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**NEVADA MEDICAID  
DRUG USE REVIEW BOARD  
MEETING MINUTES**

**Date of Meeting:** Thursday, April 28, 2016 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:** Best Western Plus Airport Plaza Hotel  
1981 Terminal Way  
Reno, NV 89502  
Phone: (775) 348-6370

**Committee Members Present:** James Marx, MD; Michael Owens, MD; Paul Oesterman, Pharm.D.; David England, Pharm.D.

**Non-voting Members via Teleconference:** Chris Shea, Pharm.D.

**Committee Members Absent:** Jeffrey Zollinger, DO

**Others Present:**

**DHCFP:** Shannon Sprout, Chief, Program Services; Mary Griffith, RN, Pharmacy Services Specialist; Darrell Faircloth, Deputy Attorney General

**HPES:** Beth Slamowitz, Pharm.D.

**OptumRx:** Carl Jeffery, Pharm.D.; Kevin Whittington, RPh

**Others:** Shane Hall, Purdue; Krystal Joy, Otsuka; Chris Adams, Lundbeck; Karen Miller, Lundbeck; Karen Campbell, Pharm.D., Allergan; Sean McGarr, Allergan; Kerry Kostman, Astra Zeneca; Jin Yun, Astra Zeneca; William Mullen, Indivior; Charissa Anne, J&J; Laura Litzenberger, Janssen; James Kotusky, Gilead; Janet Osalvo, DHCFP; Sandy Sierawski, Pfizer; Bonnie Romero, Alkermes; Brian Evans; Jeanette Belz, NV Psychiatric Association; Brooke Maylath, TAG;

**Others On Line:** Shannon Groppenbacher, J&J; Jill Sugg, UCB; Georgette Dzwilewski, Indivior; Christopher Anstead, Amgen; Ray Kong, Amgen; Michael Faithe, Amgen; Risa Reuscher, Amgen; Joanna Jacob, Ferrari Public Affairs

**1. Call to Order and Roll Call**

Meeting called to order at 5:15PM

Roll Call:

Carl Jeffery – Optum Rx

Kevin Whittington

David England

Michael Owens

Paul Oesterman, Chair

Darrell Faircloth

James Marx

Beth Slamowitz

Mary Griffith

**2. Public Comment on Any Matter on the Agenda**

Paul Oesterman, Chair: Is there any public comment to start? Please limit comments to 5 minutes.

**3. Administrative**

- a. **For Possible Action:** Review and Approve Meeting Minutes from January 28, 2016.

Paul Oesterman, Chair: Seeing no comments, we will start with review of the meeting minutes.

James Marx: I move to approve.

David England: Second.

Voting: Ayes across the board, the motion carries.

- b. Status Update by DHCFP

Paul Oesterman, Chair: We will get an update from the Department.

Mary Griffith: Shannon Sprout is our new Chief. Chapter 1200 changes, the presented criteria in April were approved, that included the psychotropic changes

for children. That policy now requires a PA for every child under the age of 6, for 6-18 years it only requires a PA for more than one drug within a class or four or more different classes. Also we approved some new criteria for Corlanor, Praluent, Invega Trinza. The other change is not requiring a diagnosis for diabetic supplies unless they are new to getting diabetic supplies. We have received several new rules from CMS. Pharmacy got off pretty easy. Right now, our department is in crunch time for the budget.

Paul Oesterman, Chair: What was the one significant change for pharmacy from CMS?

Mary Griffith: All the states are going to have to use the NADAC or acquisition cost and a 340B ceiling price, but now that has been moved to 2017.

James Marx: There was an announcement that all recipients are being moved to MCO, is that true?

Mary Griffith: No, I don't know about that.

#### 4. Board Action

- a. **For Possible Adoption:** Discussion and possible adoption of coverage policy on medications used for the hormonal transition treatment for transgender individuals

Paul Oesterman, Chair: Now we will move to the Board items. Our first is discussion and possible adoption of coverage policy on medications used for the hormonal transition treatment for transgender individuals.

Carl Jeffery: This has come up recently and is coming down from the Director, I have the Chapter 1200 limitations on hormones limited to females and males. We need some discussion from the Board for coverage of these to override the restrictions.

Mary Griffith: Right now we have gender edits. We were proposing to require a diagnosis of gender dysphoria that would override the gender requirement. But this is something that will come up again.

Paul Oesterman, Chair: Do we have any public comment?

Brook Maylath: My name is Brook Maylath, I am the president of the Transgender Allies Group in Reno. The treatment has been established in the 1930's. The guidelines have a clinical pathway for the use of hormones for the treatment of gender dysphoria. The dysphoric feelings can be eliminated with treatment. Monitoring pathways are online by UCSF and are very useful for diagnosis, signs, and proper pathways. This can be done in a safe manner for each patient. Without this, 41% suicide attempt rate and 60% suicide ideation in transgender individuals. Access to appropriate care is difficult especially in rural areas. In the Affordable Care Act, if a payer is providing a hormone therapy for

one person, they cannot deny it for another person. If estrogen is approved for post-menopausal women, you will have to pay for a transgender woman. If we fail to provide this, potential civil rights cases could be brought.

Paul Oesterman, Chair: Any other public comment? So we have restrictions in place by gender, and we are proposing to eliminate those.

Mary Griffith: Right, we want to allow for gender dysphoria.

Paul Oesterman, Chair: If we had a diagnosis of gender dysphoria for a PA?

Carl Jeffery: What we talked about doing is adding some criteria to allow bypassing the limitation at the point of sale if the diagnosis of gender dysphoria is transmitted on the claim. I think that was the simplest of the ideas.

Paul Oesterman, Chair: What do we need to do?

Carl Jeffery: Does the Board need to take any action?

Beth Slamowitz: What we are looking for is any additional input and discussion about putting the diagnosis override code on to allow to pay. I don't think we need anything else from the Board.

Mary Griffith: Unless Darryl thinks so.

James Marx: I think the crux of the situation is who can make a diagnosis of gender dysphoria? Is it self-proclaimed diagnosis? Or prescribed by a certain specialty of physicians? Who is qualified to make a diagnosis of gender dysphoria?

Beth Slamowitz: I don't think we discussed the type of provider, it just needed to be on the prescription. We didn't want to restrict access of care.

Carl Jeffery: Especially in the rural areas, we don't want to limit who can make the diagnosis.

Paul Oesterman, Chair: I think as long as it is someone that is licensed to prescribe in the State, it should be ok. I don't think there is anything we need to vote on, it is just something part of the criteria. Brook, would that meet what you are looking for?

Brook Maylath: Yes. A diagnosis is often made with careful review with the provider and many times with a behavioral health therapist. These are not easily written, so just being able to pay for the medication as prescribed is a wonderful advance forward.

Paul Oesterman, Chair: Any further discussion? No.

- b. **For Possible Action:** Discussion and adoption of coverage policy on allowance of pharmacist submitted prior authorizations.

Paul Oesterman, Chair: We will move to the next agenda item which is discussion and adoption of coverage policy on allowance of pharmacist submitted prior authorizations. Carl?

Carl Jeffery: I was hoping Chris would be able to send some information in. It is more of a prompt for discussion from the Board. Right now, we have a limited number of pharmacists that are allowed to submit a prior authorization in the name of the physician, acting as the agent of the physician. These pharmacists have access to the medical record, and can make sure all the information is listed.

David England: This would only be available to those with access to the medical information?

Carl Jeffery: We talked about some proposed criteria of the pharmacist needs to be in a clinical setting, with access to the medical record.

David England: Would the physician still need to give permission for the pharmacist to submit these PAs like a collaborative practice agreement?

Carl Jeffery: I think this is an opportunity for pharmacists to act as an agent of the physician. The criteria we talked about are: No in-patient pharmacist, have access to the clinical record, they work in a clinical setting. But we need to figure out a way for the call center to identify these pharmacists. We don't want every retail pharmacist submitting PAs.

David England: What if a retail pharmacist does have access through an EHR or something else?

Beth Slamowitz: From a system perspective, we list pharmacies as provider type. If we open up pharmacies through the portal to submit PAs, that would mean anyone listed as a pharmacy would be able to submit a PA. Picking up the phone and calling the call center or faxing something, that would be different to define who is submitting the PA request. From a system point, it will be difficult to define who we are getting PAs from.

Paul Oesterman, Chair: Can you do a subset, using NPI number?

Beth Slamowitz: The only way we could do it that way is to give pharmacist provider types, and that would take a lot of work.

David England: that is what I was leaning toward. In some cases, a retail outlet could have that same relationship. But we need to identify that pharmacist and how they have access to the records.

Beth Slamowitz: Until we can get the state to recognize pharmacists as a provider, that may be difficult.

David England: I'm not sold that you can't practice clinically without being in a clinical setting, but we need some way to identify these individuals so we know they have access to the clinical setting.

Mary Griffith: Could you do it by a location code, like place of service?

Carl Jeffery: There is place of service on the claim, but that is something the pharmacy decides on their own. It is not attached to the provider ID.

Beth Slamowitz: I think whatever you decide, we'll need to figure out the system.

Paul Oesterman, Chair: I think we are looking at two different things. One is the criteria to allow a pharmacist to submit a PA and second is how the system is going to work to do it. We are only concerned with the first part right now. I'll ask for any public comment at this point. How is it that Chris is allowed to submit and others can't?

Carl Jeffery: The call center knows his name.

James Marx: This is amusing because we have a hard time getting information from the retail pharmacies when there is a reject in the first place. I don't think there will be many pharmacies wanting to do this anyway.

Paul Oesterman, Chair: I don't think there is going to be a large number of pharmacies getting on board.

Michael Owens: I wish pharmacists had the ability to change for formulary.

Beth Slamowitz: When you're talking about Medicaid, it is pretty easy, but commercial insurances can change all the time. But many pharmacists aren't going to have time to look it up.

Chris Shea: We have been successful from the institutional side in submitting PAs. Most Med D plans allow anyone to submit a PA if the patient is in an institutional setting like skilled nursing. It takes a lot of time to get the paperwork to the physician for PAs.

David England: He is able to do that is because he is identified with the facility rather than as an individual.

Carl Jeffery: Maybe we create a list of pharmacists to pre-register and we maintain that list at the call center.

Beth Slamowitz: As long as those facilities have all their pharmacists registered or one with a backup.

Paul Oesterman, Chair: I think at this point, for updating policy, we want to say pharmacists who work in a clinical setting or who have access to clinical records have the ability to submit Prior Authorization requests, having once registered with Medicaid for that capability.

David England: I'll move that.

James Marx: Second.

Paul Oesterman, Chair: Any further discussion?

Voting: Ayes across the board, the motion carries.

- c. **For Possible Action:** Discussion and adoption of coverage policy on use of brand name products when a generic is available and Dispense As Written requirements

Paul Oesterman, Chair: The next topic on the agenda is the discussion and adoption of coverage policy on the use of brand name products when a generic is available and dispense as written requirements. Is there any public comment? No. Right now a physician has to write in their own hand writing, "Dispense As Written." That is the background, Carl can you give us more details?

Carl Jeffery: Your binder has the Chapter 1200 criteria. I included proposed changes. Right now, it still requires prior authorization as well as other requirements. The binder also has a report of brand products. The first several are all preferred brand on our PDL.

James Marx: The requirement that the physician hand write, "Dispense As Written," on the prescription seems like a punitive measure.

Carl Jeffery: My proposed criteria do not include that. The drugs we are concerned with are a little further down the list, Ativan is about half-way down the page. There are cases as a pharmacist, it is difficult to justify the use of the brand over the generic. There is no reason brands need to be dispensed. The proposed criterion says, two different manufacturers must be tried, an FDA Medwatch form must be submitted. If they truly are having a reaction to the generic, the FDA should know about it. An exception would be allowed for the narrow therapeutic index drugs, like warfarin, digoxin, lithium, thyroid medication and others and if the generic is not available, it would bypass the requirement.

Michael Owens: The most frustrating thing is formulary changes and I wish pharmacists would be allowed to substitute per formulary. Or if there was a note from the pharmacist that suggests what is formulary.

David England: This makes sense too but how cumbersome is this going to be for prescribers. But we do need something documented of why it can't be given.

Paul Oesterman, Chair: I used to work in a call center for Medco when Prilosec went generic. The pill said omeprazole but it was the same as the brand. Patients would call claiming the generic is ineffective even though it was exactly the same. I think these differences should be submitted to the FDA if it really isn't effective. I like this proposed criteria.

James Marx: There is one difference, the manufacturer variation and manufacturing differences. I have seen patients with some opioids where the generic doesn't work as well.

Paul Oesterman, Chair: Where they AB rated?

James Marx: Well, they were AB rated on the day the FDA was there, but how do you know they are still manufacturing it the same way now?

David England: I was reviewing the Orange Book the other day and there are several different codes available now. So there is some confusion about what can be substituted. So I think it is good to alert the FDA so they know and maybe there is something to it.

Paul Oesterman, Chair: Do we have a motion to approve the criteria as submitted?

David England: So moved.

James Marx: Second.

Voting: Ayes across the board.

## 5. Clinical Presentations

- a. **For Possible Action:** Discussion and possible adoption of updated prior authorization criteria for colony stimulating factors.

Paul Oesterman, Chair: Our next topic is the clinical presentation and the discussion and possible adoption of updated prior authorization criteria for colony stimulating factors. We have the proposed criteria here. Do we have any public comment?

Ray Kong: My name is Ray Kong, I am the medical science liaison for Amgen. We do not have any prepared comments but we are available for questions from the Board.

Paul Oesterman, Chair: Thank you.

Carl Jeffery: The current criteria is listed by agent, we consolidated it to simpler criteria. The utilization is shown in your binder with both regular pharmacy claims and physician administered drug claims. Utilization is all identified there, I don't think anything is out of the ordinary. Page 40 has the new guidelines

rolled into a single category rather than different medications. The criteria are the same, only consolidated.

Paul Oesterman, Chair: On the new criteria, there is a quantity limit for Neulasta, but not the others.

Carl Jeffery: I'm not sure why the others didn't get on there; they have been on past criteria.

Mary Griffith: Should the others have quantity limits?

Carl Jeffery: Yes, they should.

Paul Oesterman, Chair: So if we were to approve these criteria, we would want the quantity limit for all products.

David England: Does it make a difference on page 40 it mentions Neulasta, but not as the generic. But there is not a generic available yet. So on page 40, these restrictions would cover all the products.

Carl Jeffery: Right, and keep in mind these only apply to fee for service, not the physician administered drug. It is only the few pharmacies that dispense on an outpatient basis.

Paul Oesterman, Chair: It looks like this simplifies the process. We have the proposed criteria here, do we have a motion?

James Marx: So moved.

David England: Second.

Voting: Ayes across the board, the motion carries.

- b. **For Possible Action:** Discussion and possible adoption of prior authorization criteria for eluxadoline (Viberzi®)

Paul Oesterman, Chair: Our next agenda item is the discussion and possible adoption of prior authorization criteria for eluxadoline or Viberzi. Do we have any public comment?

Karen Campbell: I'm Karen Campbell, a Pharm.D. and a scientific liaison with Allergan. I am here to provide comments on Viberzi, indications, background of Irritable Bowel Syndrome (IBS-D), previously available treatments, review of evidence, study results for efficacy, mechanism of action, side effects and safety data. We request Nevada Medicaid make eluxadoline available for IBS-D patients.

James Marx: Do we need the ICD-10 diagnosis in there?

Carl Jeffery: We can, but there are some other step therapy proposed in the criteria. Something that isn't on here is the response rate was about 24-25% vs. placebo. It was more effective than placebo, but really pretty low. Getting in to some of the secondary endpoints, it gets a little better. For the people who respond to this, great, but if only ¼ of the population is going to respond, maybe not everyone needs to get it.

David England: So the criteria do state they need to have treatment failure with something else before getting this.

James Marx: Are we going to have some temporary approval to see if it is effective?

Carl Jeffery: We didn't include that step in the proposed criteria, but maybe not a bad idea. We added some trial of the other treatments.

David England: Karen, does the use of another product before this medication result in any decreased efficacy or aggravate the disease state?

Karen Campbell: Prior to the availability, that is all there was. Most patients will have already tried these.

David England: I just want to make sure there won't be any significant drawbacks to having patients try other agents first.

Carl Jeffery: We rely on physician testimony regarding previous failed therapy.

Michael Owens: This is not a medication used as a PRN for symptoms, you're on this medication long term.

Karen Campbell: Right, it is for patients with the more severe and persistent symptoms.

Carl Jeffery: For the next meeting, we will get the whole class for the IBS category.

Paul Oesterman, Chair: One of my concerns is the 25% efficacy. We should do a trial short period before approving a long-term.

Carl Jeffery: In the trial, the initial run-in was 12 weeks. So a 12 week PA.

Paul Oesterman, Chair: Since it is schedule 4, the PA should only be 6 months.

Beth Slamowitz: Is this something that they see a response right away?

Karen Campbell: Most patients respond within 4 weeks. The symptoms do get more progressive if they are not treated properly.

Paul Oesterman, Chair: So then a 4 week trial run to see if they will respond.

David England: Do we want to add that in and if approved, then they could get it approved for a year.

Carl Jeffery: Can this just be a phone call from the patient to the prescriber's office or will this be something the patient needs to make an appointment.

Michael Owens: I think it would just be a phone call. That is usually how it is anyway.

Carl Jeffery: So they wouldn't have to make another office visit.

Paul Oesterman, Chair: We have the proposed criteria with the addition of a 12 week initial treatment and then change to a 6 month PA after the initial treatment.

David England: So moved.

James Marx: Second.

Voting: Ayes across the board, the motion carries.

- c. **For Possible Action:** Discussion and possible adoption of prior authorization criteria for doxylamine succinate/pyridoxine hydrochloride (Diclegis®).

Paul Oesterman, Chair: Our next item is the discussion and possible adoption of prior authorization criteria for doxylamine succinate and pyridoxine hydrochloride or Diclegis. Any public comment?

Carl Jeffery: The utilization is in the binder, you may remember this as Bendectine. There were a number of lawsuits claiming birth defects. This is not approved for hyperemesis gravidarum, so it has not been studied.

David England: In the studies, were they able to use this in combination?

Carl Jeffery: I'm not sure if it was used in combination. It looks like it was all either/or compared with ondansetron or placebo.

Paul Oesterman, Chair: Did they do any comparisons with H1 blockers?

Carl Jeffery: No, I don't see anything. We don't have a huge number of claims for this. The chart is broken down by regular fee for service, pregnancy category and PAD claims. About 15-20 claims per month. The criteria are if they are pregnant.

Paul Oesterman, Chair: Do we need the female requirement if they are pregnant?

David England: I say leave it as-is.

Michael Owens: Why the age limit?

Carl Jeffery: That is just what it was studied for.

Paul Oesterman, Chair: They can always take the separate components, but they are not long acting.

Michael Owens: How much less expensive are the separate components?

Beth Slamowitz: Used to give out Benadryl and Vitamin B6 in the pharmacy for this.

Paul Oesterman, Chair: As a reminder, price is not a factor for step therapy. We have the proposed criteria. We need a motion to approve.

David England: So moved.

James Marx: Second.

Paul Oesterman, Chair: Has the P&T Committee reviewed this yet?

Carl Jeffery: They did and they made it preferred.

Paul Oesterman, Chair: Can we send this back to them and have them re-think it? Consider adding the separate ingredients.

Carl Jeffery: Sure, we can bring it back.

James Marx: I retract my second.

David England: I'll retract my motion.

Paul Oesterman, Chair: So can we send this back to the P&T, looking at ondansetron and the separate components.

- d. **For Possible Action:** Discussion and possible adoption of prior authorization criteria for Neurokinin-1 (NK1) Receptor Antagonists and Combinations

Paul Oesterman, Chair: Our next agenda item is the discussion and possible adoption of prior authorization criteria for neurokinin-1 receptor antagonists and combinations. Any public comment?

Theresa Beckert: My name is Theresa Beckert, I'm a medical science liaison with Eisai and speaking on Akynzeo for the prevention of chemo-induced nausea and vomiting, background of CINV, guidelines, dosing recommendations, packaging, efficacy, safety, and common adverse events. I request open access when prescribed by an oncologist for patients undergoing chemotherapy.

Carl Jeffery: We have the criteria in the binder. We don't have any utilization of the Akynzeo or Varubi. Just a reminder, the PAD claims are not subject to the clinical criteria and that is really where you are going to see this. Adding these

criteria is just going to make sure a retail pharmacy is dispensing it for something other than chemo-induced nausea and vomiting.

Paul Oesterman, Chair: Do we want anything in here that it is being prescribed by an oncology or in consultation with an oncologist?

Carl Jeffery: It wouldn't hurt.

David England: So we would have, B: ordered by oncologist or in consultation with an oncologist.

Michael Owens: Is this used for post-operative treatment?

Carl Jeffery: It isn't indicated.

Michael Owens: For Emend, it is listed below.

David England: So this isn't used for PONV, it doesn't look like it should be

Carl Jeffery: The way the criteria are written, they shouldn't be allowed to use it for PONV.

Paul Oesterman, Chair: We have the proposed criteria here, with the addition that it is ordered by an oncologist or in consultation with an oncologist. Do we have a motion to approve?

James Marx: I'll move.

David England: Second.

Voting: Ayes across the board, the motion carries.

- e. **For Possible Action:** Discussion and possible adoption of updated prior authorization criteria for medications used for opioid dependence.

Paul Oesterman, Chair: Our next item is the discussion and possible adoption of updated prior authorization criteria for medications used for opioid dependence. We have the existing prior authorization criteria here, we have some proposed changes. Do we have any public comment?

William Mullen: My name is Will Mullen, I'm a clinical advisor for the medical affairs team for the manufacturer of Suboxone. We agree with the proposals on the PA criteria with some additions. Section F, other states require a drug monitoring program, the PMP as one of the criteria. Section G, the one thing about the mono product, it is recommended that anyone dependent on a long-acting opioid, that the induction phase be done on the mono product. After three days moving to stabilization, they move to the combo product. With G, with pregnancy, we are not contraindicated in pregnancy, if the benefits outweigh the

risk, they can remain on the combo product. We are fine with the two units per day, but a standardization of the brands, the Zubsolv says 17.1mg is the top strength allowed in the label.

James Marx: What is the DEA limit for the Suboxone per day, it isn't two is it?

William Mullen: We have 2, 4, 8 and 12 mg, you can get to 24 mg. We don't recommend people maintained at 24 mg, but should be just the first part of treatment.

James Marx: I do all the time. I see a lot of failed patients from other programs, especially those coming from heroin. We start a fair number on 36mg per day and have had good results.

William Mullen: If you are taking on the worst of the worst, then 36mg may be appropriate. It is off label and we can't recommend that.

James Marx: I'm afraid this is becoming a big problem.

William Mullen: Other states are opening up access, but we support clinical authorizations to make sure it is used appropriately.

James Marx: Can the pharmacies dispense a three day supply without a prior authorization.

Carl Jeffery: I'm not sure, if it is a new PA with a new prescription, they can dispense up to a 96 hour override, and only works for new prescriptions.

Paul Oesterman, Chair: Your comment regarding checking the PMP is now mandatory in Nevada.

Carl Jeffery: We were prompted to bring this back because of high dose requests. The call center doesn't have any criteria to exceed the dose. And we are seeing requests to treat chronic pain, which probably isn't appropriate.

James Marx: I actually have a lot of patients using it for chronic pain. It is particularly appropriate for patients with a prior history of abuse. We have converted many from oxycodone and Belbuca seems to be effective for this.

Carl Jeffery: Ok, we can discuss these criteria, but the proposed criteria has that it can't be used for chronic pain. We also have that they are not on concurrent opioids.

James Marx: Should we address the issue of the quantity limit first?

Carl Jeffery: Yes, it is in the criteria proposed here. It is approved for up to 24 mg, we had it set a little lower.

Michael Owens: Does this medication have a street value.

James Marx: Yes, and it is abusable too. It is not a total solution.

Michael Owens: Does it show on a lab?

William Mullen: It doesn't show on a standard lab, but the metabolite can be tested

Paul Oesterman, Chair: Are we considering elimination of C on here which is the request for chronic pain.

Carl Jeffery: This drug itself is limited to the X DEA, is this something any prescriber with an X DEA number can write for this?

James Marx: When you write it for chronic pain, you don't use the X DEA. You use your regular DEA and mark it is for chronic pain. Any prescriber can do it and it is off label. It is a very good product.

Beth Slamowitz: I think that is why we are going to need that C on the criteria.

James Marx: There is peer-reviewed literature supporting the use of it.

Beth Slamowitz: Then that could be added to the criteria or the PA request.

Carl Jeffery: I don't want to see every prescriber writing for this. If we limit so it can't be used for chronic pain, then they have to use their X DEA number.

James Marx: You're inducing someone to write a fraudulent script if they are using for chronic pain because they are saying they are using it for addiction treatment.

Paul Oesterman, Chair: We could put something like chronic pain...

William Mullen: I think this would be more under analgesia criteria.

Paul Oesterman, Chair: I think that may be appropriate to have under an opioid analgesic.

Carl Jeffery: We would have to bring those criteria to the next meeting. It certainly shouldn't be first line.

James Marx: There are some that do support using as first line, as the primary analgesic.

Paul Oesterman, Chair: Let's bring that part back to the next meeting. We have the proposed PA criteria. Quantity limits set. Do we have a motion to approve as presented?

David England: So moved.

James Marx: Second.

Voting: Ayes across the board.

Paul Oesterman, Chair: So the next meeting we will discuss this being used for the opiate analgesics.

Paul Oesterman, Chair: So the next meeting we will discuss this being used for the opiate analgesics.

- f. **For Possible Action:** Discussion and possible adoption of prior authorization criteria for medications used for opioid induced constipation.

Paul Oesterman, Chair: The next topic is the discussion and possible adoption of prior authorization criteria for medications used for opioid induced constipation. Any public comment?

Carl Jeffery: This is another class that has been out for a while with a couple new products on the market. The utilization is in the binder. The proposed criteria are also included. These are very effective and have their place in therapy, but we want to make sure they are being used judiciously.

James Marx: There is going to be a step therapy edit.

Carl Jeffery: Right, they need to show they have tried one of the three traditional therapies.

James Marx: That's good because a lot of people do respond to the osmotic laxatives.

Paul Oesterman, Chair: On the Section D, the methylnaltrexone, if the patient's weight is over 140kg...

Carl Jeffery: That is just for those that exceed the quantity limit.

Paul Oesterman, Chair: In my practice setting, we have a lot of elderly opiate users, using methylnaltrexone, but they only need it about once a week. The one per day limit seems pretty high.

James Marx: We prescribe it daily, but patients come in and only use half of what they are prescribed.

Paul Oesterman, Chair: Can we look at the data in six months again to see how it is being utilized. We need a motion.

David England: So moved.

James Marx: Second.

Voting: Ayes across the board, the motion carries.

Paul Oesterman, Chair: In six months, let's look at the utilization again.

- g. **For Possible Action:** Discussion and possible adoption of updated prior authorization criteria for long-acting opioids.

Paul Oesterman, Chair: Our next agenda item is discussion and possible adoption of updated prior authorization criteria for long-acting opioids. We have the prior criteria and usage data.

Carl Jeffery: This was brought up because we have no criteria to exceed the quantity outside cancer pain. This will add criteria so the call center can evaluate consistently.

David England: Is this the new CDC guidelines.

Carl Jeffery: My understanding it was more of a recommendation.

James Marx: It supported the use of alternative agents before getting to opioids. The other option is SNRI's, but we are going to end up pushing the dose of acetaminophen to treat the pain.

David England: I don't want to go against the CDC guidelines.

James Marx: The CDC was more focused on acute pain rather than chronic pain.

David England: And this is for chronic pain here, so that is ok. I feel better about this if that is the case.

James Marx: 1B does allow for opiate exceeding the quantity as long as they meet the three criteria.

Carl Jeffery: Right, I think the bulk of the people will meet these criteria. They will only need a PA if they exceed the quantity limits. Before, all we had was A, the only time we could approve was if they had terminal cancer.

Paul Oesterman, Chair: Let's call for public comment.

Sandy Sierawski: Sandy Sierawski, I'm a pharmacist with Pfizer. I don't have a formal presentation, but I noticed on the criteria for Embeda is set for one per day and the package insert says one every 24 hours or every 12 hours.

Paul Oesterman, Chair: We have the proposed criteria. Do we want to revise the quantity limit for Embeda to up to 2 per day? I will call for a motion.

David England: So moved.

James Marx: Second.

Voting: Ayes across the board, the motion carries.

**6. Public Comment on any DUR Board Requested Report**

Paul Oesterman, Chair: Any public comment on the DUR Board requested reports? No, then let's look at the reports.

**7. DUR Board Requested Reports**

a. Cumulative acetaminophen report

Carl Jeffery: Starting on page 97 is the cumulative acetaminophen dose. The numbers on the left is an encrypted Medicaid ID. So our highest utilizer is 3500mg a day. We don't have any hard edits to stop the different ingredients. I think our pharmacists are doing a pretty good job.

Paul Oesterman, Chair: One of my concerns, are the patients taking any over the counter products that we don't know about. We won't know that. Next report?

b. Long-acting steroid inhaler combination utilization

Carl Jeffery: Starting on page 102, the long-acting steroid combination products. Advair by far, but Symbicort is coming up pretty fast. Symbicort has been made preferred.

Paul Oesterman, Chair: One of the things coming up is Breo Ellipta has been added to the hospital formulary, so that may drive some of the utilization coming up.

Carl Jeffery: Yeah, it is a good product, we have it non-preferred right now, but it will be reviewed at an upcoming P&T meeting.

Paul Oesterman, Chair: It is interesting to see the last three time periods, respiratory products are on an increase. Can we correlate this to an increase or decrease in visits to the ED. If we are using more medication and reducing ED visits, I think that is good.

David England: Would we also want to look at beta agonist use? Are we seeing more or less beta agonists?

Beth Slamowitz: I think you could look at a certain time period with a diagnosis set, and then look at what medications they are on. Look at asthma and COPD.

Carl Jeffery: It also appears to be seasonal.

- c. Utilization of short-acting insulin without long-acting/basal insulin

Paul Oesterman, Chair: Basal insulin, what do we have?

Carl Jeffery: This shows the number of members on fast acting insulin without a long acting agent. For comparison, the two charts below show the total number getting long and short-acting insulin.

Paul Oesterman, Chair: the numbers in both columns are the same. Is it the count of members or count of claims? Can you redo this and bring it back next time?

Carl Jeffery: Sure.

- d. Narcotic cough suppressants utilization

Paul Oesterman, Chair: Narcotic cough suppressants.

Carl Jeffery: We ran this looking for all opioid antitussive agents. On average we're doing pretty well with utilization.

Paul Oesterman, Chair: Interesting, the physician administered, the promethazine with codeine and Pennkinetic, is that coming from a rural area? It is not a lot, but I can't envision a physician's office administering cough syrup.

Carl Jeffery: I'm not sure, we can drill down on that if needed.

Paul Oesterman, Chair: It seems like we have been able to impact the quantities, it worked. Any of the Board have questions?

## **8. Public Comment on any Standard DUR Report**

Paul Oesterman, Chair: Our standard reports now, any public comment?

## **9. Standard DUR Reports**

Carl Jeffery: These are the standard reports and the trends are holding as from previous versions.

Paul Oesterman, Chair: What about the Abilify, it is generic now.

Carl Jeffery: We still have the brand preferred

Paul Oesterman, Chair: It would be nice to know which brand name products we have preferred so we know what we need to address.

Carl Jeffery: I'll have to look at that and see if there is an easy way to identify that. The Abilify is listed on a later report so you can see how it stands up to the other agents. Pages 106 and 107 are sorted at a different level and gets into the specific class types. We have seen the hepatitis agents level off a little. Starting page 110, we have the

specific drugs by paid amount. Nothing jumps out to me. Hemophilia certainly fluctuates quite a bit from quarter to quarter. ProDUR edits start on page 116. The last quarter starts on page 142.

Paul Oesterman, Chair: Total paid claims from third quarter to first quarter took a jump. The ProDUR report fairly consistent. What has transpired from total membership?

Carl Jeffery: Fee for service has held pretty steady.

Beth Slamowitz: It has held steady around the 160,000 mark.

Paul Oesterman, Chair: Do we have any additional topics for next time?

James Marx: I want to look at proton pump inhibitors and cardiovascular complications. That is such a ubiquitous drug now.

Paul Oesterman, Chair: Anything else?

David England: With the changes with the CDC, do we want to look at NSAID use or changes in the opioid use and could we differentiate between chronic or acute pain.

James Marx: But we are not going to be able to see if patients are getting OTC medications.

Beth Slamowitz: I think looking at opioids will be a benefit and track the changes.

James Marx: I wouldn't NOT look at the NSAIDS, but I think the numbers are going to be a little skewed.

David England: Maybe look at antiepileptics with the NSAIDS too.

Carl Jeffery: Does the CDC letters have an impact on the prescribing trends?

Michael Owens: I'm not a pain specialist and we have an opioid cap at our practice, but we get a lot of chronic pain patients that are in withdrawal. We still have the focus that pain is the fifth vital sign and our practice is the only group that will prescribe opioids.

David England: You have to treat these patients, but then these guidelines don't give any real alternatives.

James Marx: The problem is these patients are going back to the street if they can't get what they need from their prescriber. We are seeing more counterfeit opioids like fentanyl.

Michael Owens: When you talk about Suboxone for pain management, but it does not have the pull of the very abusive narcotic user.

James Marx: I like it when patients feel comfortable with me and tell me they prefer some medications over others, we try to accommodate them and they do much better.

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**6. Closing Discussion**

Paul Oesterman, Chair: Next meeting is July 28<sup>th</sup>, same time, same place.

Meeting adjourned at 7:50pm.