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DRUG USE REVIEW BOARD

Meeting Minutes

Date of Meeting: **Thursday, January 25, 2018 at 5:15 PM**

Name of Organization: **The State of Nevada, Department of Health and Human Services, Division of Health Care Financing and Policy (DHCFP), Drug Use Review Board (DUR).**

Place of Meeting: **Hyatt Place Reno-Tahoe Airport**
1790 E. Plumb Ln
Reno, NV 89502
Phone: (775) 826-2500

ATTENDEES

Board Members Present
Paul Oesterman, Pharm.D.
James Marx, MD
Michael Owens, MD
Jennifer Wheeler, Pharm.D.
David England, Pharm.D.

Board Members Absent
Marta Bunuel, MD
Yvette Kaunismaki, MD

DHCFP
Darrell Faircloth, Deputy Attorney General
Holly Long, Social Services Program Specialist
Shannon Sprout, Deputy Administrator
Cody Phinney
Theresa Carsten

DXC

Beth Slamowitz, Pharm.D.

OptumRx
Carl Jeffery, Pharm.D.

Public
Rupa Shah, Purdue
Tom Beranek, SilverSummit
Robin Reedy, NAMI
Laura Hill, Abbvie
Yvonne Lun, Teva
Sandy Sierawski, Pfizer
Mark Rueckert, Pfizer
Mark Schwartz, GSK
Ann Nelson, Vertex
Tom O'Connor, Novartis
Ryan Bitton, HPN
Jeannine Murray, Anthem

Teleconference
Jennifer Lauper, BMS

AGENDA

1. Call to Order and Roll Call

Paul Oesterman, Chair: The Department of Health and Human Services, Division of Healthcare Finance and Policy Recommendation Review Board Meeting. We'll start off with a roll call and we will start at the far left side:

Shannon Sprout: I'm Shannon Sprout Deputy Administrator for the health policy for additional healthcare financial costs.

Cody Phinney: I'm Cody Phinney, I'm the Deputy Administrator for Healthcare financing and policy for MCOs and finance.

Beth Slamowitz: I'm Beth Slamowitz with DXC Technology.

Holly Long: I'm Holly Long, Pharmacy Specialist with DHCFP.
Carl Jeffery: I'm Carl Jeffery with OptumRx.

Darrell Faircloth: Senior Deputy Attorney General, Darrell Faircloth.

Paul Oesterman: Paul Oesterman, Pharmacist here in Reno.

James Marx: James Marx, Physician, Las Vegas.

Jennifer Wheeler: Jennifer Wheeler, Pharmacist in Reno.

Michael Owens: Michael Owens, family practice physician in Reno.

2. Public Comment on Any Matter on the Agenda

Paul Oesterman, Chair: For our public, the audience and online, we will ask for public comment.

Carl Jeffery: We have Dave on the line.

Paul Oesterman, Chair: Dave, do you want to tell us you're here?

Dave England: This is Dave England, Pharmacist for Las Vegas.

Paul Oesterman, Chair: For anybody in the audience, either in person or online, we will ask for public comments at each section and also in general for public comments, but we do ask that you limit your comments to 5 minutes and if you wish to address the Board, please notify us and we will be happy to recognize this. We will start off by seeing if there is any public comment on anything in general, if there's an agenda item and you want to address that item; hold your comments to that in general. Is there anybody who wishes to address the Board before we get into our full agenda? Hearing none and seeing none, we'll go into the administrative part of the meeting. I'm going to ask a little bit to digress for a moment because it's kind of with mixed feelings and mixed emotions that I

get to say so long to somebody who has been on my side of the Board Meetings, I think we've been together for about 10 years now.

Darrel Faircloth: This isn't on the agenda.

Paul Oesterman, Chair: I know, you have to stand up because on behalf of the State Drug Utilization Review Board, for your outstanding dedication, leadership and guidance, as District Attorney General to the Drug Use Review Board and the supervision and preservation of the health and lives of citizens of the state of Nevada, we wish to thank you.

Darrel Faircloth: Thank you very much.

Paul Oesterman, Chair: Thank you for everything you've done. Good luck.

3. Administrative

a. **For Possible Action:** Review and Approve Meeting Minutes from October 19, 2017.

Carl Jeffery: I think the next item. We actually the meeting minutes on the next agenda.

Paul Oesterman, Chair: Let's take a look at the minutes from our last meeting which was October 19, 2017. Take a moment to review those and see if there are any revisions to get a motion and a second to approve them.

James Marx: Motion for approval.

Paul Oesterman, Chair: So we have a motion to approve the minutes. Do I have a second?

Jennifer Wheeler: Second.

Paul Oesterman, Chair: Any discussion? Hearing none and seeing none, I'll call for a question. All those in favor of the approval of the minutes as presented, please indicate so by saying "Aye."

Multiple Speakers: "Aye."

Paul Oesterman, Chair: All opposed say "nay." Minutes are approved.

b. Status Update by DHCFP

Paul Oesterman, Chair: Our next item is the status update from the Department and I believe we also will be looking at review and approving the updated DUR by-laws.

Shannon Sprout: Thank you everyone. I just would like to announce and not totally do the rest of the updates, but Duane Young with Behavioral Health and Pharmacy Unit, with much excitement, I would like to announce that he will be taking a promotional position with the Division of Quality and Behavioral Health. His last day was Friday. He was hoping to have actually been here for the Board but this is a week that he had an opportunity to start early so he took that opportunity. We will be recruiting for a new Chief of that position. I hope to get that

recruitment out here in the next week so we will now announce when we do have a new Chief of the Departments. Holly will be the go-to of all considered.

Holly Long, Pharmacy Specialist: For the DHCFP update, Podiatry Services have been extended as offered in the 2017 legislative session to include all Medicaid-eligible recipients who are using the services were only provided to children and participants dually enrolled with Medicare. Next, the coverage for gender reassignment services was added to the Medicaid recipients with the diagnosis of gender dysphoria and services will expand to include genital reconstruction surgical procedures based on the necessity. Registered dieticians were added as a recognized provider to support medical and nutrition therapy, physician services, medical nutrition therapy (or MNT), is going to be provider-type 15. These services may only be provided by a licensed registered dietician and must be part of a coordinated multidisciplinary team. The items went into effect on January 1, 2018, and Medicaid is just waiting for CMS approval on this.

c. **For Possible Action**: Review and Approve updated Drug Utilization Committee By-laws

Paul Oesterman, Chair: Do we have any by-laws?

Holly Long, Pharmacy Specialist: So the DUR By-Laws have just been updated, as well, and I believe each of the members have a copy of those? The first change is on page 3 under #5, we're still on that same one. All of the language was removed there under the #5 and it now reads, the director sell point one member recommended by each Managed Care Organization or MCO contracted with the DHCFP. This member shall not be an employee or contractor of any MCO. The next change is on the next page which is page 4 under section…go ahead.

Speaker: (indiscernible).

Carl Jeffery: It's not in your binder, broken down, it was sent separately.

Speaker: (indiscernible).

Holly Long, Pharmacy Specialist: If you have questions about the first one, just let me know. The second change is on page 4 under section 4 under Assistance, letter B. Just a couple of words were added here so that the language reads, the DHCFPs,, PVTM and MCOs shall provide the DUR Board with relevant clinical information, see appendix A, and would support that includes but is not limited to accepting and summarizing submissions by MCOs, Pharmaceutical Management Groups and Special Interest Groups. The next change is further down the page, page 4, under section 2, Agenda Meeting Preparation and Meeting Structure, under letter B. On the second sentence, there was additional information added so that now it reads, this shall include all pertinent information from each MCO, Manufacturers and Special Interest Groups, will be given a deadline for submission of information at time of this posting, and I think it was on the same page.

Paul Oesterman, Chair: Holly, on the last one that you mentioned, article 4 section 2, this shall include all pertinent information from each MCO, there is an s on the end of that. I don't think it needs to be there.

Holly Long, Pharmacy Specialist: Okay, thank you.

Paul Oesterman, Chair: Do we have a motion and a second to approve the revised by-laws for the DUR Board?

Jennifer Wheeler: Yes.

James Marx: Second.

Paul Oesterman, Chair: Any additional discussion? Hearing and seeing none, I will call for a question, all those in favor of the approval of the updated and revised by-laws of the DUR Board, please indicate so by saying "Aye."

Multiple Speakers: "Aye."

Paul Oesterman, Chair: All opposed, say "nay." Motion carried.

4. Clinical Presentations

Paul Oesterman, Chair: Now we are going to go into our clinical presentations. Next we will go into discussion and possible adoption of prior authorization criteria and/or quantity limits for deutetrabenazine (Austedo brand name). Is there anybody here who wishes to address the DUR Board in this regard?

Yvonne Lun: (indiscernible)

Paul Oesterman, Chair: You just step to the podium and give us your name and who you're representing. You have 5 minutes.

a. **For Possible Action:** Discussion and possible adoption of prior authorization criteria and/or quantity limits for deutetrabenazine (Austedo®)

Yvonne Lun: Oh okay. I'm Yvonne Lun, Teva Pharmaceuticals. Thank you for inviting us to come. We are Teva Pharmaceuticals. We are talking about Austedo in that it is a vesicular monoamine transporter 2 indicated for the treatment of tardive dyskinesia, also abbreviated TD and also in the treatment of chorea associated with Huntington's disease. There is a boxed warning in patients with Huntington's disease, not tardive dyskinesia. Please refer to the prescribing information. Covers studies showing efficacy, side effects and dosing. Due to the lack of FDA-approved treatment for the treatment of tardive dyskinesia and significantly burden for those patients with schizophrenia, schizoaffective disorder, or movement disorder achieved, I would ask members of the committee consider the data presented for tardive dyskinesia patients to have access to Austedo.

Carl Jeffery: We have discussed this at the last meeting. We talked about Huntington's chorea last time. We approved some criteria; the criteria is updated in the binder. It is not in chapter 1200 yet, but that is the criteria that we put in for last time. This time, we brought it back because the diagnosis for the tardive dyskinesia was added later so now we've got some proposed criteria for the tardive dyskinesia. Basically what I did, we modified some of the criteria for the, we had a drug Ingrezza last time which was actually indicated for tardive dyskinesia. We made some modifications to it, combined some of the criteria for that based on some of the input from the MCOs and created that.

So, I copied that criteria for the tardive dyskinesia here. So, that's basically the criteria from that. On this particular one, we didn't have any input from any of the other MCOs so this has just been our criteria basically of what the DUR Board created last time so it just reinstates that the recipient is 18, they have a diagnosis and this is one that we had to modify a little bit from Optum proposed criteria in that we use basically a DSM-5 criteria and they are saying at least 60 days is a stable dose neuroleptic medication first or second generation antipsychotic, presence of involuntary athetoid or chorea movements lasting 30 days prescribed by or in consultation with a neurologist or psychiatrist and having one of the following: If the patient has persistent symptoms of tardive dyskinesia despite a trial dose reduction, tapering or discontinuation of the offending agent or the patient is not a candidate for a dose reduction. So, that's the reauthorization criteria which is the documentation of the positive clinical response.

Paul Oesterman, Chair: The only thing I'm not seeing there is the initial authorization of the 3 months again like we did for the Huntington's.

Carl Jeffery: Yeah, I proposed that 3-month and then probably 12-month with the reauthorization.

Paul Oesterman, Chair: Out of curiosity, we have had some utilization of the Austedo product. Was that for Huntington's or do we know?

Carl Jeffery: I don't know. Well, we didn't have a prior physician on it yet so I can't even pull the PA data on that as this PA isn't in place yet so I'm not sure what it's used for. But, if it's just one patient, then we would taper it up, so I think it's the same basis it's on every time.

Paul Oesterman, Chair: We'll need a motion and a second to approve the revised criteria that includes the diagnosis of tardive dyskinesia for this Austedo product.

James Marx: I move we adopt the proposed criteria.

Jennifer Wheeler: Second.

Paul Oesterman, Chair: We have a motion and second to approve the revised criteria as presented with the addition of the 3-month initial authorization. Any further discussion? Hearing none, I'll call for the question. All those in favor of the revised criteria, please include so by saying "Aye."

Multiple Speakers: "Aye."

Paul Oesterman, Chair: All opposed say "nay." Motion carried.

b. **For Possible Action:** Discussion and possible adoption of prior authorization criteria and/or quantity limits for betrixaban (Bevyxxa ®)

Paul Oesterman, Chair: Our next clinical presentation and possible action is the discussion of the possible adoption of prior authorization criteria and/or quantity limits for betrixaban (Bevyxxa ®). Is there anybody in the audience who wishes to speak before the Board? Hearing none and seeing none, we will go ahead, you can present the information, Carl.

Carl Jeffery: Sure, this is a new medication. It's in the same class as some of the other anti-Xa like the Eliquis and the Pradaxa and the Xarelto and Coumadin, too, so it's all kind of there but this one has a very unique indication. It is actually made by the same company that is making the anti-Xa so it's the reversal agent, but this one is only indicated for being treated in hospital. That is why I brought it before the Board because it's very unique. Indicated for the treatment and prophylaxis of venous thrombosis, VTE, in adult patients hospitalized for acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors. So you can, I've got the utilization pulled up on the screen. You can see how we're trending with the Eliquis and the Xarelto and we're just bumping along, and I think a pretty good adoption of these newer NOACS here that are driving down the utilization of the Warfarin therapy like the other ones so we don't have any claims for the Bevyxxa yet so we haven't seen that one come through. Here's kind of our utilization, so I think it's to be expected for a new class of medications. The criteria put together was pretty simple. It was basically just following the FDA indications as being used for prophylaxis event, the VTE, the patient is currently hospitalized for an acute medical illness, and the patient is at risk for thromboembolic complications due to moderate or severe restricted mobility or other risk factors. Something to keep in mind is that patients who are in a hospital don't need to have a prior authorization. So, any criteria for them here is going to apply to the hospital so they'll still be able to get open access to it without any restriction or waiting for something they need to start right away. It is just when they're released from the hospital, then they would need a prior authorization if they are going to fill that at the local Walgreens or something.

Paul Oesterman, Chair: Could we include in the criteria if they are going to be getting filled as an outpatient, then it's a continuation of therapy.

Carl Jeffery: Yeah so it would start it, so to say something like it was started in the hospital.

Holly Long: We actually have that from another state; they have that included. Member has received an extended hospitalization and will be continuing therapy following discharge from the hospital.

Paul Oesterman, Chair: I like that wording better.

Carl Jeffery: Okay, so I've updated the criteria there.

Paul Oesterman, Chair: It's my experience the vast majority of patients are usually treated with low molecular weight like enoxaparin.

Carl Jeffery: Yeah, I honestly don't see a real big pick-up of this one and so I don't think this is going to be a huge, huge thing. I think from my perspective, my fear is always to have the prescriber that's in a hurry, they want to start a NOAC and will open the book and say, oh, here's Bevyxxa okay and write it even though it's not appropriate for the indication.

Holly Long: There was an age younger than 18 on here (indiscernible).

Carl Jeffery: It's probably indicated over 18 because that's all it's studied for. We can certainly add that to the criteria, as well.

Paul Oesterman, Chair: I think that would be a wise thing to do.

Holly Long: Two other things that I saw from another state where the member has not received up to 42 days of Bevyxxa therapy, which (indiscernible).

Carl Jeffery: Well, that's what is studied, but I think that's all its indicated for, just prophylaxis so after an event so I think that's a good dependent on duration, so would that would be like the duration of approval, so it would be a duration of 48 weeks.

Holly Long: 42 days.

Carl Jeffery: 42 days of (indiscernible).

Holly Long: Lastly, the dose does not exceed 80 mg per day or 1 capsule per day.

Carl Jeffery: One capsule per day.

Paul Oesterman, Chair: Loading doses, too.

Jennifer Wheeler: All over 40 PA okay.

Carl Jeffery: But they would get the loading dose in the hospital.

Paul Oesterman, Chair: So, I would say we could include something of a cumulative duration of 42 days; you would have to know how many days they were on it in the hospital and if they were on it for 20 days in the hospital, then our max should be 22.

Beth Slamowitz: How would the Call Center going to be able to qualify that? Because they're not going to have access to their hospital medical records unless (indiscernible)

Carl Jeffery: Right, how that's going to be…

Paul Oesterman, Chair: Whoever orders it…

Speaker: I guess you could do a checkbox for the provider to qualify it, but there's not going to be any way to actually confirm it.

Carl Jeffery: Right, not the way they are, because I know we can put a cumulative dose in there but because of the way the hospital claims would come through, well if they're inpatient, then we won't see it at all, but if they're in a clinic or something or outpatient treatment, then they may not come in for 6 weeks so they're going to be done with therapy by that time…

Beth Slamowitz: If it's okay that the understanding is it's just going to be a checkbox by the provider who is prescribing it to say that this is a duration of therapy that they're receiving.

Paul Oesterman, Chair: Or completion of therapy.

Beth Slamowitz: Right, there's just going to be no (indiscernible).

Dave England: I have a question. As I read through the indications here, it goes through the first few sentences and the last sentence, for moderate or severe restriction of mobility, is there some way it has to be documented what's considered "moderate to severe," if the patient for some reason does not have that restricted mobility after whatever treatment they've gone through, is it still appropriate to be on this medication. I don't recall any anticoagulant having that little description on it of moderate or severe restriction of mobility.

Carl Jeffery: I don't know how they would quantify that.

Holly Long: It's not quantified on what I have, either. (indiscernible)

Dave England: So if you have somebody that comes in like a 20-year-old who has had an injury or something like that but does not have moderate to severe restricted mobility because of whatever accident that may have caused the hospitalization and increased risk of DVT, would they qualify for the use of this because they don't have moderate or restricted mobility? How would we limit or define or categorize that moderate to severe mobility?

Carl Jeffery: Well, we don't actually have that in our criteria so that's from the manufacturer. That was a previous report from the manufacturer so that is not actually in our criteria. No it is, I apologize; you're right, it is in the criteria. So, we would just have to take the word from the prescriber who is filling it in that that's what they're using it for. I don't think there is any way we can verify that.

Paul Oesterman, Chair: We have the criteria for Bevyxxa coverage as on the screen right there. Is there a motion to approve the inclusion of this criteria for prior authorization? Do we have a motion?

Jennifer Wheeler: So moved.

James Marx: Second.

Paul Oesterman, Chair: And the motion and the second. Any further discussion? Hearing none, I'll call for the question, all those in favor of approval of the criteria for Bevyxxa, please indicate so by saying "Aye."

Multiple Speakers: "Aye."

Paul Oesterman, Chair: All opposed say "nay." Motion carried.

c. **For Possible Action:** Discussion and possible adoption of prior authorization criteria and/or quantity limits for belimumab (Benlysta®)

Paul Oesterman, Chair: Our next clinical presentation is for discussion and possible adoption of prior authorization criteria and/or quantity limits for belimumab (Benlysta). Is there anybody in the audience who wishes to present any information to the DUR Board? Okay, hearing none and seeing none, we will get the utilization and clinical information.

Carl Jeffery: We have another new medication. This one's kind of exciting because I don't think there's too many options to treat SLE, systemic lupus erythematosus, so it is a new medication to treat this. I don't have a whole lot of experience with SLE and I don't know if some of our other providers here do, but I think it's pretty nebulous disease where it's hard to treat and pin down symptoms. It's an autoimmune disease so it kind of fluctuates in its symptoms and similar to some other drugs, some other diseases, and good days and bad days and it kind of comes and goes. So, this medication has been indicated to treat the SLE for that, but it would be active auto antibody positive systemic lupus who are receiving standard therapy. Limitations of use of the efficacy of the Benlysta have not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. It has not been studied in combination with other biologics or intravenous cyclophosphamide and it has not been recommended in these situations. We have on page 62 of the binder has the criteria, just kind of the combined criteria. This incorporates some of the other input that we received from Amerigroup and Health Plan of Nevada. They have consolidated the criteria here so they have a diagnosis of SLE, the drugs prescribed by or in consultation with the rheumatologist, and documentation confirms that the recipient is positive for antinuclear antibody, ANA, and/or anti-double stranded DNA, and the recipient is currently receiving at least one standard of care treatment for SLE including one or more of the following: Corticosteroids, glucocorticosteroids, antimalarials, or immunosuppressant and the recipient must not have active CNS lupus.

Holly Long: And this also includes SilverSummit.

Carl Jeffery: Ok, SilverSummit is in here too, they just didn't send me separate criteria.

Holly Long: Just to clarify. The way that I organized it, all of the MCOs criteria, if they all have the same theme, then that's how it put it in the initial prior authorization criteria. They were all in agreement on the same criteria. The other suggestions possibly include maybe one MCO had to give theirs, so that's why it's different, it's separated like that.

James Marx: I have a quick question, when a patient switches MCOs or over to receives a service medications, what's the procedure for continuing the prior authorization?

Cody Phinney: Yes, when they switch between MCOs, they have a transfer of care arrangement to address that. It's slightly more challenging with the Fee for Service population in getting that information to the new MCO.

James Marx: So is it supposed to be seamless then, or what we've encountered is many times we'll do a prior authorization in December, the patient came to us in January, and we have to go through the same prior authorization again 3 weeks later. It's very time consuming.

Cody Phinney: It's clearly a place that we have opportunities to improve and we've been working with the MCOs on how we might particularly improve in that transition between Fee for Service and MCOs so that the MCO gets more information.

James Marx: Well, even from MCO to MCO, is what we see more frequently (indiscernible).

Cody Phinney: I'll take that back to our other committee.

James Marx: It's just really frustrating.

Paul Oesterman, Chair: In the recommendations, here it refers to the patient not having the evidence of severe renal disease. Do we need to have that quantified? Like the creatinine greater than 2.5 or…

Beth Slamowitz: Asking the providers to provide the lab value, like on a CA Form, again it would have to be (indiscernible).

Dave England: Also, I've got another question. I'm looking at the criteria on the page we're looking at here right now, if I filled out the continuance criteria, the documentation of the clinical response to Benlysta, now I seen above that in the other description to possibly include SLE acted by (indiscernible), I'm just looking that up on Google right now, and so the question is, would there have to be this score taken for a baseline given again before you can start this medication if we're "seeing improvement" with the change in the numbers; what percent change would we have to be looking at to see if there is improvement, 5%, 1%, 10%, 25%; what would be (indiscernible) and criteria if we are going to be using it.

Carl Jeffery: Dave what's, I'm not familiar with this SELENA-SLEDAI scoring; they did a scoring of….

Michael Owens: I mean, I've got it right here; I've never heard of it. It's a systemic lupus erythematosus disease activity index, that's SLEDAI, I've never heard of SELENA score, but it gives about 20-seizure, psychosis, organic brain syndrome, cranial nerve, kind of different criteria that you score off of and then you take that score and it gives you an idea of where the disease activity is.

Dave England: If (indiscernible) continue, it has to be a positive clinical response, but this score which we have to have this initially, to see if there's been any improvement to have a baseline to compare it with. I was thinking about the usual prior authorization criteria would have to say, an additional SELENA-SLEDAI score was given and while we're continuing this, there was a positive clinical response, and what sort of change in that would be if the top score was 150 and then next score was 120, does that mean it's getting better or worse. If (indiscernible) something to document it with.

Carl Jeffery: Yeah, so on page 63, so description of the Amerigroup criteria, so their initial approval criteria the Amerigroup has listed in here that the SLE is active as documented by the SELENA-SLEDAI score greater than or equal to 6 while on concurrent treatment regimen but then for the continuation therapy, there's no indication that that would be reviewed for renewal criteria.

Dave England: That's what I'm (indiscernible), not going to be a positive clinical response, I would think that documentation would be based on this form, so would we want to keep the criteria or raise values on that?

Carl Jeffery: What we've done with our other medications we've approved with this kind of criteria is we just take the word from the prescriber saying yes, they're having clinical improvement. There's a lot of these that we're not going to have the ability unless they submit

all their chart notes and everything, we're not going to know for sure if they're seeing clinical improvement, so we're just looking for confirmation from the prescriber that, yes, this is providing benefits for patients and they should continue it.

Dave England: Is it to specific asking for the score to be taken, but we're not doing anything with it, why bother?

Carl Jeffery: Well, I think it's a good measure for, and I'm not familiar with this so I'm learning something here, too, but I think it's-

Dave England: - I'm not saying we have the discrepancy. I'm saying like the rheumatologist or (indiscernible), here's what I think the baseline is this, I consider improvement to be on the baseline of this or underneath that would be something like this, I'm not saying we would have to say, well we're go from this we weren't allowed, but the criteria for that indication based on what they're seeing out there, but think that we could have a value and certainly consistent with asking for a value to be increased.

Beth Slamowitz: If the score is kind of subjective anyway and you're looking at improvement from a subjective standard, then I don't know that it matters either way. The checkbox again prevents that…

Michael Owens: The same amount of objective they wanted the score. I mean, when you're looking at what they want, the points that they get to score, and the scale is a change from baseline rather than giving just straight-out scores so if you've got somebody that's got, you look at all these things and they've got a score of 7. You rescore them because you think there's something that you've got a flare-up. It's not the 6, at least on the scale I'm looking at, it's mild or moderate flares a change from the baseline greater than 3 and severe is greater than 12, so I'm not sure what the-

Beth Slamowitz: -but is it just a flare-up or is it actual improvement in the condition?

Michael Owens: Well, they're calling this a flare, or at least that's the SELENA-SLEDAI score, it's a change of numbers based on these parameters of greater than 3 would be mild to moderate and greater than 12 is severe, proves that's all going in there, so I'm not sure what; this says for greater than or equal to 6 while on current treatment regimens, so they may have gotten that 6 in some other place at least on the scale I'm looking at, the numbers are 3 and 12. I don't know if that's (indiscernible).

Darrel Faircloth: It's your thought that you may want to actually deny a PA on this basis that there isn't adequate improvement shown or is this more a matter of you giving guidance in that it's most appropriate continue utilization when at least there's some improvement over time, perhaps to some extended guided by the statistics? This is just a generalization, in other words.

Beth Slamowitz: Yeah, at least that's where I was getting at, is that you don't have a way to actually validate the score or to compare scores or something and you're just basically… If they're conducting the score and you're relying on their medical knowledge to say they started here and they ended here and there was improvement and therefore would get it, and that's all really we should be asking for unless we have some way of validating that score or associating it

with improvement. I guess, we're out of time, we're just going with that. Kind of going back to what Dave said, that if we don't start with it, don't end with it. Don't include it if you're not going to use it as a marker.

Holly Long: Yeah, (indiscernable) and it was only used by one MCO where he disregarded other and get the other criteria suggesting (indiscernible).

Paul Oesterman, Chair: So let's break this down and take a look at it piece by piece. I think right now we have initially the initial prior authorization criteria, the five bullet points.

Holly Long: I'm looking to be pretty consistent with what I saw with other states as far as the other suggestions to possibly include the one that I saw that was pretty consistent in other states was the recipient is not currently receiving treatment for chronic infection and must not have evidence of severe renal disease with those two.

Paul Oesterman, Chair: I think with the studies and the recipient must be over the age of 18, also.

Holly Long: Okay.

Paul Oesterman, Chair: So, I can see where we would possibly include in the initial prior authorization criteria, those 5 bullet points that are there; they include the recipient must be 18 years of age or older, not currently receiving treatment for chronic infection, and must not have evidence of severe renal disease. (indiscernible) That goes back to the first bullet point. Do we want to add that word, the recipient has a diagnosis of active SLE?

Holly Long: It was in other states.

Paul Oesterman, Chair: It was or was not?

Holly Long: It was. It does say active in other states. Do you want to add the word active?

Paul Oesterman, Chair: Active.

Holly Long: Okay.

Paul Oesterman, Chair: Anybody have anything else they wish to add for the initial prior authorization criteria? So, we will vote on this all as one and extending down to continuing therapy criteria. Like Beth said, documentation of a positive clinical response, we will base that upon the practitioner. If they say, the patient is doing better, he is. I think we've already covered the other suggestions about severe renal disease and we already have in there the patient must not have active CNS lupus with the approval duration initially 6 months or 12 months and then continuing authorization for 12 months. Since this is relatively new, my gut feeling is leaning towards 6 months.

Carl Jeffery: For the initial authorization?

Paul Oesterman, Chair: For the initial authorization. This is not an inexpensive utilization.

Carl Jeffery: Yeah, there is some utilization in there, too. Page 75, so we've got quite a few patients that are on this already and it's not as bad as some of the other newer ones; it's not cheap. It's funny to see the spike there around June or July and it seems to be tapering off so I don't know if we don't have any criteria on it, then it's just, I wonder if there's some kind of feedback provided in the community that is actually using this medication…

James Marx: It looks like most of this is just for one or two days.

Carl Jeffery: Yeah, the day supply is, yeah, I don't see…So, it's given, it's an IV injection or subQ once weekly so it's probably given in the doctor's office to start, and so it comes in as a PAD claim, so it always come in, there's a one-day supply. The subQ injection can be given at home by the patient once they're trained on it.

Holly Long: This is the continuation that I saw for authorization in other states. They did an initial 6 months and they did a continuance in 6 months, as well.

Paul Oesterman, Chair: So, to recap what we're proposing is the initial prior authorization criteria to include more active in the first bullet point and we're also adding the recipient must be 18 years of age or older, recipient is not currently receiving treatment for chronic infection, and must not have evidence of severe renal disease.

Carl Jeffery: I've got highlighted on the screen; did I capture everything?

Paul Oesterman, Chair: Oh, yes.

Carl Jeffery: For the continuation, I think you were getting that one, too, but…

Paul Oesterman, Chair: If we were good with accepting the words from the prescriber that the patient is having positive clinical response, (indiscernible). We have this proposed criteria for the addition of this Benlysta for SLE and the motion and second to approve the criteria.

James Marx: I move we accept the criteria as edited.

Jennifer Wheeler: Second.

Paul Oesterman, Chair: We have a motion and a second. Any further discussion? Hearing none, seeing all, I'll call for the question, all of those in favor of the approval of the new Benlysta prior authorization criteria for initial and continuing therapy, please indicate so by saying "Aye."

Multiple Speakers: "Aye."

Paul Oesterman, Chair: All opposed, say "nay." Motion carries.

d. **For Possible Action:** Discussion and possible adoption of updated prior authorization criteria and/or quantity limits for Hepatitis C Direct-Acting Antiviral agents.

Paul Oesterman, Chair: Our next action item is the discussion and possible adoption of updated prior authorization criteria and/or quantity limits for Hepatitis C Direct-Acting Antiviral agents. We have

some new medications that go on the market. Is there anybody in the audience who wishes to address the Board? Hearing none and seeing none, we will move quickly then.. Carl.

Carl Jeffery: Kind of surprised there's no comments on this one but alright, so we have 2 new medications, Vosevi and Mavyret, they are all pan-genotypic so they hit all the genotypes. The Vosevi is indicated only for those who have failed previous therapies and the Mavyret is indicated for both naive and treatment experienced patients but they are a little bit more restrictive on which previous therapies that they could be on, so depending on the genotype; it gets really complex and this is where criteria gets a little bit crazy about what we need to include and they're based on what their genotype is and what the previous exposure has been and so especially for the Mavyret, it gets really complex with that criteria. Vosevi is a little bit more simpler because they have all the genotypes covered and it's only for treatment experienced so we don't have to worry about the treatment naive patients, and despite the base regimens and for 12-week approval or if they've had it without an NS5 for approval for 1a and 3 genotypes. We didn't get a combined criteria for the Mavyret on here so we've got the combined criteria for the Vosevi. I've got the Chapter 1200 criteria on here and it starts on page 96 of your binder. The criteria in here, and I think we've redone this a couple of times, and it gets confusing because I think we first tried to organize it by genotype and then if they had like previous exposure or what kind of treatment they've been on before or anything so it gets really confusing for not only for the providers who are trying to reference it to figure out, but really confusing for the call center who is constantly calling me saying, this doesn't make any sense, so that's why I've put the criteria together such that it's separate criteria so when we get a caller calling in, because they know what they want usually; they aren't calling in to say, hey I want to start something for hep-C, they say, I want to start Vosevi, what's the criteria for that. So, I think it's best to identify it by drug, so that's the basis of the criteria there. So, as we're working through these, I think we may update the criteria a little bit but it's mostly identified through drugs but I think we'll try to get the chapter cleaned up a little bit. We have some utilization in here from, this is just the Fee for Service. It starts on page 93 of the Utilization and see where we are with that. We have some claims for the Vosevi; no claims for the Mavyret yet. Also, just to let you know, the P&T Committee reviewed this class. They made Mavyret preferred and the Vosevi non-preferred and that's only because Vosevi only had the indication for prior therapy so just by default if they want Vosevi, they should meet that already, so that's the only reason to try to push people that way. On page 96, you can see the graph of utilization and kind of seeing a downward trend. Let me pull up a screen here quick, but it seems like there has been kind of a downward trend anyway with the utilization of these recently, so I don't know if that means we have treated the majority of the patients that need to be treated and I kind of hope that's where we are, but I don't know that for sure; it's hard to speculate on that, but you can see the Epclusa and Harvoni are still in the favorites.

Paul Oesterman, Chair: That's a general trend and the number meds used are definitely decreasing.

Carl Jeffery: Yeah, and, we have seen some patients already who are either they are coming up from retreatment, whether or not previous therapy has failed and they just have a reinfection from the same virus or if they're getting actually reinfected so it's hard to tell, and we don't have any criteria to specify that differentiate those.

Holly Long: I think, Carl, we have already stated that just to clarify, we do have combined criteria that was provided by Silver Summit and then by Optum which is the Vosevi. We didn't have anything for the Mavyret.

Shannon Sprout: I just want to take a moment and clarify the data that you are collecting that is combined data now, correct, with Optum?

Carl Jeffery: That's just fee for service.
Shannon Sprout: Okay, so we just wanted to make sure that we make that statement instead of…are we getting the data on it, therefore?

Carl Jeffery: Some of the classes.

Holly Long: Sometimes they don't have any yet. Okay, so that would be the reason, is that they just don't have it yet.

Shannon Sprout: They don't have the data yet.

Holly Long: They don't have the data yet or the data doesn't (indiscernible).

Shannon Sprout: Okay, so I think the report said that they are going to be able to make their decisions but we make sure that we footnote that on each one of these going forward so that we can just clarify that data and make sure that that information is there for the Board to make a decision with. And with that data, they can contact for future reference.

Paul Oesterman, Chair: I'm just going to throw something wild out there. Out of all of the prescriptions that are submitted for prior authorization, how many do not get approved?

Carl Jeffery: For, are you talking about hep-C specific?

Paul Oesterman, Chair: Mmm-hmm, yeah.

Carl Jeffery: I don't have the numbers at my fingertips. I can get those.

Paul Oesterman, Chair: I bet it's real small number; are we making this a lot more difficult than we need to, prior authorization criteria?

Carl Jeffery: Um, yeah, I mean, what we're doing is, I guess the denials that I've seen and the ones that have come out, so I just, I think we've had a couple. We've had one or two HPMs recently where people are disputing our decisions to deny their prior authorization requests. Most of them are because, one of them was, they are requesting a medication for somebody who had already been treated with something; the doctor didn't have any record. I think they either changed physicians or there were inaccurate records, but we showed that they were being treated with something with one regimen, but the doctor had something else, so it didn't match and then just some of the other criteria wasn't being met because they don't…. most of it's just missing documentation so I think it's just, you're right, some of it's just, we are adding a hoop to get through so not everybody can…

Beth Slamowitz: I think initially when we started all this, it was what 2 drugs? You know, and they were very expensive in that nature, but it was being appropriate and just like with all the other classes and more and more drugs out, at some point, you take a step back and you go, okay we will need to leave it on the provider to make the appropriate decisions, give the appropriate drug, and leave it at that.

Paul Oesterman, Chair: That's kind of the direction I'm leaning for this whole class. It shouldn't have to break the call center's heart.

Beth Slamowitz: And, I think we will be seeing utilization drop-off but that be more of an appropriate decision and we may want to give it some time before, we make that decision just to make sure that's where we're at, especially with these new drugs coming in, we kind of see where they go.

Carl Jeffery: Another thing you can do, and maybe, and I see the direction you're going, and maybe to taper them off a little bit rather than just completely do away with any kind of prior authorization criteria so maybe we want to start with; you know, there's supposed to be a criteria where they have to have a diagnosis and it is prescribed by a GI doc or some specialist in the field or something; we're still limited so not just wide open access but there are still some checks in here to make sure that it…

Paul Oesterman, Chair: So at this point in time, we have checks and balances for all of them except for these 2 new ones?

Carl Jeffery: Right.

Paul Oesterman, Chair: The usage on these two new ones is 0 for one of them at this point, so I would almost like to see us not vote on this at this point and come back next meeting with a simplified criteria because we are making this way more difficult than it needs to be. That's just my…

Beth Slamowitz: Like an overall criteria for hep-C.

Paul Oesterman, Chair: Yes.

James Marx: It's true, the prior authorization in general like maybe 3 times, I mean, 1 time in 10 years I've had prior authorization dispute and it's just what you had to deal with.

Paul Oesterman, Chair: Let's try to make life a little bit easier for our providers.

Beth Slamowitz: For something that's like, you know, kind of improving care, this is something where you're not sure how much volume of drug to be studied in 2 people and it costs thousands of dollars and not many people are appropriate to kind of limit that utilization, but we're getting to the point very quickly and that's not the issue.

Holly Long: Do you want us to draft something simple like that for next time or do you want to wait? Okay for next time.

Paul Oesterman, Chair: Yes, please. Because it's on the agenda, do we have to vote on it?

Darrell Faircloth: No, you do not.

Paul Oesterman, Chair: I think we have a Board, do we all need to vote on these or in agreement that we defer until next meeting for simplified criteria?

James Marx: It will cover all these.

Paul Oesterman, Chair: Something that will cover….

e. **For Possible Action:** Discussion and possible adoption of updated prior authorization criteria and/or quantity limits for Immunomodulator agents.

Paul Oesterman, Chair: Okay, our next agenda item for possible action is the discussion and possible adoption of updated prior authorization criteria and/or quantity limits for the Immunomodulator agents. Is there anybody in the audience who wishes to address the Board? Sandy.

Sandy Sierawski, Pfizer: Hi, good evening. I'm Sandy Sierawski, I'm a pharmacist here in Nevada and I've worked with Pfizer as a Medical Outcomes Specialist. I'm here just to make a couple comments about Xeljanz and Xeljanz-XR. In looking at your Optum review document, one indication that Xeljanz or Xeljanz-XR now has for the treatment of adult patients with active psoriatic arthritis who have had inadequate response or intolerance to methotrexate or other DMARDs, so this new medication was FDA approved in December so it's new in that area. I don't want to address the other indications with RA because we have already talked about that at previous meetings, but I just wanted you to be aware of the psoriatic arthritis indication. Limitations, it is not recommended for the use in combination with biologic DMARD and potent immunosuppressants such as azathioprine and cyclosporine. As far as dosing goes, Xeljanz is to be given for 5 mg twice daily in combination with nonbiologic DMARD and the Xeljanz-XR is 11 mg once daily in combination with nonbiologic DMARD. So, the drug does have a boxed warning on it so for safety update on the psoriatic arthritis indications, the safety profile observed in patients with active psoriatic arthritis treated with Xeljanz was consistent with the safety profile observed in patients with RA and the most common serious effort ramifications with active psoriatic arthritis was serious infections and in the patient's with RA, malignancies have been observed in clinical trials of patients with active psoriatic arthritis. I'm not going to go into a lot more data and stuff. I can supply a package insert if you'd like more data of give you the website, but what I do want to spend more time on is to address the actual criteria that you have and looking at the criteria, Section 1C under Psoriatic Arthritis, number 4, it states that the recipient had an inadequate response to any one nonsteroidal anti-inflammatory drug or contraindications for treatment with an NSAID and then it states for any of the following DMARDs. So, I'm wondering if that should be reworded to include an inadequate response to the DMARDs; kind of wounds like it's a run-in and it's a contraindication for DMARDs and is making an inadequate response for DMARDs for contraindication. So, maybe to clarify that for me as a system set up for an inadequate response; am I reading that correctly or incorrectly to clarify the regular use…

Carl Jeffery: It would be a question from the call center that would ask and I would have to go with the language that they have for their scripting but I can't, I don't know that…

Sandy Sierawski, Pfizer: But as with the other indications, with the intent to say inadequate response to NSAID or DMARD and then, or contraindication. You know what I'm saying?

Carl Jeffery: Right.

Sandy Sierawski, Pfizer: So how this is supposed to say contraindication for DMARD. Part of the indication for the dosing on Xeljanz is it can be in combination with it; it's supposed to be used in combination with the nonbiologic DMARD so it doesn't say that inadequate response and we couldn't use that indication. Does that make sense what I'm asking? Any questions or comments?

James Marx: I had a question and we've said this before, apparently we don't allow trial of samples or voucher-type supplies to be considered an adequate trial.

Beth Slamowitz: We don't have any way to document those trials.

James Marx: Why would anybody lie about that, to say that they had samples and..

Carl Jeffery: Well, I would think they would accept that as really an adequate trial, but samples are usually to get people started so I don't know. Are these people on like samples for an extended period of time; do you think they really got an adequate trial of samples?

Beth Slamowitz: But, how would you document that, how would document the sample?

Carl Jeffery: Well, it would come from the doctor's notes. They have to document that they got the sample.

James Marx: They have to chart they gave samples and then they had a response, adverse consequences. I don't see why I would have to exclude that as a trial.

Carl Jeffery: From the payer perspective, it wouldn't be any different than if the patient came from another payer and we ended up having claims data for any, having the doctors word for it, but they've been on it through another payer, so from that perspective, it's the same. There's really no difference.

Ryan Bitton, HPN: Ryan Bitton with the Health Plan of Nevada, Senior Director of Pharmacy, and some of the criteria I don't know, it's logical, some of the criteria of the Health Plan of Nevada Pharmacy on the commercial side. Sometimes we say no to taking samples because it's a way to get a new product without trying a preferred agent or trying to lower the cost of an efficacious product for that. The samples sometimes skirt the benefit we put in place around drug A being used first.

James Marx: You guys try and skirt that all the time, I don't see why that would be a…

Ryan Bitton, HPN: I was just explaining why that criteria…

James Marx: We go through this struggle all the time and skirting around it seems to be the (indiscernible).

Ryan Bitton, HPN: That's why it kind of exists is because it's not so much clinical over a cost issue, started on a sample and then go on that therapy long-term.

Carl Jeffery: I can see how it created hardship for patient because if they do start on a sample and they are stabilized on it and maybe doing well but then you go and visit the PA and say, no, they don't

meet the criteria. Now you've got a patient who can't get their medication and they've got to try something else. So, I think it would be to Ryan's point, I think it's almost a detriment to the patient to get a sample for those medications where maybe there's a risk of them not being able to continue it.

James Marx: In reality, when we encounter situations like that, we can usually get an override and it's easier to get an override in that situation than it is to say well we're just not to going to try because you might not get it. We spent a lot of time on prior authorizations and I have to say that we are almost universally successful in getting them.

Ryan Bitton, HPN: I think we clinically have a chance to review it. But that's why we put that criteria there.

Jeannine Murray: This is Jeannine, and I'm the Pharmacy Director with Amerigroup (indiscernible). I don't think that we addressed samples in our PA criteria, but to what Carl was saying earlier, generally I think in Medicaid we don't talk about using samples just because that kind of history might not be there, but with our PA, it's different because it's an application that they've been on it regardless of what (indiscernible).

Paul Oesterman, Chair: So we actually have a couple of things in front of us here. One is being the addition of Kevzara due to formality and then the point that Sandy has brought up for Xeljanz. So, let's take these separately. I think we have existing criteria for the Immunomodulators of the verbiage that the committee agrees to change to include…

Carl Jeffery: Kevzara is a new medication for rheumatoid arthritis and the way I worded the Optum criteria that's in there on page 133 I've got pulled up here, I basically copied and pasted from chapter 1200 the way it currently is and what we've done with the other one so can you see even the Siliq in our ears was the one that we added last, it was just updated, so I would propose that we just add Kevzara to the list of products and in that way, our criteria has everything else, just makes everything meet the current criteria that's already been approved. In that way, when they do as evidence from Sandy and Xeljanz that have new indications, we don't need to go back through here and update, except for the errors in it, but we don't need to update the criteria every time a new medication comes out and that's why we've got it this way.

Paul Oesterman, Chair: So, looking at approving the Optum proposed criteria is that correct?

Carl Jeffery: Yeah, and that's just the criteria that's right out of chapter 1200, so that would essentially just add the drug name to the list of medications in chapter 1200.

Paul Oesterman, Chair: So, let's take the first step here and that would be to see if we can get a motion to approve the Kevzara to the list of Immunomodulating agents and prior authorization criteria as presented here by Optum.

Carl Jeffery: On page 143, so I'll just have chapter 1200, so it's chapter 1200 (indiscernible) on there, so we just added to the list, Kevzara would be just added to the list of Immunomodulators.

Paul Oesterman, Chair: So, a motion to approve the addition of the Kevzara prior authorization criteria to the list of Immunomodulators. Do we have a motion and second?

James Marx: So moved.

Jennifer Wheeler: Second.

Paul Oesterman, Chair: Motion and a second, any further discussion? Hearing none, seeing none, and no further discussion, all those in favor please indicate so by saying "Aye."

Multiple Speakers: Aye.

Paul Oesterman, Chair: All opposed say "nay." The motion carries. We have the second issue within this for the psoriatic arthritis where we want to update our verbiage to include the inadequate response or contraindication under Section C #4.

James Marx: I move for the addition of inadequate response verbiage.

Paul Oesterman, Chair So, we have a motion to add the verbiage of an inadequate response to contraindication C4. Do we have a second?

Jennifer Wheeler: Second.

Paul Oesterman, Chair: We have a motion and a second. Any further discussion? Hearing none and seeing none, no further questions, everybody in favor of the addition of verbiage of an inadequate response to the contraindication and treatment, please indicate so by saying "Aye."

Multiple Speakers: Aye.

Paul Oesterman, Chair: All opposed say "nay." The motion carries.

f. **For Possible Action:** Discussion and possible adoption of updated prior authorization criteria and/or quantity limits for Opioid-Induced Constipation Agents.

Paul Oesterman, Chair: Next agenda item is the discussion and possible adoption of updated prior authorization criteria and/or quantity limits for Opioid-Induced Constipation Agents. We do have somebody in the audience to address this.

Rupa Shah: My name is Rupa Shah, I'm the clinical pharmacist and medical science liaison with Purdue Pharma. I'm here to review the prior authorization criteria for the Opioid-Induced Constipation Drugs. I'm available to address any specific questions you have regarding the Symproic tablets. Thank you.

Carl Jeffery: The criteria that I put there, the Optum criteria that's on page 204 is basically just again, I put the chapter 1200 criteria and adopted it into our criteria just to include the other one, so basically has for recipients 18 it's being used for FDA-approved indication which would be the OIC which could be morph depending on what else they get approved, and then there's the application that they had an inadequate response to at least one agent from the three of the four traditional laxatives, so bulk-forming, osmotic, saline and stimulant laxatives. That's what we've got approved from chapter 1200 already for the opioid-induced constipation. We also have some criteria for and I just threw it in there just for the Board's reference, irritable bowel syndrome which has similar medications, which

some of them cross over which we have indications for both, so I just threw that in there for the Board's records just in case you wanted that in there.

Paul Oesterman, Chair: The existing products, do we have an initial quantity duration?

Carl Jeffery: Yeah, in chapter 1200, no, the prior authorization is for one year; we didn't differentiate between initial or continuation.

Paul Oesterman, Chair: Has P&T looked at preferred?

Carl Jeffery: We did, yeah. They have the class a little bit different because they only have a single class for both the OIC and the chronic idiopathic constipation all lumped into a single class, so it's a little bit different, mostly Amitiza is also the other preferred. Amitiza and Linzess, so the P&T has the GI agents, functional gastrointestinal disorder drugs, all lumped into one category, so Amitiza and Linzess are preferred and Movantik, Relistor, Symproic, and Trulance are the non-preferred.

James Marx: I see a lot of opioid-induced constipation obviously, and I would say that we report that some patients don't respond and have pretty much everybody on lactulose and I have to say that have higher satisfaction with lactulose than I do with the peripheral opioid antagonists and the patient will see withdrawal symptoms, massive explosive sort of diarrhea, and I have it all, I sample it all, and I can tell you that most all the patients on lactulose after sampling, maybe a couple percent that don't like the lactulose. So, it's an expensive alternative like lactulose, they get like a 6-month supply for 10 dollars a pill.

Carl Jeffery: Yeah, I think that's the reason behind their criteria there, too. Try 3 of the 4 classes to make sure that at least doing their due diligence before getting one of these.

James Marx: I realize that's the criteria, but I seriously doubt most of these patients actually get 3 of the 4 before someone asks for something they saw on advertising and they ask for something they say, and that's my concern. Lactulose is incredibly expensive.

Jennifer Wheeler: Yeah, I'm assuming most of them probably aren't covered at all. Are you taking the physician's word for it?

Carl Jeffery: No, these would all be. Medicaid pays for over-the-counter. They need to have a prescription for it, but Medicaid does pay for over-the-counter.

James Marx: I would like to see a little bit more aggressive use of… nobody wants a sample Lactulose.

Paul Oesterman, Chair: Do we want to possibly bullet point and go through this documentation of medical record of an inadequate response for a certain period of time and try?

James Marx: If it works, if it works in only 2 days. I mean, it doesn't take 6 months of trial to determine if it will work or not, at least maybe a week at the most recorded for one product. You can give an injection of Relistor and have a bowel movement within an hour.

Carl Jeffery: You can see some of our utilization here. I don't think we have a tremendous amount of utilization, and this is just for Fee for Service, population here, but Movantik and the Amitiza are definitely in a class here but so anywhere up to 90 claims a month for the Movantik so this is for all of the Medicaid population.

James Marx: That's about right, that's a nice percentage.

Carl Jeffery: Yeah, we're not seeing a huge utilization of this stuff anyways.

Paul Oesterman, Chair: Are we looking to try to keep it as a class prior authorization?

Carl Jeffery: Right, and that's how I've got it worded. So, it would essentially just add that name to the criteria; that's how I have it worded in chapter 1200.

Speaker: There are two different criteria in the binder.

Carl Jeffery: Just because there's some drugs in this category that have crossed over.

Speaker: Okay, do they both need to be updated?

Carl Jeffery: No, because this one only, Symproic only has an indication for opioid-induced constipation, not irritable bowel. Some of the other ones that do have an indication for both of them.

Paul Oesterman, Chair: Do we have a motion to approve the inclusion of Symproic to the opioid-induced constipation agents with the criteria that are proposed to match the existing criteria for the other agents for the same indication?

James Marx: I move we adopt the criteria.

Paul Oesterman, Chair: We have a motion. Do we have a second?

Michael Owens: I'll second.

Paul Oesterman, Chair: So we have a motion and a second. Any further discussion? Hearing none and seeing none, and no further questions, all those in favor of the approval of the addition of Symproic to the opioid-induced constipation agents, please indicate so by saying "Aye."

Speaker: Aye.

Paul Oesterman, Chair: Any opposed say "nay." Motion carries.

5. Public Comment on any DUR Board Requested Report

Paul Oesterman, Chair: With that being said, we now will move on to DUR Board Requested Report and ask if there is anything that has any public comment on anything at this point in time? Hearing none, we'll go into the first Board Requested Report which pertains to the Utilization of Medications with the Orphan Designation or Indication.

6. DUR Board Requested Reports

a. Utilization of medications with Orphan Designation.

Carl Jeffery: Alright, so at our pre meeting, I was telling Paul all I learned about Orphan Indications and it was interesting to find that all sorts of medications even like Abilify and Lipitor or Crestor have orphan drug indications, so they're included in here because you pull down the list of all the drugs that have orphan indications from the FDAs website, all these are included. I ran the report of all the drugs that have been orphaned indications and put them all in here and sorted them by how much money to some of the pharmacy, what we've paid pharmacies for these. Again, this will only Fee for service data, but you can see the top here and there's only a single page of these because I think this is just to break the Board in a little bit to see what they want to do with this class or with medications with an orphan disease status but the top ones on here are definitely what we would expect to see, the hemophilia drugs are always up there, hep-C, we've got Harvoni. I really don't see anything that's too out of place on here that we haven't really addressed but I think this is a good report for the Board to see something and maybe from the provider's standpoint, too, you've heard colleagues or somebody say that we always use this medication off-label, it's not indicated for it but it works really well or they think it's works well but if there's any kind of input from the provider community you've heard for those, I think those would be ones that are worthwhile addressing. Something else we've kind of been tossing around, too, is just kind of a blanket P.A. status for medications with an orphan drug, because I think more and more of these orphan medications are coming out with these orphan diseases, we may not even have anybody in Nevada with this disease, so it seems silly to bring every one of these really rare medications to the DUR Board that we will never use the criteria for because we don't have anybody in Nevada for it. If there's some kind of blanket criteria that we may try to come up with for the Board to talk about and approve that would just say, any medication with an orphan disease status that maybe there's a dollar limit, too, it costs so much per therapy that they need to have updated approved indications by a specialist or something like that, but I think it just starts the conversation.

Paul Oesterman, Chair: It seems like the vast majorities are injectable or parental products? Perhaps would could start off on looking at those and the oral products.

Carl Jeffery: Sure.

Dave England: I had a question. On some of these medications, aren't some of these also only available through specialty pharmacies, and what would be the process the patient is not Medicaid and qualifies for one of these medications or being able to work with and provide to those specialty pharmacies?

Carl Jeffery: Yeah, the specialty pharmacies all have contracts with Medicaid to provide these medications and with provider enrollment, it gets kind of complex, too, because even within the specialty pharmacy chains, maybe only one pharmacy in New Jersey is able to dispense that one medication so that one pharmacy in New Jersey has to be licensed with Nevada and then register with Medicaid as being a provider. It gets kind of hectic with some of these new medications that are coming out.

Dave England: Even though someone may be on Medicaid, if the medications are provided by the manufacturer that has a free medicine program or drug-assistance program. Would they even qualify or would they work with us on that sort of thing or is that just something because the patient was told by the insurance they wouldn't be available to do that assistance program?

Carl Jeffery: My experience with patient assistance programs for patients who have Medicaid is that the manufacturers are really reluctant to pay for any medication because they do have Medicaid. They do everything they can to get Medicaid to pay for it first.

Beth Slamowitz: And, usually with the vouchers or something similar, there is a disclaimer that says if they receive government assistance, they won't pay for it.

Dave England: Sometimes the manufactures are more willing to work with you for the patient's situation.

Carl Jeffery: Is there anything else the Board would like to see as far as the orphan diseases or like to see any other reporting for the future and see what I can pull together. This is my first stab; I think at the last meeting we just had a real quick discussion about orphan diseases and this is my first stab of report.

James Marx: How does the Call Center deal with these situations?

Carl Jeffery: If there's no PA criteria, the Call Center doesn't get called.

Holly Long: So what we're going to propose for next time that we talked about is that we would do almost similar to what we were talking about with the hep-C list, like Carl said, some kind of general policy that we could draft up for you at the next DUR meeting that we cover, orphan drugs, new-to-market drugs, fast-track drugs from FDA since they are all kind of falling into that category. That seems to be what other states are doing, in particular and take a look at it next time.

Paul Oesterman, Chair: I think that makes sense.

b. Opioid utilization – Members under age 18 years

Paul Oesterman, Chair: Our next report is opioid Utilization for members under the age of 18.

Carl Jeffery: This one is a response from Dr. Marx. We last time talked about, added a criteria for the Tramadol and codeine the last time we talked about that. So, Dr. Marx said, well we should probably look at all the opioids for kids so that's what this is. We looked at, and again this would be just Fee for service data here, but we looked at just the opioids for children under 18 so on page 228 has it broken down by class, by all kids, and then we broke it down on page 229 to 0-5, 6-11 year olds, and 12 to 17 and this is very timely, too, because the FDA just released some information saying that probably no kid under 18 should be getting opioids. They said, there's very few exceptions of when it's probably okay but for the most part, they shouldn't be getting.

James Marx: I believe I said that.

Paul Oesterman, Chair: One thing that is fairly apparent to me when I looked at this was a lot of these are cough syrups with opioids in them and, for example, promethazine with codeine, we had 15 members under the age of 5, 74 members between 6 and 11 and it is contraindicated in patients under the age of 12.

Holly Long: We just added that FDA criteria that supports that just recently so we do have the criteria that supports that; this is probably before…

Carl Jeffery: Yeah, and this data was through October 31st.

Holly Long: We still have the tail-end of that.

Paul Oesterman, Chair: With the new FDA guidelines for being very restrictive for opioid use in children under the age of 18. I think what they're trying to get at is pretty much all of the cough and maybe the only indication would be acute pain of some kind, facture, something like that and that would be just a very short course. I think we need to revisit the prior authorization criteria for all of the patients under the age of 18 and the use of opioids and I don't want to get to the point of being ultra-restrictive when there is an appropriate indication that…

Dave England: I have a question, too, starting with our national opioid epidemic that we're having and the DEA has required a 25% reduction in community tax shares in 2017 and they required a 20% in reduction in 2018. Have we as DUR submitted to Medicaid, have we implemented the sort of reduction in the use of opioids to our clientele?

James Marx: No.

Dave England: I think the DEA is taking the wrong approach that we can just kind of cut down the use of the amount of opioids available without a case-by-case review, but at the same time, with all the emphasis being put on hospitals and health department and things like that, do we want to consider implementing the reduction in opioid use because of the epidemic going on and supply us with what the hospitals and clinics are being put on to decrease their opioid use.

James Marx: I'm totally opposed to that. I mean, we can't treat an epidemic by killing the patients before they get the disease.

Dave England: I agree. That's why I think it's ridiculous, but at the same time, are we taking it to review or are they going to look at our criteria for opioid use to see if we can possibly reduce but at the same time, not be distracted with what the DEA proposed.

James Marx: Dave, I think if there really is over-utilization, then we need to look at our prior authorization criteria and if they are properly imposed, then a decrease will occur. If there's not an over-utilization, then we won't see anything, but I don't think we should say, well we should just arbitrarily cut down everybody by 25%.

Dave England: Well that's what I was thinking, the comment and the fact that that's what society is being exposed to, but at the same time, do we feel, I think we have these numbers now, take a look at these numbers and they decreased 6 months from now after seeing a change, has it stabilized, has it increased or decreased, maybe determine if we need to take a look at our criteria again to be sure

that we're making medication available, but at the same time, are we truly taking care of our patients by not having accessibility, as well.

James Marx: I still would like, let's say, let's stop the ice cream manufacturer's from making ice cream to cut down on obesity. I mean, it has not relevance to actually how it plays out.

Dave England: I would have to agree with you. It's kind of like, we're kind of preaching to the choir here, but I think we are doing our part to show that we are showing we are interested, I think this is good to take a look a report every 6 months to see if there has been any change and if another client would have use of medication are up or down, would have to review the utilization spike up or down in that period of time to see if we are doing our part in keeping it in check being able to monitor it so that we're not allowing it to go unencumbered.

James Marx: Dave, the problem is your assumption that there's already over-utilization occurring and if that's not correct, you're not going to see a decrease so, I mean, I think we're doing a pretty good job. Maybe we can see a little bit more rigid, unless we want to authorize every single prescription for every single patient. I mean, do you really want to do that, well you really need to have more criteria like the patient's age, what's the extent of the disease, how much do they weigh. I mean, we're not doing all that and I'm not sure that it would make any difference.

Dave England: And I really don't think that's where we need to put the thumb screws on it, in order to do our due diligence, we have to continue our monitors like we're doing out there now or are you watching it, you can say yes, we have been and see what we found. Our population has increased, our utilization has increased, it is pretty much maintaining, we don't feel that we have a problem with our process.

Paul Oesterman, Chair: Well Dave, actually on the next page, there is a trend chart and I think that's very telling and it's very good news that our both member and claim count for opioid utilization and the sum of the day's supply is both trending down. If we can take the credit for it, I'd be more than happy to.

Carl Jeffery: I think the Board should take the credit for it because I think most of it is due to the 7-day quantity limit we put in place and the 60 mg equivalents we put in and the PA criteria that I don't think are overly strict but I think the need for the population.

Holly Long: And, isn't that when the trend started down is after the implementation…

Carl Jeffery: Yeah, so May is when we implemented that so you kind of see still like before it went in in May, it's bumping around here pretty steady. The trend line is down because it's dropped off pretty significantly but May 2017 is when this went in and that's really when it started to go down.

Dave England: I think we keep monitoring this and look at it at least every six months the trend isn't starting to go up again, I think if we do that, I think we are doing our due diligence in response to this issue.

Carl Jeffery: Yeah, and I think we can bring this back next time with some criteria for the children getting opioids. We don't have a huge number of kids that are on here, but there's 500 members

who are on hydrocodone and acetaminophen under 11 years old that probably shouldn't be on there. Not sure why they're getting hydrocodone with acetaminophen.

James Marx: What about the 19 under 5 that are on methadone. That's really…

Carl Jeffery: I would almost guarantee that's detox.

Paul Oesterman, Chair: That's what I was thinking. Newborn…

Multiple Speakers indiscernible.

Paul Oesterman, Chair: Good information and keep going the direction we're going and bring that information next meeting.

Carl Jeffery: So, on page 232, in the opioid information here containing…

James Marx: I just had one more thing. I think if you're going to really address Dave's concern, I think we really need to look at the number of opioid overdoses amongst our Medicaid population, and I would bet that the instances are lower in the managed Medicaid population than it is in the general population, because those patients are actually in the process of receiving medical supervision.

Holly Long: See if it's possible to get that information.

Carl Jeffery: I know it's not in our data, but… It might be in the claim's data.

Holly Long: Okay, I'll see what I can do.

Carl Jeffery: So then on page 232, I've got the top 10 opioids by quantity. I don't know if this has been much use. It gives you a breakdown of which opioids are being used for the Nevada population. It's not surprising to see hydrocodone, acetaminophen, oxycodone, and oxy/acetaminophen is the top one here.

Paul Oesterman, Chair: Can we take a look next time at the acetaminophen components…

Carl Jeffery: We have a 2.8-gram limit on all the acetaminophen already, so they shouldn't be exceeding that.

Paul Oesterman, Chair: Can we check to make sure that we are not exceeding that?

Carl Jeffery: Anything else stick out on that chart?

Paul Oesterman, Chair: It would be interesting again to take a look at the number of members who are receiving more than 4 different opiates.

Carl Jeffery: And those would be the out-layers, I would think, I would think any more than, for your chronic pain patient, any more than 2 are going to be the exception to the… I could see the

standard therapy of long-acting or short-acting for breakthrough. I think it's kind of the standard but then you get the complex patients Dr. Marx maybe sees that…

James Marx: How about somebody with a Fentanyl patch and given some morphine with that, oxycodone. It happens occasionally.

Paul Oesterman, Chair: Four is going to really…

James Marx: Four is really way outside.

c. Opioid Utilization – Top prescriber and member

Paul Oesterman, Chair: Top ten prescribers.

Carl Jeffery: And then we've got the top ten prescribers. All the IDs match so we've got prescriber IDs so that would match and see where they are. They're all sorted by so the top ones by member count and then by claim count and then day supply so it's all sorted a little bit differently. Then, there's two more on the following page so some of quantity and then by the pharmacy amount paid.

James Marx: Is there any indication of type of prescriber like the dental, veterinary…

Carl Jeffery: So, I've got the same chart that's on page 235. I put that same chart that we've been tracking on here so it's just been updated. So, that's the one you're probably looking at. So, that's the top 10 prescribers by sum of the quantity. You can see that same nurse practitioner, he always shows up there at the top, the Las Vegas, he's prescriber W if you want to go back and try to track down where he is, he's top prescriber on a couple different fields in here. But, we really don't have too much turnover on who we're seeing over here, so it's the same kind of docs and nurse practitioners that we're seeing time after time so they really don't rotate through here very much. We did do a retro-DUR and the letter is actually I think the very last page in your binder. We sent retro-DUR out because the Board requested me sending these top 10 prescribers just a letter showing where they stand and where they are compared to their peers and so the letter said, here you're number one among your peers for Medicaid and it's a self-evaluation, we'd just like you to take a look at this and see if the data we have makes sense to what you see. We had one response and it's in the very back one; it's actually the M.D. of the practice for the nurse practitioner that responded and said, yeah, we just have a lot of Medicaid patients and outlined very clearly about which practice and you can see the nurse practitioner does see most of the Medicaid patients; they're working on this. So, it was nice to get some feedback from the prescriber's office.

Paul Oesterman, Chair: Can we get next time, first quarter, just to see if the names are still the same of the top 10 prescriber list?

Carl Jeffery: It's going to be interesting to compare it to the last one because the one we had in October meeting so..

Paul Oesterman, Chair: Top 10 usual reports.

Carl Jeffery: Yeah, and these are just kind of the standard stuff; nothing outstanding to see on these. I know we've got some new members on the Board, too, so if there's anything on here you think you'd like to see that would make these more useful or maybe different, then certainly speak up. We have a lot of data and trying to mush it into something that's worthwhile and see something that's going to be worthwhile.

Paul Oesterman, Chair: ProDUR, you were going to something with the new format?

Carl Jeffery: Well, I think that will be next time. Actually, our company has an initiative to actually redo that one chart so I'm kind of waiting for them to get their act together to redo that chart, so unfortunately you get the same old ProDUR report this time. I'm hoping for next time we'll have a new updated ProDUR report and maybe it's a little bit more clear. I'm at least able to pull all the raw data and I kind of played with it a little bit and I couldn't make it any more clear than what that current report had.

James Marx: I don't see how you got this done in 3 months.

Paul Oesterman, Chair: I think it's been a while since we've looked at. Next time, we can take look at our diabetic patients and see where we're… Again, I always ask the same question, when is it going be possible to merge the medical data with pharmacy data to make sure that diabetic patients are getting their eye exams, their foot exams.

Beth Slamowitz: Well, and it may be helpful, too, because I know our medical steering committee is actually doing a presentation of diabetes and they asked what they even get pulling the medical information so if that presentation's put together, possibly put that on the agenda for use of the population.

James Marx: Hospital admissions too.

Beth Slamowitz: Yeah, and that's all part of that presentation that they're working on.
Paul Oesterman, Chair: Anything else on the Board which is requesting for yourself for next time?

Paul Oesterman, Chair: Any public comments on any subject? No going over the hill tonight?

Carl Jeffery: Yeah, Dave, it's a good thing you didn't drive over and I'm not sure you'd get back.

Paul Oesterman, Chair: Date and location of the next meeting?

Carl Jeffery: So, April 26 and the same room again, I like this place.

a. Adjournment.

Paul Oesterman, Chair: With that being said, we'll go ahead and adjourn and wish Darrell all the best.