

Diane Schwilke: We have a prior authorization specialist in our pharmacy, which is a little bit unique, and she works for the clinic. I know that there are different levels of difficulty with dealing with one plan versus another versus directly with open coupon in the state. So that verbiage might be used. So I'm just a little concerned with that.

Donna Sullivan: We'll make sure that they are implementing it in the manner per the dosage form. Is that helpful? Okay. And I can actually change that here. Any stakeholders in this class?

Michael Johnson: Yeah. There's one stakeholder in this class, Dr. Bethany Jones.

Bethany Jones: Hi. Good morning everyone. My name is Bethany Jones and I am a medical science liaison at Sunovion Pharmaceuticals. Today I wanted to talk about two products Seebri Neohaler, which is glycopyrrolate inhalation powder and Utibron Neohaler, indacaterol and glycopyrrolate inhalation powder. Today we ask you to add these COPD products with a delivered device to the LAMA and LABA/LAMA combination category, which provides audio and visual feedback related to medication delivery. The most recent 2017 revision to the gold global strategy for the diagnosis management and prevention of COPD recommends that for maintenance therapy all patients are treated with a bronchodilator. Long-acting formulations such as a LABA and a LAMA are preferred over short-acting for maintenance treatment except for patients with only occasional [inaudible]. Gold recommends to start patients on either a single long-acting bronchodilator therapy or a dual long-acting bronchodilator therapy and those with persistent [inaudible] on one bronchodilator should be escalated to two.

Utibron Neohaler is a combination of indacaterol, a long-acting beta-2 adrenergic agonist, a LABA and glycopyrrolate, an anticholinergic agent indicated for the twice daily and long-term maintenance treatment of air flow obstruction in patients with COPD including chronic bronchitis and/or emphysema. As Utibron Neohaler contains a LABA, indacaterol it carries a class wide boxed warning regarding an increased risk of asthma-related death. The safety and efficacy of Utibron Neohaler in patients with asthma has not been established. It is not indicated for the relief of acute bronchospasm or for the treatment of asthma. The clinical development program for Utibron Neohaler included two 12-week randomized double-blinded placebo and active controlled parallel group trials, Flight 1 and Flight 2, and subjects with COPD designed to

evaluate the efficacy and safety of Utibron. There was also one 52-week randomized double-blind active controlled long-term safety trial, Flight 3 that also evaluated efficacy. Flight 1 and Flight 2 evaluated Utibron Neohaler 27.5/15.6 micro grams, indacaterol 27.5 micro grams, glycopyrrolate 15.6 micro grams and placebo all dosed twice daily. In both trials Utibron Neohaler demonstrated a larger increase in mean change from baseline in FEV1 area under the curve 0-12 hours, the primary endpoint compared to placebo, indacaterol and glycopyrrolate. The pulled result showed improvements versus placebo of 246 mL versus indacaterol of 103 mL and versus glycopyrrolate of 88 mL. The mean peak FEV1 improvement from baseline for Utibron Neohaler compared with placebo at day 1 and day 85 was 185 mL and 290 mL in Flight 2 and 151 mL and 260 mL in Flight 1 respectively.

The median time to onset on day one defined as a 100 mL increase from baseline in FEV1 was 12 minutes and 16 minutes in Flight 2.

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

Bethany Jones: Thank you.

Michael Johnson: Sorry. Just for clarification, this is our Drug Utilization Review not the P&T Committee. So that means without looking at evidence we are not in the process of adding. We're in the process of selecting. There are no other stakeholders.

Donna Sullivan: The committee needs to decide whether or not drugs should be grandfathered or not and I'm not going to make a recommendation. Would you like me to go back to that other utilization spreadsheet? Okay.

These are all the clients, managed care and fee-for-service and then fee-for-service clients, managed care clients.

Amber Figueroa: Point out again one more time the ones that would not be covered based on this list.

Donna Sullivan: These two here and I believe these two here. Let me make sure that is an accurate statement. So the top two and the bottom two. It's about 7,000ish, 8,000ish.

Diane Schwilke: Just to clarify too the second one from the bottom that's kind of hard to see that. That would still be the same drug, it would just be a delivery form. So it would just be a re-teaching on how to get it in.

Donna Sullivan: Exactly. So you could recommend that that particular one not be grandfathered if you feel it is okay for them to switch.

Diane Schwilke: I was under the assumption that the handihaler was going away and being replaced by the rest of them, but we haven't seen that happen yet. We're still able to get both. So that might be something we have to consider going forward.

Donna Sullivan: We can bring that back if that should happen.

Diane Schwilke: Okay.

Nancy Lee: I recommend not to be grandfathered in.

Donna Sullivan: Is that all drugs or just the Spiriva Respimat?

Nancy Lee: All.

Donna Sullivan: Okay.

Amber Figueroa: I think this is a difficult conversation to have because either way if we say not grandfathering that's potentially up to 7,000 prior auths or something, you know, obviously not that many would do it, but at the same time part of the purpose of this is to provide good care to patients in a cost-effective manner and having all the options in the cost effective... I'm not stating either way, I'm just saying there are multiple things to look at when we're making this decision.

Diane Schwilke: Also looking at cost and if you look at patients with COPD the cost of hospitalization is pretty high and if they have some sort of a difficult transition or they have, you know, they go without for a while just because they don't understand how to navigate, I think that is a concern too. Not all pharmacies unfortunately advocate for their patients in the same way. So I think some patients are going to go without if we don't grandfather. So I would recommend we do grandfather in this case. Except for Spiriva. That's an education thing and that's pretty easy to do.

Nancy Lee: Just a consideration, also cost, but also in terms of comparative effectiveness of these agents, you know, in terms of is one better than another? Those are some things as well to consider, as well.

Michael Johnson: Thoughts?

Amber Figueroa: I recommend grandfathering as well.

Michael Johnson: I think that's reasonable if you look at people who are stable and all of a sudden get hospitalized. That would be... for that number of people. If there's no other discussion I'll go ahead and make the motion. I move to accept the recommended preferred drugs and limitations for the drugs to treat COPD non-preferred products with the exception of Spiriva Respimat should be grandfathered.

Dale Sanderson: I'll second.

Michael Johnson: All in favor say aye.

Group: Aye.

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

Donna Sullivan: So the next class is the inhaled glucocorticoids. We're recommending that Advair Discus and Advair HFA both be preferred. Budesonide Respules, Dulera, Flovent Discus, as well the HFA product QVAR and Symbicort. The non-preferred products are listed on the right hand side. The Pulmicort respules are bolded. Again, that's a class where if the agency decides to go with the brand over generic strategy based on the federal rebates making the brands cheaper there's opportunity that those brands would be preferred over their generics. So within this class the Flovent Discus and HFA are primarily preferred across all of the plans, as well as the Budesonide. So we're in line pretty close... aligned pretty closely with the current status, as well as having Qvar preferred and so utilization I believe you'll see aligns pretty closely if you follow the fives across... pretty closely with what the current preferred status is. The majority of the patients already being on Qvar. These are the Flovent products. Any questions before we go over to the limitations?

Amber Figueroa: Can you show us the highest utilized ones that would be non-preferred now?

Donna Sullivan: They are these ones here.

Amber Figueroa: I wonder at the break is there a way that you could print that out so that we could have it in front of us so that we could better track.

Donna Sullivan: I can see if they can print it, yeah. That's a good point.

So the limitations on the COPD... I'm sorry, the inhaled glucocorticoids it's really that they have tried and failed the preferred products and that the combination products are used, you know, according to the gold standards. And if you... we can also establish that these are also within the root administration. I think they are all inhalers. Any stakeholders?

Michael Johnson: There are no stakeholders for this class.

Donna Sullivan: Okay.

Amber Figueroa: Are we talking about 7,000 people again? Or is it a smaller number? I'm sorry. It's a bigger class so it's harder for me to get a feel.

Donna Sullivan: Let me see if I can highlight the preferred ones. Okay. So the highlighted ones are the preferred.

Jordan Storhaug: Is the Breo Ellipta on that list?

Donna Sullivan: I want to say... there's two things that we needed... I think there's the combination products. That's the total patients.

Jordan Storhaug: Can you tell me which one has 6,000 patients?

Donna Sullivan: The third one up. That one is actually preferred. So the 2,000 patients is the Combivent Respimat which is just the brand. So really the ones that are third and fourth down and the second one up. So these two and this one are really the patients that are impacted.

Lisa Chew: What... for those medications that we... or classes that we decide not to grandfather what are the communication plans in terms of for patients and providers and pharmacists?

Donna Sullivan: So the patients will be get a letter from the plan. I don't know if the plans want to describe what your processes are or... I forget exactly how many days we require them to provide notice.

Piao Ching: We are required to send out the letters 30 days in advance to the members.

Donna Sullivan: I would also say that we do require continuity of care too. So we can look to see whether or not to extend that time period in order to... that 30-day notification in order to provide patients and providers enough time to make necessary changes.

Michael Johnson: I think that probably you wouldn't need to grandfather this class. Any other opinions?

Amber Figueroa: Can you go back to the other one, one more time? The non-combination? So we've determined there's about 1,200 people in the combination group that it would affect and here there's potentially around 8,000 people.

Woman: How many were on the Combivent?

Donna Sullivan: It was like 1,200. I think 2,000. 2,438.

Susan Flatebo: Is the criteria for non-preferred you have to try and fail two of the preferred? Is that the criteria?

Donna Sullivan: Uh huh. Does it say all preferred? So this particular class they have lumped the long-acting combos with the inhaled glucocorticoids. And when I say they this is the supplemental rebate vender giving us these. So I think it would be they would try and fail potentially all within... if it's a single inhaled corticosteroid that they try all of the preferred inhaled corticosteroids. If they want a combination LABA corticosteroid that they would try all preferred combinations before they get a non-preferred combination. So they would have to try Flovent and Qvar before they could get Pulmicort. And then they would have to try... we could say two. I'm not married to the number. If you guys feel that there's a different number that is more appropriate, feel free to throw out a number. I believe Symbicort may be going off the market, but I'm not... I might be starting rumors. If I am, I apologize. There was... somebody had mentioned that to me. So I wasn't sure if there is any merit to that statement or not.

David Johnson: You don't have listed then the newest entry, the generic Air Duo? Do we have any data on that?

Donna Sullivan: Say that again.

David Johnson: The newest entry on this is the Air Duo and concurrent launch of the generic Air Duo combo. You don't have that mentioned anywhere.

Donna Sullivan: I don't. I don't have that data. This utilization is based on calendar year 2016. It was pulled several months ago. We haven't had a chance to update it. So I don't have any... if there are new products since then I don't have any information on those.

David Johnson: Thank you.

Diane Schwilke: Going back to the number I really personally would feel more comfortable with setting a number rather than saying all. Because this is such an intermixed confusing class grouping anyway I think we should assign a number and I'd like to see two or three. I'll just say two. Especially considering there are going to be multiple plans that are going to be deciding how they are going to go forward with this rule.

Susan Flatebo: I agree that it should be two also.

Michael Johnson: Any further discussion? Shall we start looking at a motion?

Amber Figueroa: What do people think about grandfathering or not grandfathering? I feel like if we... we could use the same criteria for why we decided to grandfather for COPD because this involves even more people. But at the same time I feel like there are some more options in the class for them to try, as well, but they may not have tried the four because... what we would consider non-preferred was considered preferred by their previous plan.

Lisa Chew: I think I would recommend not grandfathering in, but I'm open to other thoughts from the committee.

Donna Sullivan: If you feel differently, you know, you can grandfather like the corticosteroids separately from the combinations if you feel that there is more disruption in the corticosteroid arena. What I might say is be permissive. Instead of saying should maybe we should say may. So if we... as the plans decide to grandfather because we don't want to be inundated with too many prior authorizations that we might make that... we may grandfather them, but we don't have to if you don't feel that they need to be grandfathered. So that we can go back and work with the pharmacy directors amongst the plans and really evaluate kind of the volume of impact this would have on us as plans in addition to providers. So instead of saying they should not be grandfathered, you know, do you want to say they may be grandfathered and let us make that decision? Unless you feel that they should. I think if you want them grandfathered you should say they should be grandfathered. If you don't want them grandfathered maybe we could say they may be grandfathered and then we can make that decision ourselves based on volume and disruption and what we feel that we can handle.

Jordan Storhaug: I don't have a strong opinion at this point, but I'm definitely leaning towards grandfathering all of these people in just for the consummating.

Lisa Chew: I like the may be grandfathered in option.

Amber Figueroa: In thinking clinically about who's on an inhaled steroid versus a combination usually you're sicker kids are on a combination so I'm wondering if we should grand... even though it's a smaller amount of people, but they are probably the ones who are more likely to end up in the hospital with an exacerbation if we mess with them. So I'm wondering if we should split like Donna said we could about grandfathering the combination... requiring the grandfather for the combination, but not required it for the steroid alone. What do you guys think?

Michael Johnson: When you look at the utilization data is this just in adults or is this kids and adults?

Donna Sullivan: This is everybody.

Michael Johnson: So we don't really have a good idea. Are these kids with asthma or are these COPDers? We don't know. So that's another thing to consider. I like the may... they may be grandfathered. That way it gives... because there's a mixed population I like that. Instead of saying they have to do something or they shouldn't, but they may. They will have records. If someone is on their fourth steroid then that's the one I would grandfather. But if it's somebody who was just started on Pulmicort and didn't try anything else that's the one I would try on a different one. You know? If we say they may be grandfathered it would give the plans a little more flexibility. Would you guys agree with that? I see heads shaking.

Piao Ching: I agree.

Michael Johnson: Okay.

Donna Sullivan: I just want to say that we will make a decision and everybody will do the same thing. So if we grandfather all of the plans will grandfather, all of the programs will grandfather. I just want to let you know that it will not be up to the plan to make that decision to grandfather or not. So we will make that decision and everybody will be the same. Do you want to grandfather Combivent since there is a generic for it?

Jordan Storhaug: I'm not sure if Combivent is in this category.

Donna Sullivan: I'm sorry. Never mind.

Amber Figueroa: I just want to clarify. If we say may be grandfathered that doesn't mean that the plans are going to go through each person's thing and decide if... and see if they've failed two already. Right? That means that whatever is decided to grandfather or not then that will just be handed down. So if we don't grandfather the only way they would get it would be if someone... if the provider submits a prior auth and says that they have failed two. Nobody is going to sit and push numbers and see if they failed two and so we will grandfather that one.

Donna Sullivan: So potentially what we could do is we might not have a long enough look back period, but you could look back in the claims and see if there is a history in the claim for those other two products, but I don't know how long a patient would be on these medications before they would switch to a different one. I don't think we could go back several years to see, you know, five years ago did they try these? What do the plans think?

Petra Eichelsdoerfer: For some of these agents they were only introduced within the last year or two and so... and some of the plans do have them as preferred now and have for around a year or so, since they came on the market. There are people who may have, for example, been on Advair and then they switched to one of the other agents that's there. So there's... because of a formulary change and then now they would have the option of going back or staying on the one that they're on—both of which are now in the listed preferred category.

Donna Sullivan: What would you as a plan, what would be your inclination to grandfather or not grandfather based on the utilization?

Petra Eichelsdoerfer: When we made the switch with our plan a few years ago it was quite disruptive on... because of the fact that we actually moved Advair off the preferred list. Advair is now going to be on the preferred list and so... I think it's reasonable to not grandfather.

Emily Transue: So by saying they may grandfather you're essentially entrusting Donna and the plans to sit down and look at, you know, how would they set up those criteria? They might look and say we'll grandfather kids. We won't grandfather adults or we'll grandfather... it would be the same criteria, but allowing them to make that decision based on disruption as opposed to clinical decision-making.

Donna Sullivan: That's a good point, Emily, that you could say, you know, if you're concerned about children you could say that children must be grandfathered or 18 and younger or versus adults. So that's another thing to think about.

Michael Johnson: I like the may part because this is mixed data and we don't have privy to who is on the products. I think that's probably the best.

Lisa Chew: I agree. I think the population are so heterogeneous it's hard to say do for all or none.

Michael Johnson: Any further discussion? For the inhaled glucocorticoids I move to accept the recommendation... or the recommended preferred drugs and limitations, the inhaled glucocorticoid class non-preferred products may be grandfathered at the discretion of the agency.

Amber Figueroa: I second.

Michael Johnson: All in favor say aye.

Group: Aye.

Michael Johnson: All opposed same sign. All right. The motion passes. Are we coming up on break time here?

Donna Sullivan: Yes.

Michael Johnson: We'll go ahead and get started.

Donna Sullivan: While we're waiting for the print outs to continue printing I want to respond to some questions that I've been asked during the break. One of those questions is to kind of further explain, you know, how the Medicaid PDL process is going to work compared to our Washington preferred drug list. We have... this group also convenes as a Pharmacy and Therapeutics Committee and under that authority the Pharmacy and Therapeutics Committee is making decisions on the Washington preferred drug list. The Washington preferred drug list is used by the state... all state agencies that are to purchase... that purchase health care services. So those decisions are impacting Uniform Medical Plan for the public employees, Labor and Industries, as well as Medicaid. The Washington PDL also has the Therapeutic Interchange Program with the endorsing providers and dispensed-as-written on certain non-preferred products. What we're doing here, because this is specific to Medicaid for the preferred drug list we are having you convene as the Drug Utilization Review Board so that your decisions only impact the Medicaid program. Because we have the managed care plans following this preferred drug list, the therapeutic interchange program does not apply to the managed care plans and it doesn't apply to drug classes that are outside of the Washington preferred drug list. So those 30 some odd drugs that

are on the Washington preferred drug list often people think that that is the Washington Medicaid PDL, but it's not. It's the Washington preferred drug list. Those are the only classes where therapeutic interchange applies and it will apply only for the Fee-For-Service Program. The managed care plans will not be implementing therapeutic interchange and therapeutic interchange will not apply to drug classes that are not on the Washington PDL. So some of these drug classes we're reviewing today are and some of them are not. So I just wanted to make that clarification.

Michael Johnson: Questions? Thank you for that. Are we ready to start with MS medications?

Donna Sullivan: Yes. So the MS agents you did review this, I believe in June, at the last meeting and we are recommending that the preferred products be Avonex, Avonex Pen, Betaseron, Copaxone 20 mg, Gilenya, Rebif, Rebif Rebidose and Tecfidera. And that the non-preferred agents are listed on the right hand side. You'll notice now Ampyra is on the list for the MS drugs. I want to point out that it is not used to treat MS. It is used to treat one of the symptoms and help improve movement, but we are including it as a decision on a preferred status for this particular class. So I'm going to go to the limitations since we don't have the spreadsheets printed out yet.

So this is kind of a complicated class. We did our best to try to consolidate what all of the plans are doing within the MS space. All of the plans require a specialist to prescribe the MS drugs or for the MS drugs to be... or for them to be prescribed as a result of a consultation with a specialist. And so if it's a consultation with a specialist we would ask them to include their... those notes from the specialist.

We don't feel that it is necessary to require an MRI that the standard of practice of diagnosing MS is to do an MRI. So we're not going to require that that be submitted or that's our recommendation. We recommend that they only... that they are on monotherapy, only one medication to treat MS, no age limits. Some of these drugs are not indicated in children, but some people that are less than... sometimes MS does present at an age below 18 so we felt that it would be important to allow those patients to be treated. We would require that they do submit the expanded disability status scale or the EDSS. We're not recommending a certain cutoff or threshold or anything for having to get through that barrier in order to get approval, but we just want to be able to track as we renew the approvals if the patient is actually improving. We would... as far as non-preferred products recommending that they have a history of failure of contraindication or intolerance to preferred... to two preferred products. And then people using two MS drugs at the same time

would not be allowed and then exclusions based on package labeling and contraindications for Aubagio or concurrent use with leflunomide, severe hepatic impairment, active chronic or chronic infection, a positive TB skin test without treatment. I don't know what that *and* is there for. And then Gilenya the class three or four heart failure in the last six months, [inaudible] use of Class 1 or Class 3 anti-euthymic drugs, an active infection, vaccines within two months of initiation of therapy, and concurrent use of a neoplastic, amino suppressive or immune modulating drug and one of the plans had diabetes and I can't comment on why Gilenya is not used in diabetes. Any discussion about these? We felt that these criteria would be used pretty much regardless of what the actual diagnosis was. There was very little difference between the diagnostic-specific test that we are required from the health plans.

So it looks like we have the spreadsheets to pass out. So we'll go over to the utilization.

Michael Johnson: We're on the last page of the spreadsheet at the very bottom, MS agents.

Amber Figueroa: Question about the Copaxone 20 versus 40. It looks like 62 people are using... nope, me bad. Twenty-four people are using 20 and 149 are using 40. Is there a reason... what was the reasoning or can people just take two mL instead of one? Or...

Donna Sullivan: I would have to ask our vendor on the reasoning on that. I believe that this will be a class where it might be... there might be the brand over... in this case it will be the biosimilar pricing. So I really can't answer that question right now. If you feel that you want that Copaxone 40 and it should be added to the preferred list then that is something you guys can recommend as the board.

April Phillips: Copaxone 40 is only dosed three times a week where the 20 is dosed every day. I don't know if that helps.

Amber Figueroa: I know overall we're talking pretty small numbers of a pretty devastating disease, but I'm concerned that the... of the three most used agents two of them are not preferred. So Tecfidera with the 222 is preferred, but the Glatopa and the Copaxone 40 are not preferred.

Donna Sullivan: And it's the Glatopa 20 mg is the biosimilar for Copaxone 20 mg. So this will be a case where we'll have to go back and re-look at the financials between the biosimilar and the brands for Glatopa and Copaxone.

Amber Figueroa: My feel on this class is that these people should be grandfathered in. A lot of them have already tried and failed stuff anyway and that's why they are on what they're on. I think it's appropriate to have new starts be guided by our criteria, but that the people that are on what they are on should be grandfathered.

Lisa Chew: I would agree with that. I think it would be very disruptive to patients to switch.

Donna Sullivan: Do we have any stakeholders?

Michael Johnson: We do have four stakeholders. So we'll call the stakeholders now. The first one is Margaret Olmon, followed by Mary Fitzpatrick.

Margaret Olmon: Good morning. I'm Margaret Olmon. I'm with US Medical Affairs at Abbvie and I'm here to answer any questions you might have about Zinbryta. And I also want to thank you for requiring that there be only two preferred agents be tried before a non-preferred agent is available to this patients. I feel it is really important for patients with MS to have an opportunity to try medications with a unique mechanism of action as we see with Zinbryta. So I'm here to answer any questions and if there aren't any I'm going to give you the rest of the time back. Thank you.

Michael Johnson: Mary Fitzpatrick. Next up will be Maria Agapova.

Mary Fitzpatrick: Good morning. My name is Mary Fitzpatrick. I'm a medical science liaison with Biogen and I've been in multiple sclerosis for 25 years. Prior to joining Biogen I had a clinical practice as a nurse practitioner in MS. I was at the Portland VA MS Center of Excellence and OHSU. So I'm here today to provide follow-up to the testimony provided by Linda Finch on June 21st.

My understanding is there was some confusion about the label in the REMs program so I wanted to reiterate that there is nothing in the current Tysabri label or in the REMs program that would restrict Tysabri use first line. This is important especially in patients with highly active aggressive disease. You've heard the term time is brain. Just like in stroke it's the same with MS. If the patient continues to relapse and does not recover from those disabilities and then sustains axonal death there is nothing that we can do to turn it around. There are great treatments for MS currently. We have 14, but we're not in a place where we can put axons back together.

I know Linda provided testimony on the efficacy and safety of Tysabri in the early clinical trials. So Tysabri has been out for 10 years. In the Affirm Trial in a

subgroup analysis of highly active patients, Tysabri compared to placebo the relapse rate reduction was 81% and disability reduction over 12 weeks was 53%. So you take the clinical trials data and you say, "Can you replicate this in the real world?" So our long-term real world effectiveness is very similar to the Affirm Trial. There's a top Tysabri observational program which is an ongoing study multi-international following patients out to 10 years. And so data at seven years has been presented at recent congresses. What we know is that patients who initiated [inaudible] Tysabri early on with low disability or early in the disease course stabilized and not only stabilized they actually improved on their disability scores. So that is very important.

In addition to that, what do the professional organizations say about more aggressive therapy early on? So the consortium of MS centers and the MS Coalition came out with updated treatment guidelines in March of '17 and it states, "Because the severity of the disease varies at onset with some individuals experiencing early aggressive disease, patients and their treating clinicians need access to all available options." They go on further to say that, "Tysabri would be an appropriate high efficacy drug to offer to patients early on." In addition to that the American Academy of Neurology also endorses Tysabri...

Michael Johnson: Can you wrap up? Your time is up. Thanks.

Mary Fitzpatrick: In closing I would ask you to reconsider your criteria that patients are required to fail multiple therapies before they get to Tysabri. Thank you.

Michael Johnson: Maria Agapova followed by Lee Ding.

Maria Agapova: Hello. My name is Maria Agapova. I'm a medical outcomes liaison with Teva Pharmaceuticals. At the committee meeting on the 21st the P&T Committee, I spoke in support of Teva Copaxone 40 mg highlighting an additional two years of experience in exposure to the 40 mg Copaxone as a [inaudible] extension study. I'd like to ask today that glatiramer acetate 40 mg stay on remain on the formulary or the preferred list as in the Glacier Study comparing 40 mg to three times a week to daily 20 mg administration of Copaxone the annualized injection-related adverse events and the rate of injection site reactions were reduced by 50%. So that indicates there is a difference in patient experience with the two administrations. That's all I have. If the committee has any questions I'll yield the remainder of my time for that. No? Thank you.

Michael Johnson: Thank you.

Donna Sullivan: I have a question for April. I might not have completed this, but when we were having the conversation with MS did we... were we thinking that if they had primary progressive disease that they did not have to try and fail the two preferreds? I forget that's what we were...

April Phillips: Correct. Ocrevus came out and it's the only one with an indication for primary progressive. So if that's the diagnosis we're not going to force them to try and fail.

Donna Sullivan: I just wanted to put that out there. It's really for the non-preferred. So I would say even potentially Tysabri to the former speaker's point was that if they have primary progressive disease that we would not require them to try the preferred products; mostly because they probably already have tried the preferred product. I just wanted to make that clarification.

April Phillips: On the Tysabri, the previous June presentation, I misspoke and said that our criteria was based on the REMs and it wasn't. The PA criteria was put on in 2006 and at the time it was based on the REMs program and the labeling for that time, which recommended that Tysabri was not used as a first line. Since then things have been updated except for our PA criteria at the time. Sorry, that was my fault. I misspoke on that.

Donna Sullivan: I forgot we have one more stakeholders.

Michael Johnson: Lee Ding.

Lee Ding: Good morning. My name is Lee Ding and I work for Genentech in the medical affairs division. Today I'm going to present Ocrevus, which is listed on the non-preferred list right now. After I'm doing with my presentation hopefully the committee would consider moving Ocrevus for both PPMS and RMS to the preferred list. That's my ask.

Let me go on with the clinical presentation. Ocrevus is a CD20 directed [inaudible] antibody indicated for the treatment of patients with relapsing multiple sclerosis in primary progressive forms of MS.

Safety information – the most common adverse reaction for Ocrevus anything greater than 10% or upper respiratory tract infection, infusion reaction, and in the PPMS or upper and lower respiratory infection including infusion reaction and skin reaction. So for further details on adverse reactions please refer to the package insert.

Dosing of Ocrevus is administered by IV at the initial starting dose of 300 mg and subsequent 300 mg within two weeks period and subsequent dosing is 600 mg every six months. So that is twice a year.

Clinical experience based on pivotal trials – so we conducted a total of three trials. Two trials for relapsing MS and one trial for primary progressive. For RMS there were two identical head-to-head studies of Phase 3 trial going against one of the preferred drugs on the list, Rebif, which included more than 1,600 patients. Both studies met the primary end point for annual relapse rate at 96 weeks, which is two years with relative reduction of 46% and 47% respectively comparing with Rebif... over Rebif. Secondary endpoints were also met. A pool analysis of the proportion of patients with 12-week confirmed disability progression [inaudible] on the EDSS scale that you outline in your PA criteria show a 40% risk reduction and key MRI endpoints show relative risk reduction of about 95%. Other endpoints such as... most specific MRI endpoints of T1 [inaudible] enhancing lesion the relative risk reduction was 70... about 80%. In the mean number of a new and [inaudible] T2 hyper intense lesion. So for the PP, primary progressive population we studied the drug in a randomized placebo-control since there's really no proof... FDA approved medication for this subgroup of patients.

Michael Johnson: Can you wrap up? You're three minutes are over.

Lee Ding: I'm going to jump to the summary real quick. In summary Ocrevus has demonstrated superiority over Rebif for RMS and has proven efficacy in PPMS which is the only FDA-approved drug. Ocrevus is given at 600 mg every six months twice a day after the initial two intrusions and it has no black box warning and no REMs program associated with the drug. Thank you.

Michael Johnson: Thank you.

Donna Sullivan: I just want to go back to the policy. What we did not mention was that the primary progressive multiple sclerosis I just want to reiterate that they would not require the tried-and-failed two preferreds.

Amber Figueroa: I guess I still have an issue with these 149 people who are on Copaxone 40. I guess if we are grandfathering them in then that's fine, but the difference between the 20 as a daily injection versus three times a week and I think these patients are already taking a lot of other medications a lot of times for the symptoms related to MS and if we can decrease their injection... I mean I don't know the cost difference, but... I don't know. Thoughts on that.

Diane Schwilke: To me the cost would be really key. If it's a small difference then that makes sense to let them inject less. But if it is a huge cost difference...

Donna Sullivan: I don't know exactly what the cost difference is, but there is a difference and it has to do with the federal rebates for the products. If you wish... if you don't feel like you want to make a decision today, anything that doesn't get... if we don't get to it today we could bring it back next month and we might have more information regarding cost and... especially for the branded products that potentially might be less expensive than their generics or biosimilars. That's also a possibility if you don't feel like you want to make a decision today.

Amber Figueroa: In our motion can we specifically say moving one to the preferred if the cost...

Donna Sullivan: I think what you could say is that we should have a... the generic name has sailed out of my head. That the equivalent to Copaxone 40 mg there should be a 40 mg product on the PDL. It will either be... the reason why Glatopa 40 is not on this spreadsheet is there was no utilization for it, but there is a Glatopa 40 on the market. So it would either be Copaxone 40 or the Glatopa 40 that would be preferred. Glatopa, remember, is the biosimilar to Copaxone.

Amber Figueroa: What's our motion look like?

Michael Johnson: How do people feel about grandfathering? Should we say may or should?

Jordan Storhaug: I do speak in favor of grandfathering these patients.

Michael Johnson: If we say something like that... should with the exception of biosimilars. If we...

Donna Sullivan: I'm sorry?

Michael Johnson: If we say they should be grandfathered with the exception of biosimilars is that... I'm trying to figure out how to word this.

Donna Sullivan: If you want to recommend that the equivalent to Copaxone 40 product be added I can add it on here. So I can put Copaxone 40 mg or its biosimilar. Is that what you're trying to get accomplished? So this is the new recommendation then. And then I don't think you need to address anything about biosimilars here in the motion then.

Michael Johnson: Perfect. Any other discussion?

Dale Sanderson: I move to accept the recommended preferred drugs and limitations for the drugs to treat MS. Non-preferred drugs should be grandfathered.

Amber Figueroa: I second.

Michael Johnson: All in favor say aye.

Group: Aye.

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

Donna Sullivan: The next class is the cytokine and CAM antagonists, also known as the TIMs class when look at it with the P&T Committee, but this is what our supplemental rebate vendor called this class. I'm not sure which spreadsheet page it's on. The spreadsheet, if you want to know, is ordered by the generic product identifier number. So that's the reason why it is in the order that it is and doesn't follow the slides. We are preferring... recommending Enbrel and Humira to be preferred and all other drugs in this class be non-preferred. That is, I believe, currently the case with all of the health plans, at least the Enbrel and Humira are preferred and is the PDL... has been that way for the Washington preferred drug list for many years now.

Amber Figueroa: It's under analgesics on the first page.

Diane Schwilke: The Humira pen kit is in preferred and non-preferred.

Donna Sullivan: That is a good question. I would have to go back and look at the...

Julie Hartford: The Humira pen kit is in the preferred.

Donna Sullivan: Okay. So I will jump to the utilization. And if you're ready we can talk about the limitations. So what we are looking at is with this particular class most of these requirements are very similar, but they are slightly nuanced. Ankylosing spondylitis that they have to have active ankylosing spondylitis, age over 18 years, a negative TB test and then history of trying either NSAIDs, DMARD or non-biologic DMARDS and then tried and failed two preferred biologic agents and the prescribed by rheumatologist and most of the plans had very similar criteria regarding ankylosing spondylitis. Crohn's disease that they have moderately to severely active Crohn's disease, age 6 or more for Humira, [inaudible] and Remicade and 18 years of age for Cimzia, a negative TB test for all of these. That they have tried and failed Humira and that it is prescribed by a gastroenterologist and that it is used in combination with any of the following –

a non-biologic DMARD... I'm sorry, it would be excluded if it is being used with another biologic DMARD, a [inaudible] ACE inhibitor or PDE4 inhibitor. There are a bunch of different diagnoses within these classes and most of them it's... again, they have the diagnosis that the appropriate specialist is prescribing it and that they are not using other treatment and... I'm sorry, I did not know this wasn't that big. So juvenile idiopathic arthritis that they must be greater than or equal to 2, negative TB test, that they have tried NSAIDs or at least one NSAID or a corticosteroid and at least one non-biologic agent DMARD that's prescribed by a rheumatologist. Plaque psoriasis, again that they have to have moderate to severe psoriasis, 18 years of age, that they've tried photo therapy or other systemic therapies and it is prescribed by either a rheumatologist or a dermatologist. Psoriatic arthritis pretty much the same. It can be prescribed by rheumatology or dermatologist. And rheumatoid arthritis pretty much the same. That they've tried and failed the two preferred products before they get the non-preferred product for rheumatoid arthritis. Ulcerative colitis – that they've tried conventional therapy and that they've tried the preferred products. And then there is uveitis – that they have tried conventional therapy and it's a specialist and I think that's it. Any questions about those criteria?

Amber Figueroa: It looks like the majority of the patients are on covered meds, but for the ones that are... would have to be switched I would favor either grandfathering or doing that extended 90-day period instead of just 30 days to give providers a chance to complete the prior auths to say that they have failed. So there is less likely an interruption in their treatment.

Michael Johnson: Before we do that we have several stakeholders. We'll call these one at a time. Michele Mui is first followed by David Gross. Again, we have a three-minute time limit just to try and get through everything.

Michele Mui: Hi. Michele Mui, I'm a medical science liaison for immunology and managed markets for... at UCB. I'm here to support Cimzia. I just wanted to let you know it's a structurally unique TNF inhibitor with an active fab region and it is FDA approved in ankylosing spondylitis, rheumatoid arthritis, Crohn's disease and psoriatic arthritis. So I just want to start off by saying that there are a significant number of women suffering from chronic inflammatory conditions who are pregnant, who are trying to get pregnant or who choose to breastfeed their infant and for the mother it can be a very agonizing decision whether to either start or continue therapy if there is a perception of risk to their baby. The data showed that for these women the [inaudible] control is a direct correlation to better outcomes for both mother and baby. So UCB has a very strong commitment in this special population, the women of child-bearing age and as you know the recent FDA changes to labeling for pregnancy lactation make it

that there is a real necessity for data to share in the scientific community and to add information for the physicians to share with the patients and give reassurance. There is some recent clinical studies that have been prospective in the pregnant and lactating women and that these were recently published and these results from Cimzia in a placental transfer, a milk transfer study, show minimal to below quantifiable limits and Cimzia in both breast milk, as well as infant and core blood. So, you know, maternal antibody transport is really highest in the second and third trimester to infer fetal immunity and this biologic process does not distinguish between a maternal antibody versus a foreign antibody and the unique structure of Cimzia and the lack of an [inaudible] region has been suggested for this decrease active transport. Other fully monoclonal antibodies with an FC region have been detected in infants up to seven months. So a [inaudible] on board at infancy and this is due to really their immature immune system. For all of the side effects and potential side effects of Cimzia please refer to the complete prescribing information.

I was really happy to hear that one of the opioid dependent medications has an authorization process in pregnant women and so I really ask at this time that you consider having such a process for Cimzia for... if the mother is pregnant... if the patient is pregnant or breast feeding or wants to become pregnant and this is my ask of you. Thank you.

Michael Johnson: Thank you. David Gross is next followed by Mary Kemhus.

David Gross: Good morning. My name is Dave Gross and I'm with the medical affairs division of Pfizer. I know this isn't a P&T Meeting so I'll be very brief and hit some highlights. I'm here to support Xeljanz and Xeljanz XR. Xeljanz is an oral small molecule [inaudible] ACE inhibitor and it's indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response for intolerance for methotrexate. It's dosed 5 mg twice daily with the Xeljanz or 11 mg once daily with the Xeljanz XR. As you know rheumatoid arthritis is a costly condition to treat and drugs one of the high cost items. Therefore the judicious use of agents in this class need to be considered, especially among non-responders to a first therapy.

As many as 50% of patients do not respond to methotrexate within two years so often times these patients are in need of other medications. In a study using Corona registry data there were 28% to 40% non-responders to first and sequential second anti TNF biologics after 12 months and many formulary designs, including this one, require that two TNF inhibitors be prescribed before a provider can prescribe a non-TNF agent.

In conclusion, RA is costly to manage, but to manage the disease effectively there needs to be alternative disease modifying agents available earlier in the formulary continuum and adding medications with a novel mechanism of action and available for oral administration and potentially removing barriers for the ability for providers to utilize products with alternative and novel mechanism of actions would greatly benefit patients suffering from rheumatoid arthritis in our Medicaid population. Thank you very much. I'd be happy to answer any questions.

Michael Johnson: Thank you. Mary Kemhus followed by Margaret Olmon.

Mary Kemhus: Hi. Thanks for allowing me the opportunity to testify. I'm Mary Kemhus and I'm a pharmacist with Novartis Medical Affairs. So today I'm actually asking that you reconsider the criteria to require patients to try and fail two preferred agents before accessing Cosentyx, specifically the current preferred agents act by the same mechanism, they both act on the TNF pathway and in patients with autoimmune conditions as the previous speaker mentioned it's important to consider alternate mechanisms of action. So requiring that a patient try and fail the same mechanism twice doesn't always make sense in these conditions. Additionally, in psoriasis, there's actually comparative data showing that Cosentyx has significantly better posi outcomes versus etanercept, one of the preferred agents. So in light of the comparator data which is available multiple indications including psoriasis, ankylosing spondylitis, and psoriatic arthritis, and long-term safety and efficacy, which now goes out to four years in psoriasis, I would ask you to consider taking another look at the requirement for patients to try and fail two preferred agents before accessing Cosentyx. Thanks. And I'm happy to take any questions.

Michael Johnson: Great. Thank you. We have Margaret Olmon followed by Chris Conner.

Margaret Olmon: Hello again. I'm Dr. Margaret Olmon with medical affairs at Abbvie and I want to thank you for the opportunity to be in front of you today and talk a little bit about Humira. I realize this isn't a clinical discussion so I'll make this very short, but if you have any questions I do have the prescribing information with me and I can answer any questions you might have.

I want to remind you and thank you for putting Humira on the preferred list of drugs for the TIMs class. It includes 10 indications in its profile and it's been most recently approved for the treatment of patients with non-infectious intermediate posterior and panuveitis in adult patients. It follows nine other approved indications for Humira, which include moderate to severe rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, psoriatic arthritis,

ankylosing spondylitis, Crohn's disease, chronic plaque psoriasis, ulcerative colitis, pediatric Crohn's disease and hidradenitis suppurativa. With over 70 global clinical trials, which I won't review today, enrolling over 23,000 patients, Humira has a well-defined published benefit to risk database. As a targeted immunomodulator patients treated with Humira are at increased risk for developing serious infections that may lead to hospitalization or death as do the other drugs in this class. With the proven efficacy and well-established safety profile of Humira and the maintenance dosing across a wide range of indications I want to thank you very much for having this as a preferred agent on your PDL and I would like to have you continue to have Humira as an option for your patient. Happy to answer any questions you might have. Thank you.

Michael Johnson: Next up is Chris Conner followed by Sylvia Churchill.

Chris Conner: Hello. I'm Chris Conner with Bristol Myer Squibb and before I came back into the industry with BMS I was actually working as a consultant where I was assisting in the management of formularies for two large ASO employers that had custom formularies. So I completely understand and appreciate, Donna, you know, all the work that you're doing here and as a committee, all the work that's ahead of you in the months leading up to January go-live.

But what I wanted to say and I think Amber mentioned this before you had stakeholders come up and provide comment, but I was thinking this may be the only situation where Orenzia or abatacept being an agent that traditionally has had a fail one or two other biologic DMARDs is a good thing, I guess for us in that as you think about where these patients came from and all these other health plans and the number of agents that they had to fail before they had access to Orenzia in many cases you're dealing with a situation where these patients have already cycled through perhaps multiple TNFs. And so as you're thinking about the utilization that you currently have or are seeing with Orenzia that you... that this comes up in the discussion, I guess. I'm encouraged if that is something that you guys do discuss and considering that and what the patients have been there.

The other thing I'd like to mention, and I know this isn't the P&T Committee, but we have had two important updates to our label that I think are worth mentioning since the last time I came up here to testify in front of the P&T Committee. So we're now approved in adults with psoriatic arthritis, and we're approved in children 2 years or older with moderate to severe polyarticular juvenile idiopathic arthritis and I'll yield the rest of my time if I don't have any questions.

Michael Johnson: Thank you. So Sylvia Churchill is up next followed by Carrie Johnson.

Sylvia Churchill: Hello. My name is Sylvia Churchill. I am a clinical pharmacist here in Washington State for the last 20 years. I currently work for Amgen as a health outcomes and pharmacoeconomic specialist and thank you for the opportunity to say a few words about etanercept or Enbrel. Enbrel has been used in the United States since 1998 so we have over two decades of long-term safety and efficacy data, which is reassuring to both healthcare providers and patients. It is approved in rheumatoid arthritis, juvenile idiopathic arthritis, plaque psoriasis, psoriatic arthritis and ankylosing spondylitis. Specifically in children, because this is a Medicaid population, Enbrel is approved for patients 2 years and older with juvenile idiopathic arthritis and we have over 17 years of long-term safety and efficacy data for this indication. Enbrel is also the only biologic approved for pediatric plaque psoriasis in children ages 4 and up. So just to comment on the criteria that you guys had for plaque psoriasis, currently I think it says 18 and over. Just a note that in the last year we did get approval for pediatric. So if that could be changed to age 4 and older if it's for Enbrel. Please see the Enbrel PI for specific safety and efficacy information. Can I answer any questions about etanercept? All right. Thank you very much.

Michael Johnson: Thank you. Carrie Johnson and following her will be Lee Ding.

Carrie Johnson: Hi. I'm Carrie Johnson. I'm a pharmacist and medical liaison with Celgene. Thanks for the opportunity to talk in support of apremilast or Otezla. Apremilast was approved in 2014 indicated for adult patients with active psoriatic arthritis in patients with moderate to severe psoriasis who are candidates for photo therapy or systemic therapy. I want to highlight some key reminders about the product that I'd really like you to consider and then give you three important updates that support those reminders.

Apremilast is not a biologic. I want you to understand. It's a completely different profile for this product. It's a small molecule that gets inside the immune system cells and inhibits [inaudible] or ACE 4, inhibition of that enzyme through pathways tells the cell to reduce its production of pro inflammatory cytokines and increase its production of anti-inflammatory cytokines. So it's going to work on TNF, isle 17, a multiple cytokine instead of just one targeted cytokine. In terms of safety that has implications because you're not trying to ablate one cytokine profile. We have no black box warnings with this product. No warnings or precautions even for infections and malignancies, no laboratory monitoring, no prescreening. This product has a profile that's similar in terms of safety in patients under 65 and over 65. That's different than what you see with the other products.

In terms of efficacy it also has implications. We're not just mopping up excess cytokine. The FDA sets an endpoint at week 16 for ACR and posi responses. This product profile continues out to week 40. The biomarkers for those cytokines continue to change out to week 40 in our controlled periods of our trials we see an increase in efficacy out to week 52 with this product. Important update on that are long-term data in psoriasis and psoriatic arthritis shows no increase in safety signals, no new safety signals. We still have no black box warnings, no warnings for infection and malignancy. In terms of efficacy we show durable and sustained responses. Again, this product is not a biologic. It doesn't elicit an anti-drug antibody response by the body. It has a flat dosing so you're not going to see up dosing with regards to this product. Please refer to the PI for the warnings and precautions related to this product. They are related to nausea, vomiting, diarrhea, weight loss, depression and drug interactions.

Three key updates that support that unique profile – long-term safety and efficacy data for psoriasis and psoriatic arthritis now out to three years in psoriasis and four years in psoriatic arthritis. Our psoriasis safety data out to three years from our esteemed trial program. It's fully published now just a few weeks ago in the Journal of American Academy of Dermatology. Again, no indications that this drug effects malignancy infection rates in these populations. In fact, the Institute for Safe Medication Practices at ISMP.org pulls apremilast out of the category of biologics putting it in its own category because, "It has no identified immunal suppressant properties." This product works very, very differently. Right now in your current situation you are pushing patients through two products that work on a specific cytokine, TNF, that have black box warnings and laboratory monitoring requirements.

Michael Johnson: Can you wrap up?

Carrie Johnson: I'll complete it. Thanks. Again, apremilast is a unique product and I'm available if you need any additional information. Thank you.

Michael Johnson: Thank you. The last speaker is Lee Ding.

Lee Ding: Hi again. This is Lee Ding from Genentech. I'm going to be very brief and quick here. I just want to remind the committee or actually... we have a new indication that was just approved May 22nd of this year for Actemra which [inaudible] cell arthritis. So again this is the only medication approved by the FDA to treat this disease and it is dosed once every week. In the trial basically we successfully... patients successfully discontinued a corticosteroid which is the

main stay of therapy and they could be on it for years. So the main thing is to get them off and decrease the dose of corticosteroid. So that's all I have.

Michael Johnson:

Thank you.

Donna Sullivan:

So what I realized was that during this presentation is that some of these drugs are in different classes. They are not considered CAMs and cytokines. So they are not listed on the spreadsheet that we passed out. I've been trying to pull up what that utilization is, which is what we have now on the... being displayed. So Cosentyx – you'll see that on your spreadsheet you don't have these and so we can scroll back and forth if you want to see what the utilization is on some of these other products. I'm trying to do it so we can see them better. It includes the... the psoriasis ones make it difficult because it pulls in dermatology and I didn't have time to ween them all out. So if you want to look at the utilization compared to... for these products we can scroll.

Amber Figueroa:

This is a really tough class because there are so many different mechanisms of action that it almost seems wrong to put them all in one group.

Donna Sullivan:

I'm going to say part of the problem with this particular class is the drug manufacturers have put themselves in this group because they consider all of these drugs competitors of one another because of their indications and so oftentimes, you know, their rebates that they are offering are tied to... if you have one of my competitors in the class whether it be the same mechanism of action or not or possibly it has a unique indication. It does impact rebates. So that is part of the issue with this particular class. It makes it very complicated.

Michael Johnson:

Looking at... I mean it's not a real homogenous group. I mean you're looking at multiple indications as well, multiple disease processes. So I would, you know, because of what we have covered I think that covers most of the clients and then you have a smattering of the off brand and it looks like to me three or four of the seven agencies covered have probably had some of the other ones preferred, which is probably why you might get four clients in this one group who are on this drug or three in the other one. So I mean I'm leaning towards saying they may be grandfathered. I wouldn't try to force this on anybody. What does the committee think about something like that?

Amber Figueroa:

I think that they should be grandfathered. I think a lot of these people probably have already done some step therapy. I do have a concern about 171 people on the Otezla. And I also like that it doesn't have the infection risk and the malignancy and there is less lab monitoring. I really feel like... I also like the discussion about the women of children bearing age and the breastfeeding, but

I don't know if any of the others have that potential option, as well. I feel like we need some more education in this group.

Donna Sullivan: I'm not sure if that is something that DERP is including in their reports or not, but lack of evidence doesn't mean evidence of not occurring. I think they are the only ones that have done those studies as opposed potentially to the other drugs. I'm not sure. I don't know what the body of evidence is out there right now.

Jordan Storhaug: I am heavily in favor of grandfathering these people and that so many of these programs have had Step Wise programs wherein some of these issues where the preferreds have just married it seems like in this drug class that virtually all of these patients likely have gone through a Step Wise program. I think it would be an unnecessary burden to force them to go through that process again.

Donna Sullivan: I'm just scrolling through looking at the concordance and it is kind of all over the board. It looks like most of the plans have at least Enbrel and Humira preferred and then it's kind of like a smattering across all the other ones—half of them do, half of them don't. My thought would be to write... I would feel that this should be a class that would be grandfathered. You have made that decision as the P&T Committee I think in the past too that they are not interchangeable and so you wouldn't require them to switch. So that would be consistent with what this group has done.

Diane Schwilke: Can we also look at the limitations one more time?

Donna Sullivan: Is there a particular diagnosis that you're interested in?

Diane Schwilke: I think we have a little inconsistency and some diagnoses say one or more preferred, some say two or more. Do we want to be consistent with that?

Donna Sullivan: I think that is diagnosis related because not all of them are... they don't all have the same indication. So like Humira is indicated for Crohn's. So if you were going to try Remicade you wouldn't... it would be inappropriate to say you have to try Enbrel and I'm not sure if there are two with Crohn's disease indications other than those two. So I think that is the reason. Why there's either one or two, but we can scroll through and look to see what they are.

Jordan Storhaug: What I'm hearing you saying is that really for all of these the requirements is that they have to try all indicated preferred medications. Sometimes that is one and sometimes that is two.

Donna Sullivan: Correct. And with hydra [inaudible] we won't... we don't... there is no tried and failed on that one... for that diagnosis. So they are really diagnosis specific. Again, if you want us to bring back more information or if you're not ready to make a decision on this class that's an option too and we can try to revisit it next month. I think right now we're... decide if may or should.

Lisa Chew: I would be in favor of should be grandfathered.

Donna Sullivan: Thank you.

Amber Figueroa: I move to accept the recommended preferred drugs and limitations in the cytokine and CAM antagonist class. Non-preferred drugs should be grandfathered.

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

Group: Aye.

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

Donna Sullivan: It is now lunch time so we are going to go ahead and take a lunch break.

Michael Johnson: We'll reconvene at 1:00. Thank you.

We'll go ahead and reconvene the Drug Utilization Review Board. I think we left off on growth hormone. We'll go ahead and start there. There are no stakeholders for this topic.

Donna Sullivan: So the growth hormone class... if you don't already know growth hormone products are also atotropin. So the products that are preferred the genotropin and norditropin were selected strictly based on the price of those compared to the products that are considered not preferred. And the preferred products that are being recommended are the genotropin and the norditropin.

I'm pulling up the spreadsheet since I see you guys are already looking at it. I've highlighted the preferred drugs.

Dale Sanderson: Is there an advantage to the omnitrope? I mean there's a number of patients who are on it.

Donna Sullivan: In my opinion I don't think there is an advantage to omnitrope. It's likely that the three plans have it preferred and are steering their patients towards

omnitrope, away from the others. So this is a class where the plans/formularies are quite different mostly because of the contracts they are able to negotiate.

We'll move on to the criteria if there's no questions. So this one is a little complicated because again it has multiple indications, but there are... it's pretty much the same. So we're requiring that the prescriber specialty and I would say this would be an endocrinologist or in consultation with an endocrinologist. And then with genetic disease... so with primary effects on growth hormone... growth on the kids that for like Prader-Willi Syndrome they do have to have to have open epiphysis. They have to have genetic testing. The weight should be less than 35... a BMI of less than 35. For Turner Syndrome, again, genetic testing confirming the diagnosis. The bone age needs to be less than 16 years for males and less than 14 years for females. It is similar to the open epiphysis. The mean height growth velocity needs to be greater than 3 standard deviations below the mean or the standing height is two to three standard deviations below the mean with a deceleration of two heights... with a deceleration looking at two heights measured by an endocrinologist six months apart for children greater than one year or four heights measured by a primary physician at least six months apart for kids two years or older or have a growth velocity less than two standard deviations below the mean and be over one year old.

The Noonan Syndrome, again, generic testing. Same bone age for males and females. The same criteria for height and growth velocity. The shocks deficiency, again, genetic testing, less than 16 years for males... same bone age for males and females. Same height and growth velocity. Prader-Willi for adults when they transition from a child to an adult they don't have to go through further testing. So it would be approved. And then we get down to small for gestational age. So for two years old, and we might need to come back to this one at a later time. For birth weight and length below the mean age for the standard deviation would be greater than two standard deviations away from the mean for their age with a failure to catch up by the age of two. Bone age of less than 16 for males and females, which is the same as others. And the same... I know this says chronic kidney disease, but the same growth and height velocity issues. And for kidney disease they have to have structure or functional abnormalities in the kidney, a GFR of less than 60 for three months, or the occurrence of one of each of those together for any duration of time. Same bone age. Requires a specialist. Short bowel syndrome they have to be over eight years of age and prescribed by a gastroenterologist and then approved for HIV wasting and cachexia. For somebody over 18 with unexplained weight loss more than 10% from baseline and weighs 90% or less of their ideal bodyweight. And again being... for the cachexia being followed by somebody that specializes in HIV. So I know this one is really sloppy. Questions?

Dale Sanderson: Are there other genetic syndromes? There's hundreds really that might be a factor here. You've got these included specifically, but there are probably a number of them that would fit into this category that are not listed.

Donna Sullivan: These are all of the ones which I believe the drugs have indications for. I'm trying to make this so we can read it a little bit easier. So the primary one is really the growth hormone, the actual deficiency. So they have to show that they actually do have the growth hormone sufficiency and I don't see it on here. So rule out other causes such as pituitary or other hormonal diseases and then they have to have like the two different growth hormone stimulation tests with one of these tests or have three other pituitary hormone deficiencies or have a history of radiation of the hypothalamic area or surgery and CMS abnormalities or a genetic cause. So if there are other genetic causes that might not be one of these diseases but that would impact the hypothalamic or the pituitary then those would be considered on a case-by-case basis. I don't think... I think those would probably be pretty rare.

Here, again, they have to have the two provocative GH tests and responses are less than 10 micrograms per liter or the age less than one year and they have the insulin growth factor one or the IGFBP3 is below the normal adjusted range.

Lisa Chew: I don't know what the implications are from switching from one product to the other, but looking as if omnitrope seems to have the highest number of users in the group whether we... to provide the most flexibility in terms of grandfathering maybe we should say *may be considered*. Grandfather may be considered versus should, but open to others thoughts.

Amber Figueroa: I agree with that. I think leaving some flexibility for them to decide is good.

Dale Sanderson: I move to accept the recommended preferred drugs and limitations in the growth hormone class. Non-preferred drugs may be grandfathered.

Lisa Chew: Second.

Michael Johnson: All in favor say aye.

Group: Aye.

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

Donna Sullivan: Moving on to the hypoglycemics, insulin and related agents. So the preferred products being recommended are Humalog, the different formulations of Humalog, Humulin 500, Humulin 70/30, Humulin vial, Lantus Solostar pen, in addition to the vial, Levemir pens and vial, and then the various Novolog products that are listed. The non-preferred products are listed on the right, which include Afrezza, Apidra, Basaglar, Humulin, Humalog 200 pen, Novolin and Toujeo and Tresiba.

And just by looking at the data most of the utilization is in the Lantus and the Humulin area. I believe that the recommendations marry up pretty well with the current formularies of the health plans, as well as the utilization. It's going to be difficult to put them all up at the same time and be legible. The majority of them are already on a preferred.

Michael Johnson: This is a fairly straight forward class. I think most of the types of insulins you would start with are covered and even in switching I mean it fairly immediate dose response so I wouldn't even think that grandfathering would be necessary unless they had some intolerance to all the other ones.

Jordan Storhaug: Is there an NPH option on the preferred?

Donna Sullivan: You know I believe they are not... we will make sure that one is. I think what it is, is it might be that those particular products like the R, the NPH, are not part of the contracted class with the vendor, but we will make sure that there is an NPH preferred.

Nancy Lee: Is it the Humulin N that is on there? That's the OTC vial.

Donna Sullivan: That might be why because they are over-the-counter.

Nancy Lee: I have a question that kind of goes back to the air duo question with Basaglar. So I know that Basaglar just got... it's the bio similar that just recently got... was in this past year so that's probably why it's not on a lot of the PDLs. I'm just curious, you know, if cost... because it's glargine.

Donna Sullivan: It's very interesting how the bio similar are going to impact the Medicaid program. So the federal rebates with manufacturers also come with what we call a consumer price index penalty or CPI penalty. So as the manufacturer increases the price above the CPI they have to pay additional money to CMS or to the state's Medicaid programs because of that price increase. So as we see over time with many of these drugs that are the older drugs on the market that have gone through these significant price increases over the years and appear

to be very expensive, they are actually the most cost effective drugs after that rebate for the Medicaid program. So in most instances it will likely be that the biosimilars, because they are considered brands, not generics will actually cost more to the Medicaid programs after the federal rebates. Then they are the originator product. So you will see... that's one of the reasons why we were preferring Copaxone 20 and the question about whether or not it will be Copaxone 40 and again why we're preferring Lantus over Basaglar. So that's a great question and it will be interesting moving forward.

Piao Ching: Just keep in mind that the Basaglar like you say is new and most of the [inaudible] actually moved to Basaglar effective July. So the numbers you see on the screen doesn't reflect the market share for Basaglar. So there might be quite a significant switch from Lantus to Basaglar so that will be something you think about whether you want to do grandfathering or not.

Donna Sullivan: We probably won't want to grandfather that just because of the cost. This is one of the interesting things that... with this situation is that, you know, the health plans when they are paying the pharmacies you are paying that higher price, but the state, after we get those federal rebates. So it appears to be more expensive with commercial plans or the managed care plans. That was one of the reasons why they made the switch because financially for them it did make sense, but we're doing really what's the cheapest at the state after all rebates are collected.

Michael Johnson: Any other discussion? There are no stakeholders for this topic.

Diane Schwilke: I just have one question. So we have a concentrated Humulin 500 option here but there's not a Humalog 500. Would that fall under just the vial in general or is that specific to just the regular 100 units per mill Humalog vial? Could they get the 500 or the 100 under that or is Humalog 500 excluded? Because I don't see a lot of use of Humulin 500. If I see it, it's not very common either way. But if I see it it's the log version. It's the newer rapid, more immediate acting insulins rather than the lins.

Donna Sullivan: I would have to double check on that. Julie, do you remember seeing it on any of those lists?

Paige: This is Paige from United. There's... the only 500 unit insulin product on the market is the Humulin.

Man: There is no log 500. There's a log 200. 100 and 200, but not a 500.

Donna Sullivan: So the 200 is on the non-preferred side. I think we were going to the criteria. So our current criteria for type 1 diabetes is that you... we have an expedited authorization code if you have type 1 diabetes. So you don't have to try the NPH first. But you do have to try the preferred products before the non-preferred products would be allowed and we can have a discussion about the all because there are the different types and we'll... we can discuss how that should be determined. And so this one is really looking at just the long-acting insulins and not... this is our policy on the long-acting insulin. So it's not the immediate-release insulins. For the non-preferred rapid acting insulins it's really just try and fail the preferred products. These here are the plans currently preferred products. So we're not recommending those as the preferred. And then inhaled insulin. And then diabetes, type 2 diabetes are current policy is that they have to have tried NPH for three months before they can go to a long-acting insulin and then they have to try... have a history or failure to NPH or have already failed it. I think that's the same. And then just try and fail their preferreds.

Woman: Sorry, Donna. Yeah, that's the same. One is the vial. One is the pen.

Donna Sullivan: It was just a little confusing the way it was set out, but... so it's pretty much the same with gestational diabetes. NPH for one month or try the preferreds. Thank you, April.

Leta Evaskus: I'd like to just remind everyone to state their names before they speak.

Donna Sullivan: Any questions?

Jordan Storhaug: For clarification all type 2 diabetics need to have a trial of NPH before trying a different insulin even though they are preferred?

Donna Sullivan: That is the current policy with the fee-for-service program. I don't know if the health plans... do you have limits at all or PA on the long-acting insulins or do you just have try and fail your preferreds?

Petra Eichelsdoerfer: We do not.

Donna Sullivan: And part of this was looking at the cost of Lantus and doctors were starting to dose Lantus twice a day and the rationale really behind Lantus, you know, why it was supposed to be better is that it was only dosed once a day. So if you're already doing multiple injections a day if NPH was a less costly alternative it made sense to try NPH before you jump right to Lantus. That was the clinical rationale for trying the NPH prior to the long-acting.

Amber Figueroa: So clarifying is that going to apply to the managed care plans then?

Donna Sullivan: Yes. If we go ahead and decide to implement that then, yes, it would apply to the managed care plans as well. However, I might recommend grandfathering. Not necessarily because for clinical purposes, but mostly with the administrative hassle of trying to get through all of that and potentially even, you know, it's up to you if you want to continue that. We're just telling you that those are the current limits with the fee-for-service program. So I put them in as proposed. If you want to stop doing that then we can stop doing that as well.

Diane Schwilke: Working in the pharmacy I work in, since that was implemented there are a lot fewer patients on fee-for-service, but the ones that were, it was a big pain. I have to say that because they are already on Lantus or they are on Levemir and trying to switch them to NPH at that point it's just not feasible. I would love to get rid of that.

Donna Sullivan: Yeah. That was the idea. I thought they were supposed to have been grandfathered if they were currently on a long-acting. So if it didn't work that way then that was a claims processing error in our programming. But that was the intent to implement it with everybody being grandfathered.

Jordan Storhaug: I still feel like that would be a huge change in clinical practice for a lot of physicians in the area where I think kind of what the standard that I'm seeing is that when you're starting insulin you're starting with a long-acting insulin. At that time you're getting away with Lantus once a day and then granted that there is a point where then you need to do multiple injections of Lantus over the course of a day and maybe it would be quite reasonable to switch to NPH at that time, but we would be really limiting people and forcing quite a big physician... change in their practice behaviors that I wish we had better information on the cost differential for that as well because my understanding is that it is not as big of a cost savings as it used to be between NPH and Lantus.

Donna Sullivan: We can look at that.

Nancy Lee: I agree. I think back in the day it used to be a big cost different but now I'm not sure it has that big of a difference anymore. I would appreciate actual data to support that.

Donna Sullivan: I'm going to put a note in here. We'll go ahead with the product that... we'll make sure that there is an NPH product. It will either be the Novolin or the Humulin.

Diane Schwilke: Can we go to those limitations again and kind of look at that and see if anybody has a strong opinion about leaving it in there, because I would love to see us take it out.

Michael Johnson: I agree. I think we should take that out.

Donna Sullivan: Okay. Do you agree on the trying and failing the preferred long-actings before they get a non-preferred long-acting?

Michael Johnson: Yes. With that one change I agree with all of the products that we have including NPH as an option, but not forcing everyone to start with NPH with type 2.

Lisa Chew: I would like to see some data sort of on the cost differential at a future meeting between NPH and the...

Donna Sullivan: Yeah, we'll definitely bring that back.

Diane Schwilke: Usually cost is a huge motivator for me in the decisions that I make, but in this case I feel like evidence is not steering us that way. That's not the way we're practicing. That's not the way guidelines are written with NPH. We need to have that long-acting as a first choice.

Amber Figueroa: I move to accept the recommended preferred drugs and limitations in the hypoglycemic insulin class.

Jordan Storhaug: I second the motion.

Michael Johnson: All in favor say aye.

Group: Aye.

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

Donna Sullivan: So not we will do the metformin class. We've looked at this not too recently. The Metformin products that are being considered to be preferred at the Metformin combinations with Glipizide, Glyburide, as well as the immediate release Metformin and the extended release Metformin that is specifically the generic for Glucophage. Fortamet, Glucophage, Glucophage XR Glucovance, Glumetza, Riomet and the generic products that are the generics to Fortamet and Glumetza will be not preferred.

I think that there is only tried and failed criteria on these. I'll double check. Yeah. You can see that the vast majority of the utilization is already in the Metformin preferred products. I don't have the combination products up here.

Going back to the insulins did you say something about grandfathering or no?

Nancy Lee: I think maybe the grandfathering was around the basal or the long-acting insulin. But since we're going to revisit that... that's my understanding is that since you removed the NPH as required first line I think that was maybe the sticking point. I don't know if that's...

Donna Sullivan: So the question would be... what the grandfathering would do is like people that are currently on Tresiba or Toujeo would stay on them without having to go through like a prior authorization or having to go back and try Lantus and Levemir.

Jordan Storhaug: I feel comfortable with people on long-acting insulins being required to transition onto their preferred long-acting insulin.

Donna Sullivan: Okay.

Amber Figueroa: I move to accept the recommended preferred drugs and limitations in the hypoglycemic insulin class. Non-preferred drugs should not be grandfathered.

Jordan Storhaug: I second the motion.

Michael Johnson: All in favor say aye.

Group: Aye.

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

Donna Sullivan: Okay. So now the metformins. Sorry. Thank you.

Michael Johnson: Any discussion on this from the committee? I move to accept the recommended preferred drugs and limitations in the hypoglycemic/metformin class. Non-preferred drugs should not be grandfathered.

Lisa Chew: I second.

Michael Johnson: All in favor say aye.

Group Aye.

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

Donna Sullivan: Okay. Moving on to pulmonary arterial hypertension. In this class the preferred products recommended are Adcirca, Letairis, Sildenafil and Tracleer. And the non-preferred products Adempas, Opsumit, Orenitram, Remodulin, Revatio, Tyvaso, Upravi both dose pack and the regular and Ventavis.

Amber Figueroa: So it looks like we have most of the patients covered in the ones that are going to be preferred. This is kind of like the previous class where there is actually multiple mechanisms of action of these. We don't have anything in the prostaglandin and vasodilator category that's considered preferred although it doesn't capture a lot of patients.

Donna Sullivan: So for PAH they have to have the group 1 and functional class 2 and 4 classification. They need to go through the right heart catheterization that shows 25 mm of mercury. The left atrial pressure, the LVEDP less than 15, and the PVR of greater than 3 wood units. History or tried or is contraindicated to the preferreds or calcium channel blockers. And then for WHO group 1 and functional class 2 through 4 being prescribed by a specialist and then exclusions would be if they are getting the phosphodiesterase inhibitors for BPH or erectile dysfunction. I am not the expert in this so I don't know what the guidelines say about, you know, which drugs do you start with? I'm thinking it's the phosphodiesterase inhibitors once they've tried other cardiovascular medications. I don't know... and then for chronic thromboembolic PA pulmonary hypertension it's the WHO group 4 and functional class 2 through 4. So just an angiogram via the right heart, catheterization showing the same results and that it is caused by a thromboemboli in the pulmonary artery. And then again treatment for BPH or erectile dysfunction is not covered.

Many of the other drugs, I'm not exactly sure which ones off the top of my head are I think infusions or injections and so may not be... might be why the utilization appears to be less.

Michael Johnson: Did it say how many preferred someone would have to try?

Donna Sullivan: It does not look like it. So that is something you could decide.

April Phillips: I do have to say they have a tendency to add on rather than subtract so there's a good chance that they are on multiple ones at the same time.

Donna Sullivan: So it would have to be that they have to be on one of these preferreds before they could add a non-preferred of the other like mechanisms of action.

Michael Johnson: Having said that people on multiple agents probably this is a class you would also probably want to grandfather.

Donna Sullivan: Are there any stakeholders in this class?

Michael Johnson: We have two stakeholders. Dr. John Hartney first and then followed by Robert Martin.

John Hartney: Hi. My name is John Hartney. I'm a medical science liaison with Actelion Pharmaceuticals. I wanted to thank you today for the opportunity to speak with you about Opsumit, which is indicated to delay disease progression and reduce hospitalizations for pulmonary arterial hypertension or PAH. Opsumit is the only endothelin receptor antagonist approved to delay disease progression and reduce PAH related hospitalization as both monotherapy and in combination with phosphodiesterase inhibitors or inhaled prostanoids. In the [inaudible] study 492 symptomatic PAH patients were randomized to receive either Opsumit or placebo once daily. Over 64% of these patients were on a PAH specific background therapy at baseline. The median treatment duration in the Opsumit group was 118 weeks. [inaudible] Opsumit reduced the risk of disease progression by 45%, which was consistent irrespective of patients on background therapy or treatment naïve. Opsumit reduced the rate of PAH related hospitalizations by 50% and the number of hospital days by 52%. Opsumit reduced the risk of disease progression by 60% in treatment-naïve incident patients and reduced the risk of PAH related hospitalization or death by 77%. Opsumit significantly improved health-related quality of life and reduced the risk of a clinically-meaningful reduction in health-related quality of life in PAH patients. With regard to the safety profile Opsumit like all FDA approved ERAs has a boxed warning for embryo fetal toxicity for which there is a REMS program for females. ERAs have caused elevations in amino [inaudible], hepatotoxicity and liver failure. Decreases in hemoglobin concentrations have occurred following administration of other ERAs and in clinical studies with Opsumit.

In summary, Opsumit is indicated to delay disease progression and reduce hospitalization for PAH. Opsumit is dosed once daily and can be used for either monotherapy or in combination therapy. For these reasons please consider adding Opsumit to the preferred drug list. Thank you for your time and consideration and I'm happy to answer any questions.

Michael Johnson: Thank you. Robert Martin.

Robert Martin: Good afternoon. My name is Robert Martin, PharmD. I'm a medical science liaison for Bayer, the maker of Adempas. I'd like to ask for some clarification on the use of Adempas for chronic thromboembolic disease. The way it was presented it would appear that patients would have to try a preferred drug first or did I get that wrong?

Donna Sullivan: A preferred drug that has the same indication, if there is one.

Robert Martin: There isn't. So Adempas is the only FDA approved drug for chronic thromboembolic hypertension. The evidence in the preferred drugs for chronic thromboembolic disease is scanty. There is only one well-done clinical trial with any of those drugs and it was with [inaudible] and that drug failed to meet its primary efficacy endpoint for that study. The evidence is really skimpy for those preferred drugs in chronic thromboembolic disease. So I would ask the committee to be... to allow Adempas first line. Again, it's the only FDA approved drug for that indication. Any questions? I have no other comment.

Michael Johnson: All right. Thank you. Let's go ahead and look at...

Nancy Lee: I have a question about the add-on therapy. There was a comment by April about secondary agents being added on. So I just want to make sure that was addressed.

April Phillips: A lot of times a secondary agent is put on and we would never require them to stop the first agent. They can just continue both as the prescriber.

Nancy Lee: So when you do look at that are a lot of the other agents the preferred drug agents that you see?

April Phillips: Yes. I would say the most common ones I see are on our preferred list.

Dale Sanderson: I move to accept the recommended preferred drugs and limitations in pulmonary arterial hypertension class. Non-preferred drugs should be grandfathered.

Catherine Brown: I second.

April Phillips: Just a second. Did you guys want to recommend a tried and fail or... because it... since it wasn't actually addressed in the policy presented. Sorry about that.

Donna Sullivan: I missed that.

Michael Johnson: Like a tried and failed criteria in the policy. What are the managed care... what do you guys doing now? Do you have a tried and fail? This is a hard class because they can be on three of these agents at the same time. Is it a failure? Is it a progression of disease?

Dave Johnson: Either one, yeah.

Michael Johnson: So we don't always know.

Dave Johnson: Right. Right. They usually end up on two or three.

Michael Johnson: Maybe that's why in the policy it doesn't say you have to try to fail, you know, a certain number. That's why because they start on one and if it is improved and then at some point they are worse and they get another one on. So is that...

April Phillips: My question was, did you want them to try one before going to a non-preferred? Three going to a non-preferred? I guess you guys can pick the magic number.

Donna Sullivan: So the example would be do you start with a phosphodiesterase inhibitor and then add the one from the other preferred class? Or try that one before you add one from the non-preferred drugs? So an example is... the way that the health plans... it looks like most of them have their criteria set is that... at least for a PAH that you have tried calcium channel blockers and Sildenafil or you are... it's contraindicated. So it looks like they are stepping through the phosphodiesterase inhibitors and then moving on to other medications.

Amber Figueroa: I think we should have them start with one other preferred and then they can choose where to go from there. I don't think that necessarily they should be limited to trying one in both of the classes that are represented in the preferred before they step to the non-preferred. I don't know exactly how to word that.

Donna Sullivan: So do you want that calcium channel blocker and one preferred?

Jordan Storhaug: I would suggest that we say that patients must try one preferred medication and then they move onto non-preferred medications.

Amber Figueroa: Calcium channel blockers are not listed under preferred but I'm assuming they are in a different class. Right?

Donna Sullivan: Yeah. They are preferred in the... they are almost all generic now but I believe that's part of the conventional treatment. So you move on from calcium channel blockers to these other medications. Is that for both... we don't have history down here under the chronic thromboembolic...

Amber Figueroa: That's the one that only has the one... this is the only one that is indicated and approved. Uh huh.

Donna Sullivan: Indicated for that. So we could make Adempas preferred and limit it to this particular indication as first line and say it's second line for primary PAH that they need to use one of the other preferreds first.

Michael Johnson: I think that's reasonable.

Donna Sullivan: Okay. I'm not sure how to do that. Okay. So I'm just going to say Adempas is preferred or allowed for first line for this indication only and then we don't need to put it into a motion. And then it sounds like you want to grandfather people because they have probably already gone through the other medications first.

Michael Johnson: So with those changes we have a motion on the table. I'm going to second that motion. All in favor say aye.

Group: Aye.

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

Donna Sullivan: I think we have breached the summit of mountain. I think we are on a downhill slide. Okay. So the long-acting narcotic analgesics and I'm going to get rid of the word narcotic in the next version and call them opioids... long-acting opioids. So the preferred products that are being recommended are the transdermal Fentanyl, the hydromorphone extended release, oxycodone extended release, morphine extended release and the oxycodone extended release. I'll point out that the morphine extended release is the MS cotton generic, not the generic for Avanza or Chadian. There is a slight difference there. And then the non-preferred products are everything else. Methadone is... I'll go over slightly what our long-acting criteria is, but actually we'll bring that back to you in September. We're developing a long-acting policy. We've... the DUR Board has looked at their policy several times, but we're finalizing the actual policy for a rollout soon. So we'll let you know what that is at the next... or review that at the next meeting next month. Let's go to the utilization.

The Fentanyl that's on your spreadsheet is only the Fentanyl transdermal. As you can see the utilization is other than one of the methadone products the utilization is mostly in the preferred products and the intent is nobody would be asked to switch away from methadone.

Amber Figueroa: What about OxyContin?

Donna Sullivan: People would be asked to switch away from OxyContin. And what this doesn't include... so... is whether or not... we don't know why they are taking this. It includes patients that have cancer pain or whatever reason that they are taking the medication for. So there was no specific diagnoses that were included or excluded. So this is just straight utilization.

Nancy Lee: I had a question about oxymorphone on the preferred list and looking at the Excel sheet. So the Excel looks like just three plans and then the number is like 245. I just wasn't sure what the...

Donna Sullivan: So 245 patients are taking it.

Nancy Lee: Was wondering what the background was to put it on preferred.

Donna Sullivan: It's generic and its cost. We are trying to have multiple options for patients to try. It's been generic, I know, for the Fee-For-Service Program for quite a while and utilization hasn't... we have 27 patients on it. And the criteria really for the long-acting is that they have to have tried 42 days of a short-acting or have medical justification why a short-acting wouldn't work before they can get to a long-acting. We'll go into more detail next month with the... we're going to roll out an entire opioid policy and we'll... it makes more sense to talk with the acute pain and chronic pain together. We'll do that next month. So for the motion we can get rid of the limits part.

Michael Johnson: We have one stakeholder, David Gross.

David Gross: Good afternoon. Dave Gross with Pfizer. I'm here to briefly discuss Embeda, which is a unique schedule 2 combination opioid and agonist sequestered antagonist extended release capsule for oral use. The capsule is unique in that it contains pellets of morphine sulfate with a sequestered core of naltrexone hydrochloride. The sequestered naltrexone in Embeda is intended to have no clinical effect if it is taken orally. However, if the capsules are crushed or chewed up to 100% of the sequestered naltrexone could be released equivalent to giving naltrexone oral solution. So the idea is if you take it orally you're getting the sustained release morphine. If you crush it, inhale it or snort it

whatever, the naltrexone that has been released acts as an antagonist. More importantly we all know, looking at the news and the headlines and our new president and everybody, inappropriate opioid use is a huge public concern and given the significant increase in abuse and diversion of prescription opioids in recent years, the Food and Drug Administration has developed guidelines for abuse to turn opioid evaluation and labeling which states, "That abuse deterrent formulations should target known or expected routes of abuse for the opioid drug substance for that formulation. The FDA considers the development of these products a high public health priority." Obviously to treat this you need a multi-pronged approach and abuse to turn opioids or abuse to turn formulations in general are just one prong, but a very important prong and it's a complex issue.

So in summary Embeda is a unique abuse-deterrent extended release opioid product, again, formulated using agonist in a sequestered antagonist technology that has properties that are expected to reduce abuse via the oral and intranasal routes. And again the FDA has been involved in the studies and design of these studies for these abuse deterrent formulations and again it's just one prong. So providing access to abuse-deterrent in opioids can help support your provider's efforts to mitigate potential opioid abuse. If you have questions specifically about Embeda I would gladly entertain them. Thank you very much for your time.

Michael Johnson: Thank you. I want to change the verbiage pulmonary artery hypertension to...

Donna Sullivan: Oh yeah. Thank you.

Woman: Hi. This is CHP. Just a quick question on the oxycodone ER. It's listed on both the preferred and the non-preferred.

Donna Sullivan: It should only be on the preferred, but thank you for that clarification.

Lisa Chew: Just a question with the wording about non-preferred drugs with the exception of methadone should not be grandfathered. If the utilization data included patients who had cancer pain whether we want to change that to maybe grandfathered rather than should be grandfathered.

Donna Sullivan: It says should not be grandfathered.

Amber Figueroa: I think what she's saying is if it is a cancer patient that's on a non-preferred drug can they stay on that until they die?

Lisa Chew: Thank you.

Donna Sullivan: So in our policy that we will be looking at next month the policy is for patients that are... it excludes those that have treating active cancer pain meaning you can't have cancer 10 years ago and you're free and clear now that you're in Hospice or you're receiving the medication for palliative care or end-of-life care. So they should not be grandfathered unless they are in one of these. Did you want *may* or *should* be grandfathered? So it is opioids used to treat active cancer pain or a patient in Hospice palliative care or end-of-life care may be grandfathered.

Diane Schwilke: I move to accept the recommended preferred drugs and limitations in the long-acting opioid class. Non-preferred drugs with the exception of methadone should not be grandfathered. Opioids used to treat active cancer pain or a patient in Hospice, palliative care or end-of-life care may be grandfathered.

Lisa Chew: I second.

Michael Johnson: All in favor say aye.

Group: Aye.

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

Donna Sullivan: Okay the next class is pancreatic enzymes. We are recommending preferring Creon and Zenpep. Non-preferred with Pancreaze, Pancrelipase, Pertzye and Viokace.

Michael Johnson: On the second page under digestive aids...

Donna Sullivan: So those two products by far have the vast majority of the utilization with 1,278 on Creon, 300 on Zenpep and then I would say less than 100 on the rest of them.

Michael Johnson: There are no stakeholders for this class.

Donna Sullivan: And this criteria is just tried and failed and we're trying and fail all because there are only two. But we can change this to two if you would like. We're not requiring a diagnosis. It looks like the pancreatic enzymes ran away too. We just need to decide if you want them to be grandfathered or not grandfathered. They are such small utilization in the non-preferreds it really doesn't make a difference one way or the other in my opinion.

Jordan Storhaug: I suggest we do *may*.

Michael Johnson: I agree.

Amber Figueroa: I move to accept the recommended preferred drugs and limitations to the pancreatic enzyme class. Non-preferred drugs may be grandfathered.

Dale Sanderson: I second.

Michael Johnson: All in favor say aye.

Group: Aye.

Michael Johnson: All opposed same sign. All right. The motion passes. Next topic is inhaled antibiotics and there are no stakeholders.

Donna Sullivan: Okay. So in this class all of these products, I believe, are tobramycin. So we are recommending Bethkis and Kitabis as the preferred products with Cayston, Tobi and the Tobramycin generic is actually more expensive than the two products we're recommending. So we are recommending that they be non-preferred.

Amber Figueroa: Donna, can you clarify that? I was looking at the paper and seeing that 100 and... the majority of them are on Tobramycin which we're saying isn't covered.

Donna Sullivan: It's actually... it's more expensive than the Bethkis and the Kitabis so we would recommend, since they are all Tobramycin, we would recommend transitioning people over to the other products. The criteria... they need to be 6 years of age or older. They must have pseudomonas aeruginosa and not have burkholderia and their FEV1 needs to be greater than 25% to greater than 80% and tried and failed both preferreds. They are all Tobramycin so there is no reason to expect one would work better than the other.

David Johnson: Just to clarify Cayston is not Toby.

Donna Sullivan: Thank you.

David Johnson: Cayston is aztreonam.

Donna Sullivan: Thank you for that clarification. It is probably in a different classification because it is aztreonam so I don't know what the utilization is on the Cayston at this point. I could pull it up on that other spreadsheet if you really want to look

at it. We don't have to look at it if you don't want to. It's gonna take a while for it to open.

Michael Johnson: These are just simply antibiotics. You're just switching one product to another. I don't think there is any magic here. I move to accept the recommended preferred drugs and limitations in the inhaled antibiotic class. Non-preferred drugs should not be grandfathered. Did we choose *may*?

Donna Sullivan: You could use *may* or *not*.

Michael Johnson: I would say *should not be grandfathered*.

Donna Sullivan: Okay. Then I can blame you for doing it, not me.

Jordan Storhaug: I second the motion.

David Johnson: From what we see, you know, if... like... Cayston... since Cayston is the only one, if they are on Cayston they have gone through Tobi. So I mean we're not going to... regardless of what you say we're not going to kick anybody off of it. It would probably be good to grandfather them.

Jordan Storhaug: That's a question that I have, should Cayston be a different category and potentially be preferred?

Michael Johnson: Do we... Is there data to support that? This is just... this is Donna. I think most... if it is usually non-preferred or it is on prior authorization that the requirement is that they have already stepped through Tobi to get to Cayston. So Tobi wasn't working. We'll just say non-preferred drugs with the exception of Cayston should not be grandfathered. So the Tobramycin products will not be grandfathered.

Michael Johnson: I think that's reasonable. For the record I'll re-read it. I move to accept the recommended preferred drugs and limitations in the inhaled antibiotic class. Non-preferred drugs with the exception of Cayston should not be grandfathered.

Jordan Storhaug: I second the motion.

Michael Johnson: All in favor say aye.

Group: Aye.

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

Donna Sullivan: So antipsychotics. Pretty much all of the drugs or... with an ingredient is preferred. So every... the recommendation is every product with its ingredient is preferred. Not all formulations are preferred for the oral products. So all of these are preferred and there are some where the... like Aripiprazole solution is not preferred. The Olanzapine/Fluoxetine combination. I think those are the only two that are not preferred that are generic. These would be the non-preferred drugs pretty much any branded product that has a generic available will be non-preferred. I did not do a hyperlink on this one. So the utilization is on page 4.

Dale Sanderson: I'm wondering if the title of this should be second generation antipsychotics. I mean if... there's a lot of antipsychotics that are included here. Many of them are used commonly. Certainly the patients coming out of institutions.

Donna Sullivan: Thanks for that clarification. We can definitely do that.

[inaudible]

Donna Sullivan: We started to include those in here but there's no rebates on those. I took them out at the last minute, but they are in the data that you're looking at in front of you.

Dave Johnson: Donna, you've got Vraylar on both lists.

Donna Sullivan: That I do. I think... So Vraylar should be preferred. And the criteria for the antipsychotics is the same as it has been approved from you previously where is the trial of one generic and two preferred products before they can get a non-preferred product. Everything... most everything is preferred as far as the actual drug ingredient at this time.

Michael Johnson: We have four stakeholders. The first one is Michael Boskello followed by Lyle Laird.

Michael Boskello: So good afternoon, again. Mike Boskello. I'm a medical science director with Alkermes Pharmaceutical and I'm here to support Aristada, our long-acting injectable antipsychotic of aripiprazole lauroxil and I'm here to answer any questions that you may have. If not, I'll give you back some time.

Michael Johnson: All right. Thank you. Next up is Lyle Laird followed by Paul Thompson.

Lyle Laird: So good afternoon. My name is Lyle Laird. I'm a PharmD, a director and medical science liaison with Sunovion Pharmaceuticals. I want to thank you for this opportunity to address the committee today. I'm just going to briefly provide an important update on lurasidone Latuda. On January 28th, 2017, lurasidone was approved by the FDA for the treatment of schizophrenia in adolescent patients age 13 to 17. This was done through a six-week registrational trial doses 40 to 80 mg that were found to be effective and generally well tolerated with minimal observed changes in weight, lipids, glucose or prolactin. Lurasidone is approved now for schizophrenia in adults and as you see in adolescents 13 to 17, as well as in adults with bipolar depression both as adjunctive to lithium and valproate and as monotherapy. Please refer to the full PI for a complete list of warnings, precautions and adverse events. I wish to thank you for the... maintaining lurasidone Latuda on the PDL for the Washington state formulary and I'll be glad to answer any questions that you might have. Thank you.

Michael Johnson: Thank you. Next is Paul Thompson followed by Dinah Aldrich.

Paul Thompson: Hi and thank you for giving me the opportunity to come up here and talk with the committee. I'd also like to thank the committee for your previous decisions with the preferred drug list back in December 2016 maintaining open access. My name is Paul Thompson. I'm the director of pharmacy for Navos Mental Health Solutions. We are one of the largest mental health care providers in the King County area covering about 15,000 patients. We are an affiliate of Multi-Care Health Systems and work with them accumulatively to provide services for about 30,000 behavioral health patients in the Puget Sound area. I would like to thank the committee for the decisions made today to continue open access. I would also like to thank the managed care organization partners in the room that have worked with this committee's guidance at the previous meeting that have worked month in and month out to maintain access and quality care for the patients that do need these antipsychotic agents for the patients that we serve. The only request I had, had already been motioned and voiced by Dr. Jarvus... Dr. Anderson regarding the differentiation of the second generation antipsychotics and the first generation antipsychotics. I would like to... I suppose I'm... just wanted clarity that the all first generation antipsychotics are still intended to be covered without any restrictions, as well as the second generation. I don't know if you have any questions for me, but I'd be happy to answer if anybody does. Well, thank you.

Michael Johnson: Thank you. The last speaker is Dinah Aldrich.

Dinah Aldrich:

Good afternoon. Thank you for the opportunity to speak with you. My name is Dinah Aldrich and my son lives with a serious mental illness. This is what led me to serve on the board of directors for the National Alliance on 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. NAMI Washington continues to be concerned that the Health Care Authority would consider adding [inaudible] step therapy requirements or require therapeutic interchange for non-preferred 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 second generation antipsychotics were added to the PDL at the P&T meeting after Drug Effectiveness Review Project review. Thank you for that.

Statutory refill protection exists for antipsychotics. Therapeutic interchange has never been allowed in this class of medications. The reasons for this unique recognition are well documented. Studies show 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 the oral second generation antipsychotics. This is due to enhanced compliance. Second generation antipsychotics are much less toxic in the first generation products. The side effects of psychopharmaceutical medications can be severe and debilitating which often leaves a person with mental illness such as schizophrenia or my son's, schizo effectiveness disorder, to stop taking their medication. 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 undermine the wellbeing and continued recovery of the patient and shifts costs to these other more expensive systems.

Based on independent data the costs are \$77 per day for the... is the cost of the most expensive antipsychotic without regard to required Medicaid rebates. \$156 per day is the cost for King County jail, mental healthcare only. \$737 per day is the average cost for routine inpatient treatment at Eastern State Hospital and \$618 a day at Western State Hospital. The potential cost savings are obvious and we encourage the Health Care Authority to prioritize the use of the most clinically-appropriate medication which offers the best outcome for those living with mental illness like my son.

NAMI Washington urges the P&T and the DUR Board to continue to allow access to all second generation antipsychotics on the single state Medicaid preferred drug list. The National Institute of Mental Health notes that a medication that works well for one person with schizophrenia often doesn't work well for another. This is further direct evidence that health care providers, with their patients, not review committees or health plans are best suited to make treatment decisions.

Michael Johnson: I'm sorry...

Dinah Aldrich: While we understand the need for cost savings, such savings should not be made at the expense of patient health and safety. So please make the priority... make your priority improving patient outcomes so people living with a particular illness, mental illness, can live a full meaningful and productive life. Thank you for your work and the work that gave open access for all of these medications and for hearing me today. And as I stated, my son has schizo effectiveness disorder. In the seven years he has had the illness he's been hospitalized at least seven times and has not been hospitalized once in the two years since he began having a long-lasting injectable medication. Thank you.

Michael Johnson: Thank you.

Dale Sanderson: I move to accept the recommended preferred drugs and limitations in the antipsychotic class. Non-preferred drugs should be grandfathered.

Amber Figueroa: Can you clarify about Haldol? Did you say it's not included here?

Donna Sullivan: So we will bring the first generation antipsychotics to the meeting next month. So it wasn't to make them not preferred by not including them. It was just getting to be too much information in one table. So we will bring those next time.

Dale Sanderson: It's a long list.

Donna Sullivan: Correct.

Amber Figueroa: I second that.

Michael Johnson: All in favor say aye.

Group: Aye.

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

Donna Sullivan: It's up to you to take a break or do you want to plow through?

Michael Johnson: Let's take a 10-minute break.

Donna Sullivan: These next two classes are quick.

Okay. I think we're good to go.

Michael Johnson: We'll go ahead and get started again. Two more classes to go. No stakeholders in either class.

Donna Sullivan: Okay. I guess they have all left. So the next class is the anticoagulant class and we are recommending as preferred... I put Warfarin on here just kind of for Warfarin's sake that it is going to be preferred, but it is not considered a preferred in the try and fail preferred status. So we are recommending that Warfarin in addition to Eliquis and Xarelto be the preferred agents in this class and then non-preferred would be the branded Warfarin products Pradaxa and Savaysa.

I'll go to the criteria and really it's that they would try and fail the two preferred products. So they would... in order to get Pradaxa or Savaysa they would have to try both Xarelto and Eliquis before getting one of those non-preferreds. But there is no requirement that they try Warfarin before they get any of these. I just wanted to make that clear.

It appears that the majority of the utilization, these two here are both Xarelto products and then the Eliquis. So the vast majority of the utilization is in the recommended products. And then Warfarin is up here. So we just need to discuss what to do with the non-preferred. Should? Should not? May be grandfathered? And if you want me to put anything back up, please let me know.

Michael Johnson: I think may is reasonable. We're not looking at a lot of people.

Jordan Storhaug: I move to accept the recommended preferred drugs and limitations in the anticoagulant class. Non-preferred drugs may be grandfathered.

Dale Sanderson: I'll second.

Michael Johnson: All in favor say aye.

Group: Aye.

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

Donna Sullivan: Okay. The next class is the antiemetics. We did review this class I think in either... June also. We are recommending that Ondansetron and Ondansetron ODT be preferred and that Diclegis will be preferred positioned in a... preferred for use during pregnancy. So we'll talk about that in a minute. Non-preferred products being Emend, Granisetron, Sancuso and Suplenz. So the recommendation for the limitations is that to get a non-preferred product they have to try two preferred products with the exception of Diclegis if the indication is for pregnancy then they do not need to try two preferred products. However, for all other indications they would.

Diane Schwilke: I would have to argue that there really aren't two. Besides Diclegis there's really only one. I mean it's ODT versus swallow it.

Donna Sullivan: So we'll just say Ondansetron. So the utilization you can already see the vast majority right here is with Ondansetron. Very little and then Diclegis is the next biggest one.

Susan Flatebo: Should palonosetron be included on the non-preferred side or is this oral and patch only?

Donna Sullivan: I believe that the... our vendor only did this for the orals. So we can include palonosetron on either side depending on what you feel is appropriate.

Susan Flatebo: Personally I think palonosetron should be included on the non-preferred side.

Donna Sullivan: I'm trying to see what we put for the... okay. I would agree that it's not preferred on the Washington PDL either. So that would be in line with that. Any other recommendations or suggested changes?

Susan Flatebo: I think non-preferred drugs may be grandfathered in.

Lisa Chew: I move to accept the recommended preferred drugs and limitations in the antiemetic class. Non-preferred drugs may be grandfathered.

Susan Flatebo: I second.

Michael Johnson: All in favor say aye.

Group: Aye.

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

Donna Sullivan: There's nobody left to hear it, but I thank you so much for slogging through all of this with us and the great discussion we had about the product selection and the criteria. I think it was really helpful and I was not expecting us to get through the agenda. I'm actually glad we did. Now I can have a little bit more time. With the exception of the hepatitis C drugs, we will not be adding... we'll be adding I think hepatitis C, HIV, oncology and the first generation antipsychotics for next time. The hepatitis C, because we do have two new products that are potentially less costly than our current preferred products, so we need to review those. So we'll have to review those for the P&T Committee, as well as for the DUR Board and that is so that we can get rebates on those newer products the last quarter of 2017, so this year. We'll figure out how that's going to work and going forward once we start reviewing these classes and we have the vendor in place there will be clinical documents not like the DERP reports, but there will be like drug monographs for you all to review. So this was just really to kind of get the baseline, a starting place, and then moving forward as we re-review the classes there will be clinical presentations for you.

Thank you very much. I really appreciate all your work.

Amber Figueroa: I think this is really helpful to be able to have this printout. I wonder if we might be able to also have the, you know, when you're going through the 10 diagnoses?

Donna Sullivan: Yes. That's great information and then Petra also had a great recommendation. I will try to do a better job of getting the drugs put together instead of where they are broken... some of the times where like with the Tim's class that based on, you know, if it was for psoriasis only it was listed as a dermatologic. So they kind of got broken up. I will work to get those more... the data all together so you can look at it all at once. We'll bring both spreadsheets for you to look at.

Leta Evaskus: I'm missing one person's travel document. Could you turn that in?

Donna Sullivan: I also want to thank Julie and call out to April and Julie. They both slogged through all of the policies and put them into that Excel spreadsheet and Julie helped put the slides together with April as well. Thank you. You're great!

April Phillips: I think she just wants us to take credit for the mistakes on the slides.

Michael Johnson: Great. We are adjourned.

Donna Sullivan: Thank you.