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DRUG USE REVIEW BOARD

Meeting Minutes

Date of Meeting:

Name of Organization:

Place of Meeting:

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

Thursday, October 19, 2017 at 5:15 PM

(DHCFP), Drug Use Review Board (DUR).

The State of Nevada, Department of Health and Human Services, Division of Health Care Financing and Policy

Event Number:

315 214 493

Phone: 1-763-957-6300 Event: 315 214 493

Board Members (Present)

Paul Oesterman, Pharm.D. James Marx, MD Michael Owens, MD Marta Bunuel, MD Attendees

Board Members (Absent) David England, Pharm.D. Chris Shea, Pharm.D. Jennifer Wheeler, Pharm.D. Michael Casal, MD

Reno

DHCFP: Darrell Faircloth, Deputy Attorney General Holly Long, Social Services Program Specialist Duane Young, Chief, DHCFP

DXC: Beth Slamowitz, Pharm.D.

OptumRx: Carl Jeffery, Pharm.D.

Public:

Niren Shah, PTC Bio Don Moran, Teva Deron Grothe, Teva Nera Hartman, Neurocrine

Teleconference:

Joanna Jacob, Ferrari Stephanie Ferrell, DXC Anastacia Marvi, DXC Lisa Stroup, Neurocrine Mark Swartz, GSK Christy Lemons, Orexo

Johnna Young, DXC Jeannine Murray, Anthem Ryan Bitton, HPN

AGENDA

1. Call to Order and Roll Call

The meeting called to order at 5:39PM.

Paul Oesterman, Chair: We're going to go ahead and call the meeting of the Drug Utilization Review Board to order. We'll start off with a roll call.

Beth Slamowitz: Beth Slamowitz, DXC Technology

Duane Young: Duane Young DHCFP

Holly Long: Holly Long, DHCFP

Carl Jeffery: Carl Jeffery, OptumRx

Marta Bunuel: Marta Bunuel, Psychiatrist

Paul Oesterman, Chair: Paul Oesterman, Pharmacist

Darrell Faircloth: Darrell Faircloth, Senior Deputy Attorney General's office

James Marx: James Marx, Physician, Las Vegas

Nevada Department of Health and Human Services Helping People -- It's Who We Are And What We Do Michael Owens: Mike Owens, Physician, Reno

Dr. Casal on the phone

2. Public Comment on Any Matter on the Agenda

Paul Oesterman, Chair: So we do have a quorum so we will go through our agenda and we'll start off by asking if anybody in the audience, either online or in person, who has any public comment on any matter on the agenda. If you have one specific agenda item you can make public comment at that time. Also just as a reminder public comment is limited to five minutes. Seeing no comment or hearing none... You know we do have one. Please provide us with your name and who you are with and your topic.

Christy Lemons: Absolutely. Good evening and thank you for the opportunity to be here tonight. My name is Christy Lemons, I am the National Account Director at Arexa Pharmaceuticals. I am here on behalf of requesting consideration around opioid dependence treatment. Specifically, given not only the known national epidemic, but also to consider the President's recent elevation of opioid dependence as a state of national emergency. I would like to read to you a brief statement by the President. President Trump's Commission on Combating Drug Addiction and the Opioid Crisis. Dated August 17, 2017. All FDA approved medication assisted treatment should be offered by authorized providers. Not just one or two of these approved options. These decisions of which medications to treatment used must be based upon what is best for the patient. I would like to hand out for your review a copy of ASAMS standards of care for the addiction specialists around opioid dependence and also thanks for your time and attention and ask you to consider parody for all opioid dependence treatments for this very important treatment area. Any questions?

Marta Bunuel: Just one. Is it all opiate and does it also include heroin and anything else that is an opiate, not just prescribed treatments to seek parity for all addiction treatment?

Christy Lemons: We refer to all opioid dependence treatment including Zubsolve and Suboxone and other generics and brand in that area.

James Marx: As the only Drug Utilization Review Board now, does that mean that all the Fee For Service and the managed Medicaid, do we all use the same criteria? Or do they get independent criteria to what we have here?

Duane Young: So, yes. They do have independent criteria so what this establishes going forward is they have to adopt whatever criteria we have here. So we may have to revisit certain drugs or certain criteria that we have done in the past.

3. Administrative

a. For Possible Action: Review and Approve Meeting Minutes from August 24, 2017

Paul Oesterman, Chair: We have the minutes from the August 24 meeting, they need to be reviewed and I will ask after a moment of review for a motion and second.

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James Marx: I move to approve as submitted, Jim Marx.

Marta Bunuel: I second.

Paul Oesterman, Chair: We have a motion and a second, any discussion? Hearing and seeing none, I'll call for a question. All those who approve say Aye. Those oppose say nay, all abstaining. I was not in that meeting so I can't comment. They are approved.

b. Status Update by DHCFP

Paul Oesterman, Chair: We're going to start with our clinical presentations And Our First. Oh, Status.

Duane Young: Going to public hearing on next Wednesday will be the state plan amendment change to offer 12 months of contraceptives. This was done by our legislature and two bills of Assembly Bill 249 and Senate bill 233. Both protections around women's health. We will be one of the first states to offer a 12 month contraceptive package in the state plan. The policy will be a bit more intricate as it will allow for three months and then a renewal of six months and then after six months they can renew each year. It will be a stepped in policy. For the purpose of the state plan we only outline 12 months. Also going back to the workshop October 26 is the added services for adult podiatry, registered dietitians and medical nutrition therapy and then our gender reassignment surgery. Those will hopefully be added to the state plan beginning January 1st as well as we were given budget authority during the last legislative session.

Marta Bunuel: Why is the birth control in three months then six months?

Duane Young: In order to get all the various insurance providers to sign off on it, they agreed that they do it phased in so that people can get three months supply initially and if they don't like it or they want to try something else and they can do that. So it would allow them some kind of choice before they're locked in for an entire year supply.

Paul Oesterman, Chair: So on the six months, will they only get six months at a time or three months because most of the time we do a 90 day fill?

Duane Young: They do 90 days until they are locked into the one that they like and then move to six months and then a year.

Michael Owens: Forgive me, is it only oral contraceptives. Do we cover intrauterine devices?

Duane Young: Yes, those are covered as well. So it's a little bit different with the implant.

Paul Oesterman, Chair: Same with that Depo-Provera I guess.

4. Clinical Presentations

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

Paul Oesterman, Chair: We'll start with the Clinical presentations. Our first presentation is in regards to the discussion of a possible adoption of prior authorization criteria and or quantity limits for Austedo. We will ask if there is anyone in the audience. Please step up to the mic and introduce yourself. Your five minutes start when you start.

Don Moran: (Difficult to hear on recording) – I'm Don a pharmacist with medical affairs for Teva. Offered some observations, Austedo approved for Huntington's chorea, a rare condition with a progressive and fatal outcome. Also has a high rate of depression and suicide ideation. Five months later the FDA approve an indication for tardive dyskinesia. The coverage criteria are focused on the treatment of Huntington's disease, but excludes tardive dyskinesia. Requested the board also discuss the tardive dyskinesia indication.

Paul Oesterman, Chair: Thank you for your presentation. Just one word of caution. Right now we have in front of us the prior authorization for that one indication. The second indication which you're talking about was not on the agenda. I don't believe we can take action on that.

Darrell Faircloth: I believe you are correct. I'm not sure this is within what you've proposed to do. So let's agendize it for a later time. Because it would include other drugs as well.

Carl Jeffery: So it says that the agenda is just the drug name. It doesn't talk about any indications. So it has the indication for the tardive dyskinesia and it did come out after we put these guidelines together so that's why it's not in there. There is criteria under the Ingrezza tab for tardive dyskinesia that I would propose the board adopt also for Austedo because it would also qualify. I don't want to get you out of your comfort zone so if you rather us bring this back for the next time to talk about tardive dyskinesia or if the board is able to do it now.

Darrell Faircloth: If you can independently incorporate the criteria for this drug that seems appropriate. You did agendize this drug and limitations and approval criteria for this drug. I don't see a problem doing it that way.

Carl Jeffery: No there wouldn't be any other drug involved.

Don Moran: Thank you, my hope was for not seeing it on the agenda that meant the product would be excluded.

Carl Jeffery: Duane brought up a good point. Because we have to incorporate the MCO data with this too. We didn't give them an opportunity to opine on any kind of proposed criterion. We may bring this back next time and maybe it would be fairer. OK. So this time we are going to talk about the criteria for Huntington's chorea. I think and just for completeness sake what will happen is we'll tell the PA call center if they get requests for tardive dyskinesia there won't be any criteria, they will just approve it based on the requested indication. So we're transitioning to kind of a different format for the DUR Board because we're incorporating the MCO data too. In your binders there is proposed criteria from OptumRx on page 17. On the next page the criteria that one MCO that submitted and this is from Amerigroup. In the future we may have the other two additional criteria to incorporate together. Amerigroup had some exclusion criteria that would say that people would be excluded if they're suicidal or treated inadequately for depression or have hepatic

impairment or utilizing an MAOI. It comes down to a diagnosis of Huntington's chorea and is prescribed by or in consultation with a neurologist.

Holly Long: Did we also want to include the age 18 requirement?

Carl Jeffery: No I didn't say that but we can add that. My understanding of the diagnosis of Huntington's chorea is really not diagnosed until 40s or 50s anyway. So I don't know that it is that critical, but we can certainly put it in.

Paul Oesterman, Chair: For safety's sake I think it should be in there. In terms of the two criteria it appears the Amerigroup criteria encompasses everything the Optum criteria has plus some additional points like 18 years of age or older and contraindications.

Carl Jeffery: Amerigroup doesn't include the requirement for being a neurologist.

Paul Oesterman, Chair: I propose we approve the Amerigroup criteria with the addition that a neurologist has been consulted.

Carl Jeffery: We had our initial authorization would be for three months and then 12 months after that based on a response to therapy.

Paul Oesterman, Chair: This will be a small number of patients who will be getting this. I will ask for a motion and a second to approve the criteria that's on the page with the addition of the consultation with neurologist being bullet point three.

Marta Bunuel: So it doesn't need to be prescribed by a neurologist just in consultation with one.

Paul Oesterman, Chair: Right. Rural Nevada provides a few challenges.

Marta Bunuel: Yes.

James Marx: And initial authorization of three months.

Paul Oesterman, Chair: I'm good with 12 months.

James Marx: I so move.

Marta Bunuel: Second.

Paul Oesterman, Chair: We have a motion and we have a second any further discussion. We'll make sure Dr. Casal is still on the line.

Dr. Casal: Still Here.

Paul Oesterman, Chair: Okay. Speak up if you have any comments or questions. Any further discussion? Hearing none I will call for the question, all those in favor of the proposed criteria for Austedo indicate by saying aye. All opposed say nay. Motion carries.

James Marx: Is the Amerigroup utilization per quarter or year or what?

Carl Jeffery: That's a good question. They didn't specify. The page where you see the Amerigroup utilization go ahead and tear that out because you will need to reference that in the future because they put all their utilization on one page.

Duane Young: We asked them for a year.

b. **For Possible Action:** Discussion and possible adoption of updated prior authorization criteria and/or quantity limits for Cerliponase Alfa (Brineura ®)

Paul Oesterman, Chair: Our Second product is discussing the possible adoption of prior authorization criteria and or quantity limits of the Brinuera product. Is there anybody in the audience or on the phone who wishes to address the board? Seeing none, we will go ahead and take a look at the criteria here, Carl.

Carl Jeffery: Again this is out of my realm of expertise. This is an extremely rare condition, late infantile neuronal ceroid lipofuscinosis type 2. Brinura is indicated to treat this. It's a rare brain disorder, I was trying to read and understand how it all works is kind of a dysfunction how the brain metabolizes lipids. Our criteria here I think we're a little bit more strict than the Amerigroup criteria. We just wanted to make sure we have some safeguards in place to be sure that this was not going to be used inappropriately or outside the indication. I don't know what the price is but I'm sure it's not cheap and it has to be given intrathecally every two weeks. It's not an easy medication to give. We don't have any claims for it yet. My proposed criteria which is somewhat problematic requires a lab test to diagnosis and confirm this TPP1 enzyme is detected by dry blood spot tests. The state currently does not reimburse for that test. So I don't know if that's in the works or I'm not sure how you're going to diagnose this without the gene test.

James Marx: This is an insurmountable barrier.

Beth Slamowitz: There are ways to get the test. They have to apply for it.

Carl Jeffery: Our criteria is just the diagnosis and then avoiding the contradiction. So if they have a VP shunt or any kind of intraventricular access and in consultation of neurologist with expertise in the diagnosis of this disorder. And then under the care of a physician knowledgeable in intraventricular administration. It does have to be given intrathecally in a three year old which I don't think is an easy task.

James Marx: The indication is to slow the process. So they are ultimately going to lose the ability to ambulate?

Carl Jeffery: That's my understanding of the disease progress. It just slows it

Marta Bunuel: Do you know how long it slows it? For years maybe.

Carl Jeffery: They have some studies that show that the clinical efficacy. They needed to study it for the whole 96 weeks to see any kind of significant change. And so it's not a real significant change.

Paul Oesterman, Chair: It's a five year extension phase starting.

Marta Bunuel: I wondered about this phrase before, "With expertise in the diagnosis." How does the neurologist demonstrate expertise? Is there criteria?

Carl Jeffery: I think it's a valid question. I think it's a concern because is it just a physician who read an article, does that qualify them as being an expert? How does the call center judge that? I think sometimes you just have to put trust in the prescriber's office that they know what they are doing.

Michael Owens: All these kids are going to come from large centers, Davis, Stanford, and UCSF. And then will be farmed out to [local specialists], these are kids that are going to be coming from study centers because that's where they are going to get diagnosed. All of those orders are going to come through and have a neurologist here in Reno but the origins of the medications are going to come from large teaching centers. You might find one that sneaks through miraculously.

Paul Oesterman, Chair: For now it seems that one of our concerns is to have the ability for the diagnostic test done but there are options for patients. That's not going to be a barrier to approving. Going out of sequence here, I would ask that for the next meeting, could we see some utilization data on these orphan drug products to see what kind of use there is? I feel like the Optum criteria is a little bit more finite and descriptive. Those include the criteria from Amerigroup. Can I get a motion to approve?

James Marx: I move to approve the Optum criteria.

Paul Oesterman, Chair: I will second it, is there any further discussion.

Marta Bunuel: When the disease is so rare and patients are put on treatments like this, do they also automatically get included and the information sent to perhaps one of the centers so the study can continue in a way?

Paul Oesterman, Chair: I would think not necessarily. If it was being conducted as an investigational agent then it should be provided at no charge by the company. That's something to see if patients for whom this is prescribed if they are in the clinical trial then that should not be impacting us. So we have a motion and a second. Any further discussion? Hearing none, I will call for the question. All those in favor of approval of the Optum presented criteria for the Brinuera product indicate so by saying aye. All opposed say nay. The motion carries.

c. <u>For Possible Action</u>: Discussion and possible adoption of updated prior authorization criteria and/or quantity limits for Valbenazine (Ingrezza®)

Paul Oesterman, Chair: Okay, our next product that we are discussing is the valbenazine or Ingrezza. I will ask if there's anybody here in the audience, on the phone or in person. I know we have one in person here. So is there anybody on the phone wishing to discuss that. If not we will ask our guest in the audience to step forward.

Lisa Stroup: Thanks for having us here, my name is Lisa Stroup, I am the neuropsychologist and medical liaison with Nurocrine biosciences. Nurocrine is excited to hear approval of the first medication indicated for tardive dyskinesia in adults. Ingrezza is a new chemical entity. Covers

approval process. There was a discrepancy around the modifiers to the diagnosis, the DSM 5 is the gold standard for diagnosis. There are no modifiers in the DSM criteria.

Marta Bunuel: I'm assuming this would not be a first line medication. There are other things that we try in the meanwhile, aside from discontinuation. I'm not saying they don't work well. I'm just wondering.

Lisa Stroup: This is the first medication indicated for TD. So if you go to the guidelines, we are not in there yet. They were last updated in 2013, there was not a level A recommendation. Level B was for gingko biloba and clonazepam. There are no strong studies. APA was most recently updated in 2009, they suggested a second generation over a first and consider reduction of the dose, but there is some question with that recommendation. There was a recent epidemiological study looking at prevalence in first generation vs. second generations and second generation reduced and was better but did not eliminate TD.

Paul Oesterman, Chair: There are mixed reviews for the use of benztropine, it is not an approved indication, however we still see it fairly widely. Are there any studies comparing and contrasting the two products?

Lisa Stroup: No, we actually allowed patients on benztropine. The interesting thing if you talk to a movement disorder neurologist, they typically advise that benztropine could be contraindicated in a hyperkinetic movement disorder. In something like Parkinson's in a hypokinetic disorder, benztropine would be expected to reduce those symptoms, but the evidence is not there to support its use. We did go ahead and include and do some sub-analysis. When broken down by those on benztropine vs. not, the ones on benztropine had a more robust response.

Paul Oesterman, Chair: There's no black box warning?

Lisa Stroup: No and nor were there any signals seen in our trials for increased depressive symptoms or suicidal ideation.

Michael Owens: For tardive dyskinesia, so this is a not a permanent illness?

Lisa Stroup: It often is. If you take a patient off all their dopamine blocking agents, you can still see this indefinitely.

Michael Owens: Okay, all right.

Marta Bunuel: Over time it seems to be related to the amount of exposure, length of time and total dose exposure. At least is seems to be once they start showing.

Michael Owens: Discontinued medications that kind of thing doesn't help?

Marta Bunuel: If you catch it quickly, some people certainly do stop it. Now you're in this dilemma, are you going to go to Clozapine or Seroquel or one of these other ones that are not strong on the dopamine blockade or are more specific or at least in terms of their striatal dopamine blockade. They've probably been tried of many things already, is my guess. How bad is their psychosis,

what is the impact on them perhaps. And people around them versus letting them have the movement disorder.

Michael Owens: For prior authorization we always ask, have you tried this and this and this. So if you really don't have much room for argument for trying a couple different medications and get back with us.

Lisa Stroup: Once you have gone through the hard work of stabilizing a patient, to be asked to reduce or destabilize the patient is a big ask. Discusses trial including how the movement disorders were rated.

Michael Owens: Are there and indications for Tourette's?

Lisa Stroup: We are just starting a phase 2 study in pediatrics. To date, we had a phase two in adults and pediatrics. Both failed to hit, especially in the pediatric trial, but there were some benefits so we are starting a new trial this month in ages 6 to 17.

Holly Long: I have a question. A couple of the other states included in their PA criteria that they require chart notes confirming no suicidal thoughts or violent behavior or has stable psychiatric symptoms and we don't have that.

Lisa Stroup: I'm not sure what that is a response to. It may be a black box warning on other medications. We didn't' rule out a rule history of suicidal or psychiatric symptoms. About 40% of the sample had a history of suicidal ideation. The patients in the trials did not show any changes in their psychiatric stability over the 48 weeks of the trials.

Paul Oesterman, Chair: There are pieces and parts from both criteria that are good. I would like to see a blend of the two where we use the diagnosis based on the DSM 5 criteria, the duration of treatment from Amerigroup criteria is good. The contraindications are pretty similar. The Amerigroup criteria did not include the patient not being a candidate for a trial dose reduction or discontinuation of the offending medication.

Carl Jeffery: Yeah I think it's worth consideration. It's going to be the exception. But if they have a patient and they can probably do without this they stop it and their symptoms get better, fantastic. I know it's going to be rare but if one out of 100 can do without it.

Paul Oesterman, Chair: Do we have consensus here for the blended criteria?

Carl Jeffery: On the screen, we're going to use the DSM 5 criteria for a diagnosis of tardive dyskinesia.

Paul Oesterman, Chair: And I like the A and B components from Amerigroup.

Carl Jeffery: And then the patient is 18 years or older. So one of the following the patient has persistent symptoms of tardive dyskinesia despite a trail dose reduction tapering or discontinuation, or the patient is not a candidate for a trial reduction tapering or discontinuation and prescribed in consultation with a neurologist or psychiatrist.

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Paul Oesterman, Chair: Yes. And this is one I think the initial authorization of three months makes sense.

Michael Owens: Is there any wiggle room on the age restrictions?

Carl Jeffery: Do you really see TD in under 18?

Marta Bunuel: I don't have extensive experience with children, the atypicals are usually the ones to be approved first for them, and so the incidence in theory is less. I don't know all the study data. But I think it would be pretty unlikely to see a child, but I don't know if there are other studies that show something else.

Lisa Stroup: We don't have data for children. Tardive dyskinesia increases with age and exposure. There are cases and it does happen, but we do not have data for the pediatrics.

Carl Jeffery: You can see on the screen the criteria from a and b from Amerigroup. Everything else look good?

Paul Oesterman, Chair: We have a request for a motion to approve the revised and updated criteria for valbenazine.

Marta Bunuel: Motion to approve.

James Marx: Second.

Paul Oesterman, Chair: We have a motion and a second. Any further discussion? Hearing and seeing none, we will call for the question, all those in favor say aye, all those oppose say nay. The motion carries.

d. <u>For Possible Action</u>: Discussion and possible adoption of updated prior authorization criteria and/or quantity limits for Safinamide (Xadago®)

Paul Oesterman, Chair: Our next topic is the discussion and possible adoption of updated prior authorization criteria and or quantity limits of safinamide or Xadago. Do we have any public comment, in the audience or via phone? Hearing none, we will go ahead with the criteria.

Carl Jeffery: Xadago is indicated for Parkinson's disease who experience an off episode. The study participants had to have an off-episode for at least one hour. They have the freezing episodes. They had some strict criteria about what else needs to be with it, it needs to have a dopamine agent and that is why we wanted to bring it to the board to make sure these patients are not getting this as a monotherapy where is wouldn't be effective. That reflects our criteria, they have a diagnosis of Parkinson's disease, and they will continue on their dopamine agent and have 1.5 hours of off-period per day.

Paul Oesterman, Chair: The Amerigroup has their list of preferred and non-preferred agents. Does that mirror what we have?

Carl Jeffery: We don't have this class in our preferred drug list, so they are technically all preferred.

Paul Oesterman, Chair: I would like to request we look at these at the next meeting to bring consistency between the two groups.

Carl Jeffery: The P&T handles the preferred and non-preferred.

Paul Oesterman, Chair: OK, I would like to recommend the P&T handle this class.

Carl Jeffery: Okay, we have some of these. We have the pramipexole and ropinirole in a class. It is something the MCO's are still allowed to have their own preferred drug list, they are not required to follow ours.

Paul Oesterman, Chair: To me this is an example of we are going to have a difficult time with a single criteria. If you look at Amerigroup's approval criteria, you can't incorporate that into ours.

Carl Jeffery: I don't know how that incorporates with their PDL. If they have a requirement to try two preferred agents before getting a non-preferred, and we don't have that requirement, I'm not sure how that will work.

Duane Young: Whatever criteria we adopt, they won't require the true preferred.

Carl Jeffery: They couldn't require two agents first, so that would essentially be preferred.

Duane Young: What they do on their cost containment is a little different. Technically if we adopt criteria they do not have to have two fails, they would have to abide by that.

Darrell Faircloth: Are all the preferred generics? Is that the basis of their differentiation?

Paul Oesterman, Chair: No, they have some generics as non-preferred. They already have this product as a non-preferred agent. Where does apo-morphine stand on our formulary?

Carl Jeffery: We don't have that class, so it would be open access.

Paul Oesterman, Chair: Do we know in their trials how long it took to notice improvement?

Carl Jeffery: I don't remember seeing that. It was a 24 week study.

Paul Oesterman, Chair: It seems like there are several contraindications including opioids, SNRI's and TCA's. I have a feeling a lot of these patients will be on these medications.

Carl Jeffery: The contraindications have been added, the member is not on opioids, SNRI, TCA's.

Paul Oesterman, Chair: This is one of these drugs that if we don't add criteria it becomes blanket open access. My personal feeling is to have some kind of criteria and it should be relatively strict. I see a lot of potential as it being added on and widely misused or having the potential. I wish the manufacture had a representative here.

Marta Bunuel: What would you propose then like you have to try certain drugs first?

Carl Jeffery: We can take this to the P&T and have added in the class of the preferred drug list and maybe require step through some other agents. I suppose we could lump all the Parkinson's drugs in one class.

Paul Oesterman, Chair: Since the trial was 24 weeks, I would lean toward a 3 month initial authorization to make sure it is effective. As a recap for the Board, if we do not approve criteria of some kind, then the product becomes cart Blanche available for use. It is important for us to establish criteria that can be modified at a future meeting, but I think we do need to address with some kind of criteria. I am open to anything.

Carl Jeffery: I have recapped the changes on the screen, diagnosis of Parkinson's disease, levodopa or other dopaminergic treatments will be continued and patient reports greater than 1.5 hours per day of off-period and patient not on an opioids, MAOI, SNRI, TCA, cyclobenzaprine or methylphenidate/amphetamine, St. John's Wort or dextromethorphan. The initial authorization will be for three months.

Marta Bunuel: The Parkinson's patients I see, they have a high incidence of depression. What are the risks when we use with SNRI's, do we have any sense of how risky it is when combined? I'm just thinking it might be a problem. I'm wondering how risky combining these really is.

Carl Jeffery: It is essentially an MOAI, it is the same risk with mixing an MOAI with any of the other agents. Similar to selegiline to treat Parkinson's as well.

Paul Oesterman, Chair: I will ask for a motion and second to approve our revised criteria as shown on the screen.

James Marx: Motion to approve.

Michael Owens: Second.

Paul Oesterman, Chair: Any further discussion? Hearing none, I will call for the question, all those in favor or accepting the criteria say aye, those opposed say nay, the motion carries. We can again review the usage of this product moving forward.

Carl Jeffery: There were not any claims of this so far.

e. <u>For Possible Action</u>: Discussion and possible adoption of updated prior authorization criteria and/or quantity limits for Deflazacort (Emflaza®)

Paul Oesterman, Chair: Our next topic is discussion and possible adoption of updated prior authorization criteria and or quantity limits for Deflazacort or Emflaza. Anybody in the audience or on line to address this? We do have someone in the audience.

Niren Shah: I'm Niren Shaw, I am a MSL at PTC Therapeutics. PTC therapeutics is company focused on rare orphan conditions for two decades now. With a deep focus on Duchenne muscular dystrophy. I appreciate the fair and balanced review and based on pivotal study one and two. PTC acquired Emflaza because we felt it was an important treatment for Duchenne. DMD is a

progressive and fatal disorder. Patients in the early phases lose muscle mass and as they get older lose the ability to walk. By teenage years become wheelchair bound. In late teens they acquire pulmonary dysfunction that often leads to their demise. The data used to approve Deflazacort was based on studies conducted in the 80's and 90's, we decided to move them to old data set that were collected by independent investigators. By using new outcome measure, we find there is a striking difference between other agents. We looked at active DMD, a phase three study compared to placebo, the patients were all on corticosteroids. We found that Deflazacort has a 36 meter improvement. The threshold from the FDA for meaningful benefit is about 30 meters. I would like to share the data, it is in a slide format.

Carl Jeffery: Is it something we can post publicly?

Niren Shah: Not yet.

Carl Jeffery: Sorry, it isn't something we can distribute to the board without being able to post publicly.

Niren Shah: I'm happy to take any questions.

Paul Oesterman, Chair: Looks like the criteria is very similar between Optum and Amerigroup. With one difference being the duration of prednisone treatment being 6 months in the Amerigroup criteria.

Carl Jeffery: I was going to recommend a change, I think it is a good idea to have a minimum trial of prednisone.

Paul Oesterman, Chair: One thing on the Amerigroup criteria, section 4 and item D, weight gain is likely a side effect of prednisone. If used in a five year old they will be gaining weight anyway, how do you attribute that to the medication?

Niren Shah: That is a good question, we looked at real world data, Deflazacort has been in Europe for a number of years, there was a program called the UK Master's program allowing some US citizens to get it. We found that physicians found these patients typically don't change dosing as they get older.

Marta Bunuel: Does it take six months to show the side effects of prednisone? The patients I have seen it is fairly quickly they show neuropsychiatric effects.

Niren Shah: We feel the same way. Most of our patients who have this PA criteria typically have complaints within the first couple weeks. It is mostly behavioral. Other adverse events are usually up to six months.

Holly Long: The other states that provided criteria to me also had a six month duration, but none said why they chose that duration.

Carl Jeffery: I think the requirement should be a fair trial. As long as it is a significant attempt. If prednisone works, all the better.

Paul Oesterman, Chair: The Emflaza is a synthetic steroid, how do the side effects compare to other steroids?

Niren Shah: Most studies compare to steroids, Deflazacort is shown to have less behavioral side effects, less weight gain, it doesn't affect the metabolic compared to prednisone. Deflazacort is associated with a higher incidence of cataracts.

Paul Oesterman, Chair: Are the side effect differences clinically significant?

Niren Shah: They were not measured that way, so it is hard to say. As a patient gains weight, they are higher risk of facture since they have brittle bones anyway. So just something to consider.

Carl Jeffery: On the bottom of page 58 shows the adverse events. Cushinoid appearance, increase weight, upper respiratory tract infection, cough.

Paul Oesterman, Chair: Ok, that is verses placebo, not prednisone.

Carl Jeffery: Right, they are similar to the prednisone. Is it a pro drug to a steroid?

Niren Shah: It is.

Marta Bunuel: Can we say that since there are some side effects that are later in onset, can the criteria reflect that? If there are neuropsychiatric symptoms from prednisone that present early, they would not have to continue?

Paul Oesterman, Chair: Would the three month timeframe capture that? Or do you need something shorter?

Marta Bunuel: When I see problems with prednisone, it is pretty early on with neuropsychiatric side effects. It usually presents within weeks or days.

Carl Jeffery: Could you say three month trial unless neuropsychiatric symptoms within one month?

Marta Bunuel: Could we break it up to something to what we see more clinically in general?

Paul Oesterman, Chair: Is there a difference in the neuropsychiatric response from steroids in peds vs adults?

Marta Bunuel: I don't have the knowledge. I know aggression is one, and they certainly see it in adults. Children may be acting out and may not be due to the steroid initially. Maybe a little more time than a couple weeks.

Paul Oesterman, Chair: We can always change it down the road if we need to.

Niren Shah: I can address the peds vs adults. A lot of the boys with DMD also have a spectrum of autism. It is interesting with the side effects, the level of irrationality is a little higher in these boys. When you do see it, it is clear. When it is in adults you can still see it. We had a case study where a boy with OCD got much worse with prednisone.

Marta Bunuel: I think we should take into consideration the aggression and especially if these boys also have autism. We don't have a lot of medications to treat autism and if the prednisone is going to make it worse, I would want them off it.

Carl Jeffery: Would you consider neuropsychiatric symptoms a contraindication for prednisone use? I'm just trying to think of some terminology we can use.

Marta Bunuel: The problem is when you take off prednisone, you are adding a bunch of other stuff to control other symptoms. I think the better choice is to remove the prednisone rather than start other medications. Children that have autistic spectrum disorder, they don't act predictably to medications.

There don't seem to be guidelines to say which medications first. The children I have worked with have been very aggressive. It is very hard for everyone in the family.

Paul Oesterman, Chair: Do we know why Utah went with three months?

Holly Long: They didn't provide that information.

Niren Shah: They didn't say anything, they just put three months.

Holly Long: The other states that sent information listed six months, Utah was the only state with three months and nobody had details as to why. The individual had a six month trial, contraindication or intolerance to a six month trial of oral prednisone.

Marta Bunuel: And intolerance isn't defined. So then we get some wiggle room.

Carl Jeffery: Right now we have a patient has had a trial of at least three months of prednisone or intolerance to prednisone.

Marta Bunuel: I think that sounds reasonable.

Paul Oesterman, Chair: Do we need to expand beyond prednisone to include prednisolone with is the liquid form.

Carl Jeffery: I think all the studies were done with prednisone, so I'm not sure.

Holly Long: I have one state that says both prednisone and prednisolone.

Paul Oesterman, Chair: I think if we include that it saves the call center some possible headaches.

Carl Jeffery: Or equivalent steroid dose since we do list the specific prednisone dose. I updated the criteria on the screen to read for at least 3 months or intolerance.

Marta Bunuel: It doesn't define a timeframe.

Paul Oesterman, Chair: At any point at which they have an intolerance to the prednisone, then there is no time requirement. Do we have any other discussion before we look for a motion and

second for the revised criteria? Then I will ask for a motion and second to approve the revised criteria.

Marta Bunuel: So move.

James Marx: Second.

Voting: Ayes across the board, the motion carries.

f. **For Possible Action:** Discussion and possible adoption of updated prior authorization criteria and/or quantity limits for Omalizumab (Xolair®)

Paul Oesterman, Chair: Our next item is the discussion and possible adoption of updated prior authorization criteria and/or quantity limits for omalizumab or Xolair. Do we have any public comment?

Carl Jeffery: This will be a fast one. All we are doing is changing the age. They got an updated indication for six years old instead of 12 years old. The red-lined version of Chapter 1200 on page 61. All we did was update the criteria to read the recipient must be six years of age or older instead of 12.

Paul Oesterman, Chair: Anybody on the board have anything to discuss?

Michael Owens: So moved.

James Marx: Second.

Voting: Ayes across the board, the motion carries.

g. <u>For Possible Action</u>: Discussion and possible adoption of updated prior authorization criteria and/or quantity limits for codeine and tramadol use in children.

Paul Oesterman, Chair: Our next item is the discussion and possible adoption of updated prior authorization criteria and/or quantity limits for codeine and tramadol use in children. Do we have any public comment? I think the board members should have received the supplemental information for codeine and tramadol in children. It was from the dental provider response. Dr. Capurro who is the Nevada State Dental Health Officer has sent this additional information from the dental perspective. When looking at the usage of these products, it appears some was from dental practitioners. And it is being used off label for pain management in pediatric patients. Carl, do you want to go over the information?

Carl Jeffery: This is very timely. I was on a call with our commercial formulary group, and they are rolling out all the opioid cough syrups where they will not allow for anyone under 12, not obese, does not have severe lung disease or have sleep apnea, is not undergoing tonsillectomy or

adenoidectomy and the lowest effective dose for the shortest duration is being requested. We have quantity limits for the codeine related products. We don't have those applied to the tramadol related products. I think it should be just for one fill or one month. This would only apply for members under 18. But nobody under the age of 12 would be approved.

Paul Oesterman, Chair: I think this is consistent with the standard of practice for where these products are not approved for under the age of 12.

James Marx: there was an article a few days ago showing ibuprofen was just as effective as morphine for post op pain. Morphine was not superior to ibuprofen.

Paul Oesterman, Chair: The chart on page 80, we see that 11 and under, the primary agent is acetaminophen with codeine elixir.

Carl Jeffery: We have almost just as many claims in the zero to five group in the same time-frame.

Paul Oesterman, Chair: I wonder if some of this wasn't used for the anti-tussive properties. My question for the medical practitioners, would they want to include any tramadol quantity limits, we already have the codeine quantity limits.

Carl Jeffery: You could not allow tramadol for under 18, there really isn't that much use.

Paul Oesterman, Chair: You take away the codeine, I think you would see shift to tramadol rather than ibuprofen.

Holly Long: Colorado implemented a 400mg daily limit for tramadol.

Paul Oesterman, Chair: That is a pretty hefty dose.

Carl Jeffery: I was going to suggest 200mg daily for kids, that would be four tabs a day, for a seven day limit.

Holly Long: Arkansas has a limit of less than 17 years of age for tramadol. Tramadol/APAP is done separately, only indicated for five days or less for management of acute pain. Ages 16 or less will reject at the point of sale. They added some age edits at their last DUR.

Paul Oesterman, Chair: My thoughts are under 12, no, between 13 and 17, 200mg max and a five day limit for tramadol. Contraindicated if there is an SSRI on their profile? What is the lethal dose of tramadol?

James Marx: I never use it, so I'm not sure.

Paul Oesterman, Chair: I'm just thinking if we give them four tablets per day for 5 days, is that enough to cause problems if they took all of them.

James Marx: I suppose there would be some serotonin syndrome symptoms, but I don't suspect it would be deadly.

Beth Slamowitz: It says toxic dose starts at 500mg.

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James Marx: A single dose of 500mg, at what age group.

Beth Slamowitz: A toxic dose starts at 500mg for the immediate release.

Paul Oesterman, Chair: I don't think we should cover any of the extended release product.

Beth Slamowitz: I would think a lot of these kids are getting it for tonsillectomy. Like Dr. Marx stated, using ibuprofen and acetaminophen are just as effective. I don't think it is necessary for children under 12 to have access to these agents.

James Marx: I think there are better options.

Paul Oesterman, Chair: Right now, under 12 would not be able to get either.

Carl Jeffery: Do you also want to include the tramadol with acetaminophen? I neglected to include that on the sheet.

Paul Oesterman, Chair: Yes. Authorization for one month hypothetically, they get a prescription with four refills...

Carl Jeffery: The way I thought it would happen, the authorization would be for one month, but they would only get one fill in that timeframe.

James Marx: Is this for antitussives or is this for pain?

Carl Jeffery: We don't know for sure what they are using it for. From the reports from the last meeting, a lot of the prescribers were ER doctors.

James Marx: I think seven days is more than adequate.

Carl Jeffery: I think there are better antitussives.

Marta Bunuel: If you're talking about kids, they may abuse it.

Paul Oesterman, Chair: Are we in agreement with these criteria with the inclusion of the tramadol limit of 200mg and a max of 5 days and no extended release and this would also include the products in combination with acetaminophen. And a one fill only. Do we have a motion to approve the criteria as presented on the screen with the modifications just made?

James Marx: Should we look at the opioids in general? I don't think we have pressed the whole issue, we should broaden our scope. I don't have a problem approving this motion, but we should drill down deeper.

Carl Jeffery: There are no restrictions for other opioids, they might move to hydrocodone. I think it is a good idea to roll out to all opioids.

Paul Oesterman, Chair: So I did hear approval of the motion.

James Marx: I think this is just a temporary solution, I move we approve as presented.

Marta Bunuel: Second.

Paul Oesterman, Chair: The only discussion is that at the next meeting we look at some of the other controlled substances and make that an agenda item.

Voting: Ayes across the board, the motion carries.

5. Public Comment on any DUR Board Requested Report

Paul Oesterman, Chair: Do we have any public comment on any of the board requested reports? No, we will go to the board requested reports. The first one is looking at the anticonvulsant medications used for children and adolescents.

6. DUR Board Requested Reports

Carl Jeffery: This was a difficult report to match up with the diagnosis. The request was to see why the anticonvulsant was being used in children. I ran a list of all the recipients that had a prescription for an anticonvulsant and sent to the medical side and they gathered the diagnosis codes for those members and pulled their primary diagnosis. That is what you see here compiled in the number of primary diagnosis. The pharmacy claims data and the medical claims data doesn't match because they are submitted at different times and there is nothing to match them up. So you can't really pair them up. So this is the best I could come up with. You get down to the forth one down, you get convulsions, the top three are just artifacts, I don't think they have anything to do with anticonvulsants. If you have a child on an anticonvulsant, they go to the doctor for a well child check they get their immunizations. It has nothing to do with the doctor writing, they probably just renewed their anticonvulsant. It is impossible to tease that out of that data. They start getting into some behavior issues, they start to make sense.

Paul Oesterman, Chair: I think one of the concerns is that we have so many drugs with multiple indications, they may be on an anticonvulsant classified drug, and they may be using it for something totally different.

Carl Jeffery: Especially the way our criteria is now, if they are over five years old, they can get one anticonvulsant without any PA. They could be using for sleep, and we would not know.

Marta Bunuel: Certainly there are a lot of these are being used in familiar ways, behavior, mood disorders, autistic disorders because of behavior issues. Migraines are also treated with these drugs. I have seen Topamax for weight loss, but most are neurological or psychiatric.

Carl Jeffery: Is there anything else you would like to see with this or some kind of analysis?

Paul Oesterman, Chair: I know in the past one of the concerns was children in foster care vs. children in care homes.

Carl Jeffery: Those reports are on the next page, starting page 82. We broke down the different programs the recipients are enrolled in. The number of claims and number of members.

Paul Oesterman, Chair: I looks to me that the number of claims per member, the ratio is pretty consistent across the board. The members in foster care are not greater than the regular program. This is very telling. Your efforts are paying off.

Carl Jeffery: I tried to get the number of how many kids are in each program but I wasn't confident in my numbers, but the majority of the children will be in the first CHAP program. I don't think you will see as many in the disable programs, but those that are in there are likely to have a need for anticonvulsants. It is encouraging to see the foster kids, they are up there, maybe a higher percentage than the average population, but it is not through the roof. In the other charts, the program is broken down by age. They go through phases for which medications each program is on. For CHAP utilization, antidepressants are favored and then antipsychotics start to creep up after age 11. In the foster kids, the antipsychotics are up there even with the antidepressants and six to 11 you have a lot more antipsychotics. It is interesting to see the changes as you go through the programs. As expected, the independent living has a lot of anticonvulsants.

Paul Oesterman, Chair: This is a good report, thank you.

Carl Jeffery: The last page breaks it down for all programs for the children and psychotropic utilization.

Paul Oesterman, Chair: Do we have any follow-up requests or questions regarding these reports? We will move to our opioid utilization report. The report on page 88, those are trends, I think this is good news, it looks like they are all trending on the downward side.

Carl Jeffery: May 15, 2017, we implemented the quantity limits for the opioids where we limit to 60 mg morphine equivalents, seven days supply or 13 fills in a rolling 12 months. I'm surprised how little pushback from the provider community we have had.

Michael Owens: I think it makes everyone happy. In our clinic and you inherit patients that say they have been on opioids. The FBI coming down and arresting the physician has caused some changes in our clinic and we start to refer out to others that can manage their opioids. Patients are much less likely to push back if you can put the blame on someone else. It makes you a lot more comfortable as a provider. If I can get them to a lower level of opioids until they can see a pain specialist, it makes both me and the patient feel more comfortable. It has made it a lot easier for me.

Carl Jeffery: I have some friends in retail pharmacy. It may be the exception, but patients will get the Medicaid allowed amount and then pay cash for the rest. They are getting it one way or another, we are just not paying for it.

Marta Bunuel: Do we track who gets it? In Phoenix, they would flag them and notify us.

Carl Jeffery: I have asked the board of pharmacy to get some reports out of the PMP. They are pretty strict on what reports they let out and I will continue to work with them. If we could see a breakdown of who the payer is. We don't know when they pay cash, but the board of pharmacy does. I wonder if they could break it down to see who has a Medicaid claim and paid cash on the same day.

James Marx: There was always for the last 20 years, there was someone from Medicaid at the task force meetings. I don't think there was any intention to exclude that kind of data with a legitimate reason to have it. What you are looking for is de-identified data anyway. There is a meeting on November 9th at 9:00.

Duane Young: They have invited me, but I have not been able to attend past meetings.

James Marx: There have been for many years, a representative from Medicaid at those meetings.

Paul Oesterman, Chair: The top 10 opioids by quantity, there are not any surprised here. Maybe tramadol is higher than I thought.

Carl Jeffery: I thought there would be a shift to tramadol after the quantity limits were put on, but that didn't really happen. Page 90, the breakdown for the top prescriber is shown. I went back to just one year of data and we get a different list. The top is the same nurse practitioner in Las Vegas that we have been talking about. I think the Board of Pharmacy may have them on the watch list too. The fifth one down with the high expense, that is from the fentanyl lollipops that are so expensive. He has about 8 patients.

James Marx: I thought we had utilization criteria on there, didn't that have some effect?

Carl Jeffery: Yes, the criteria is still on there.

James Marx: I think it is limited to terminal patients.

Paul Oesterman, Chair: I think this is an opportunity to let this provider know where they stand. Maybe it is just fine.

Carl Jeffery: I don't think it would be a bad idea to send this chart to these physicians and let them know they are in the top 10.

Paul Oesterman, Chair: On page 91 we have the impact of the 90 day supply when that got rolled out.

Carl Jeffery: That was the end of February. March was the first full month and you see a big spike there and then every three months, in June and then a little spike in September. It is stabilizing a bit as we go on.

Paul Oesterman, Chair: One of my concerns is that two years out, the pharmacy paid amount should drop back down and be consistent.

Carl Jeffery: This isn't the total program spend, this is only the 90 day fills.

Paul Oesterman, Chair: Oh, total program spend would be interesting to see. Gradually over two years you would expect to see it come back down.

Carl Jeffery: Yeah, we can look at those numbers. We run them every month anyway. I did look at the total dispensing fee for pharmacies, it came back really funny and didn't have time to QA. It would be interesting to see how the average dispensing fee over time changes.

James Marx: What is going to be the impact of the CVS policy of limiting to seven days, how is that going to be handled?

Carl Jeffery: What program is that?

James Marx: A few people were informed that CVS is only going to allow a seven day fill for opioids.

Michael Owens: Is that for new prescriptions only?

James Marx: No, for ongoing maintenance.

Beth Slamowitz: Yes they are going to limit all opioid prescription to seven days for certain conditions. It is for new patients.

Michael Owens: A lot of the requests are coming through, if you have been on the prescription for the past three months, you can get it. It is only for new prescriptions, for short-course therapy.

James Marx: I'm talking about the CVS policy.

Beth Slamowitz: It doesn't roll out until February 1st. It says patients that are new to pain therapy.

James Marx: So how is Medicaid going to deal with that? That means subsequent prescriptions will be on a seven day fill. That will quadruple the dispensing fee.

7. Public Comment on any Standard DUR Report

Paul Oesterman, Chair: Our standard DUR reports. Do we have any public comment?

8. Standard DUR Reports

Marta Bunuel: I have a question on the antipsychotics and antimanics and then psychotherapy and neurological agents. How are those separated out?

Carl Jeffery: The antipsychotics would be Abilify and Seroquel and Haldol. The antimanic are lithium. Tegretol falls within the anticonvulsant class even though it can be used as a psychotherapeutic. The psychotherapeutic and neurologic agents will have dopamine agents for Parkinson's.

Paul Oesterman, Chair: Do we have anything of significance going off patent coming up?

Carl Jeffery: Abilify went off patent, that was a big change, Strattera a few months ago, Crestor a few months ago. We do have two new Hep C agents are coming out fighting for best price. I think there is some room for case management for hemophilia. The state could probably hire a nurse for full time and easily pay for their salary.

Paul Oesterman, Chair: Was there a big change in membership between Q1 of 2017 and Q2? There appears to be the count of claims has really taken a big jump. On page 95, the anticonvulsants, it took a big jump in Q2. Opioid combos went up by 10,000.

Carl Jeffery: We can double check our numbers, the first two quarters have January and March that are big months and then the next big month is in July or August. The second quarter, April, May and June are big months. January and March are long months and beginning of the year and they have new insurance. Those are historically high months for number of claims.

Paul Oesterman, Chair: Top 50 looks pretty standard.

Carl Jeffery: Not a whole lot changes with those.

Beth Slamowitz: Just for a clarification for the CVS policy, it is the CVS PBM, it is all their clients that their policy will apply to. For commercial or Medicaid clients. Anyone that has CVS/Caremark for their pharmacy benefit manager. Express Scripts has done the same thing.

Carl Jeffery: You will see the same thing coming from Optum pretty soon. I think it is a pretty standard move coming from the PBMs.

Carl Jeffery: The question about the numbers not adding up, you can have more than one reject per claim. You can have a high dose alert and short duration on the same claim for example, that is why they don't add up to 100.

Paul Oesterman, Chair: These report still confuse me.

Marta Bunuel: The top drug interactions, what does it mean on this?

Carl Jeffery: This is the number of claims that have been submitted. Our system flagged the pharmacy and told the person filling the prescription. The pharmacy got a message, most of the time you have a technician that enters these and blows by these messages. Some have a hard stop, that requires a pharmacist to enter a code and indicate what action they took and enter a code. The claim would go through or they get the message and contact the prescriber and reverse the claim. These are helpful mostly when patients go to different pharmacies.

Paul Oesterman, Chair: Seems to me a lot of these messages are being done by a tech. Maybe we should look at some of these messages only and convert to hard stops so they have to act. All of them were message only.

Carl Jeffery: We really don't have many hard stops, like duplicates.

Paul Oesterman, Chair: On page 110, we have promethazine and age less than four, we got a message and they probably went right through it. In the past we have set up some criteria to prevent children from getting this.

Carl Jeffery: Some of these may not be where Medicaid is the primary, if they have another insurance that pays the claim, we follow the rules of the primary. We would have to look into those.

Paul Oesterman, Chair: I would like to spend some time at a future meeting looking at these in a little more detail so we can help provide quality care for our patients.

Carl Jeffery: Right, and make them more meaningful to the Board and the pharmacies. I don't know what the board is supposed to do with these reports. I will see what I can dig into.

James Marx: If there are so many messages being blown through, they may go through some significant messages and miss something serious.

Marta Bunuel: On page 112, some of these are single medications and there was a message, for what?

Paul Oesterman, Chair: TD is therapeutic duplication.

Carl Jeffery: If they are getting an extended release and immediate release, then it would flag.

Marta Bunuel: There are some other medication or some other form in their profile causing this to interact, I see.

Paul Oesterman, Chair: On page 137, therapeutic duplication, levothyroxine and thyroxine, it isn't uncommon to have a patient on both of those. But I would be concerned with a patient that is getting two strengths of medications, if we could tease those out, that would be a benefit. Knowing if the combination is deliberate or is it a transition is hard to tell.

James Marx: There is no way to call back a discontinued therapy when there is a change. A pharmacist doesn't have any way to get that medication back, so the member has both strengths.

Paul Oesterman, Chair: I have had a number of practitioners say to discontinue all prior medication.

James Marx: But that medication doesn't go anywhere.

Paul Oesterman, Chair: Speaking of which, the take back program is coming up. Do we have anything else we wish to discuss?

Carl Jeffery: For the retro-DUR, we have about 55 letters for the tramadol and codeine ready to go out to the prescribers. We can provide some education before we cut them off. We have some Hep C treatments for follow-up. A question to see why they didn't finish therapy and if they did, are they cured.

James Marx: Aren't those supposed to be through a specialty pharmacy and track those?

Carl Jeffery: They might, but they don't tell us. I don't think a lot of prescribers draw a follow-up viral load.

9. Closing Discussion

Paul Oesterman, Chair: We will ask for any public comment, hearing none. What is the next time and place for the meeting?

Carl Jeffery: January 25, 2018.

Duane Young: We will send a reminder and we are looking at some other options and times. If there are any changes we will reach out to you. We are looking at two locations. We had only one of the MCO's criteria, for January's meeting, we may need to move the time up.

Paul Oesterman, Chair: I think moving the time up is going to be difficult to those who are working.

Duane Young: We can keep it at this time, but we may be here until 9:30. When we add the other two MCO's criteria, it will take longer to review. One thing we can do is look to synthesize the criteria prior to the meeting and add some research from other States.

James Marx: Can we get Carl's criteria to the MCO and have them comment so we don't have contradictory and exclusionary criteria.

Duane Young: We will have a pre meeting and come up with some combined criteria.

James Marx: That way it is red-lined before we get to it.

Paul Oesterman, Chair: Ok, the meeting is adjourned.

Meeting adjourned at 8:22 PM.

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