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DRUG USE REVIEW BOARD

Meeting Minutes

Date of Meeting: **Thursday, October 18, 2018 at 5:15 PM**

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

Place of Meeting: **Grand Sierra Resort and Casino**
2500 E 2nd St.
Reno, NV 89595
Phone: (800) 738-1410

ATTENDEES

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

Board Member Absent
Marta Bunuel, MD

DHCFP
Holly Long, Social Services Program Specialist
Beth Slamowitz, Pharm.D., Social Service Pharmacy/DME Program Chief
Amy Crowe, Senior Deputy Attorney General

DXC
Camilla Hauck, RPh

OptumRx
Carl Jeffery, Pharm.D

Managed Care Organizations
Thomas Beranek, RPh – Silver Summit Health Plan
Ryan Bitton, Pharm.D. – Health Plan of Nevada
Jeannine Murray, RPh – Anthem

Public
Mark Schwartz, GSK
Deron Grothe, Teva
Sandy Sierawski, Pfizer
Marc Rueckert, Pfizer
Don Moran, Teva

Public On-line
Jill Carroll, BMS
Lisa Wilson, Biogen
Tony Wang, BMS
Lori Howarth, Bayer
Joanna Jacob, Ferrari Public Affairs
Judy Stein, Amgen
Alice Swett, Alexion
Micah Johnson, BMS

AGENDA

1. Call to Order and Roll Call

Camilla Hauck, RPh, DXC
Beth Slamowitz, Pharm.D., DHCFP
Holly Long, DHCFP
Carl Jeffery, Pharm.D., OptumRx
Paul Oesterman, Pharm.D.
James Marx, MD
Yvette Kaunismaki, MD
Netochi Adeolokun, Pharm.D.
Michael Owens, MD
Jennifer Wheeler, Pharm.D.
Ryan Bitton, Pharm.D.
Thomas Beranek, RPh

Via phone:
David England, Pharm.D.
Amy Crowe – Senior Deputy Attorney General

2. Public Comment on Any Matter on the Agenda

Paul Oesterman: Is there any public comment?

No public comment.

3. Administrative

a. **For Possible Action**: Review and Approve Meeting Minutes from July 26, 2018.

Motion to approve the meeting minutes as presented. Second. Voting: Ayes are unanimous, the motion carries.

b. Status Update by DHCFP

Holly Long: We are working on the antibiotic policy that was approved at the July 26 meeting. We've been making quite a bit of progress. I'll go over that when we get to that item on the agenda today. As far as just general updates, we have had the federal qualified health centers or FQHC section has been relocated in the Medicaid Services Manual from chapter 600 which is physicians services now it has its's own chapter, it's going to be chapter 2900. This was effective on October 1, 2018.

Beth Slamowitz: This is the first meeting I am with DHCFP, no longer with DXC. I just wanted to make sure everyone was aware. My official title is Pharmacy Programs Chief. Any questions for the State would be directed toward me.

4. Clinical Presentations

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

Paul Oesterman: Is there any public comment?

Sandy Sierawski: I'm Sandy Sierawski. I'm a pharmacist here in Nevada and I work for Pfizer in the medical division. I'm here to just make a couple of comments about Xeljanz. Xeljanz XR in the immunomodulator class of drugs. You are looking at that PA criteria and we have rheumatoid arthritis indications, psoriatic arthritis indications falls in line with the criteria they already have established, but we have newly added an indication for ulcerative colitis for the treatment of adult patients with moderately to severe colitis disease. Take note that this is the first line of therapy for that so if you look at the criteria established for ulcerative colitis, the criteria says the recipient failed to adequately respond one or more of the following standard therapies for having a prior failure before getting this medication. I just wanted you to be aware that this medication is the first line of therapy. It's a novel mechanism of action and is available orally so you get some additional treatment options for UC in your patient population. Just kind of to give you the whole picture, I just want to comment on the recommended dose for ulcerative colitis is 10mg twice daily for 8 weeks and then 5 to 10 mg daily. Discontinue therapy after 16 weeks at 10mg twice daily if they don't get adequate response or benefit. Just to offer balanced information, I do want to let you know that here is a box warning on Xeljanz and that is for serious infections and malignancy and when studied in the UC population, the Xeljanz treatment was 10 mg twice a day and it was associated with greater risk of infection compared to 5 mg twice a day. I have complete package insert information and complete all the safety and warnings. If you want me to go through anymore of those, I just wanted to give you a brief overview. Any questions for me?

Carl Jeffery: A lot of what is in the binder and I think the Board is going to revamp this; I think we're going to talk about it later after the meeting to see if we can kind of narrow this process

down, but what Optum is recommending is just the addition of the new drugs. There are two new agents in this class that we're including and then going through the reviews, there's a couple new products that have been introduced recently that weren't included previously so these are now included into the criteria. I propose we just add the names of the drugs. We have them all listed out here and then the unique criteria because they come and go. They get new indications all the time so the easiest way is just to add these new ones on there. All the subsequent pages are all the different criteria from the MCOs and they have a lot of pages of criteria in there.

Paul Oesterman: I know we're dealing with different MCOs but it is possible to try to consolidate into a…

Holly Long: Yeah, we're going to talk about that later. We have a proposition to solve that.

Paul Oesterman: Going back to Sandy's presentation on the Xeljanz for ulcerative colitis, with the current PA criteria, if a patient has ulcerative colitis and they want to use that, what kind of process would they have to go through for that particular indication?

Carl Jeffery: Well, and the criteria's on there, so we have criteria for the ulcerative colitis already and so the recipient with the diagnosis of moderate to severe ulcerative colitis, they are appropriate age, but this is what Sandy was talking about was the fail first corticosteroids or 5-aminosalicylic acid or immunosuppressant or thiopurines. I'm not prepared to discuss changes to the criteria at this time but we can bring it back for a future meeting. Ryan and Tom what do you think about bringing this back and maybe you can modify this criteria. I was just reading through the HPN criteria to see if you guys address it.

Ryan Bitton: We normally cover conventional therapy first and that is pretty standard.

Carl Jeffery: So maybe in the future we can bring this back and do some more research and find out what's best standard therapy.

Paul Oesterman: Just for clarification purposes, what we have in front of us is the proposal to add the new agents that have not been previously been included in the class? So what we're looking at is the addition of agents?

Carl Jeffery: That's right.

Paul Oesterman: Do we have motion to add these newer products that have come to market and their inclusion in this class of agents?

Motion to accept criteria as presented. Second. Voting: Ayes are unanimous, the motion carries.

b. **For Possible Action**: Discussion and possible adoption of prior authorization criteria and/or quantity limits for opioid use in members under 18 years of age.

Holly Long: The proposed criteria didn't make it into the DUR binder, but this is what the state was proposing and was suggested. This mirrors what we already have for opioids. The differences are in bold so you'll see everywhere where it says 7 day has been changed to 3 day and of course the age and the change there. I also added chiropractic treatment as an example for where pain cannot be controlled through the use of non-opioid therapies. It was that because Medicaid does

pay for chiropractic treatment for those under 20 years old, so that was as an example and then I also on the second page added the HHS reference because it's specific to opioids in adolescents. Otherwise, it's mirroring what we already have.

Paul Oesterman: So, the primary difference is the change from 7 down to 3 days and there are the exceptions for post-op and others. Just for reminder purposes, we already have separate criteria for cough syrups.

Holly Long: Right. Tramadol there will be a few more specific for under 18, but this will be blanketed for opioids in general.

James Marx: What about medication treatment like your Suboxone?

Holly Long: Suboxone has its own criteria, so it would be different.

Paul Oesterman: Were you able to send Dave a copy of this?

Holly Long: I'm not sure if he has a copy of this.

James Marx: I'm kind of confused. How is this being impacted by let's say, 14-year-old who had complicated complex spine surgery where there's rods and instrumentation?

Paul Oesterman: Post-surgery with prolonged recovery, there's an exception.

James Marx: How does that get conveyed to the call center?

Carl Jeffery: The way the call center works, that would be one of the first questions they ask for it to be approved.

James Marx: I think medication assisted treatment should be in here too under the exceptions. So, it doesn't get confused.

Beth Slamowitz: Medication assisted treatment is also part of behavioral health. It is it's own program and doesn't necessarily fall under the pharmacy program. They have their own policy they are developing. Because it is in combination with behavioral health treatments as well. It is not something included in our standard therapy criteria.

James Marx: I'm concerned someone with a prescription for Suboxone who is 16 or 17 years old, they go to the pharmacy…

Beth Slamowitz: This policy is based on pain treatment. If they were getting treatment with Suboxone, and we wouldn't pay for it for the treatment of pain, that diagnosis would have to be on the prescription.

James Marx: So, they would pick up the ICD-10 code? They saw an opioid dependence and accept that?

Beth Slamowitz: This isn't for those medications, so this is separate criteria from what we are discussing.

James Marx: So, you are not considering Suboxone under the opioids?

Beth Slamowitz: No, they have their own criteria within the chapter.

James Marx: Ok, that answers my question.

Holly Long: This is what we would do. This criteria would be put in with opioid preparations at the last meeting in July and then incorporating that into the existing opioid criteria that we have. It got tagged onto the very bottom of it and there is a reference to where it is, so if it is approved, it would also be put in there within that opioid criteria. I got this information that was recommended by the state of Washington as one of their recommendations that they're taking to their DUR board.

Ryan Bitton: This is the criteria that we put in place as well, but we have the age at 20 years old for three days max. HPN is in support of this criteria.

Holly Long: Washington did 20 years of age too, is there a big difference between 18 and 20? I was looking at the age group that is most at risk. Ages 13-17 seem to show as the most at-risk age group. If it is helpful to do 20 and under, we can do that.

James Marx: I am a little concerned with 60 mg morphine equivalent. That is a lot for a 4 year-old. Hopefully it wouldn't be prescribed, but I have seen cases of high doses. It was written in error and the pharmacist didn't catch it.

Beth Slamowitz: It says "Or less" per day. This was made to limit the initial prescriptions when there are alternatives. Hopefully they won't reach that amount for a three-day supply.

Carl Jeffery: We have the utilization starting on page 421 in your binder. You can see the different programs. For the fee for service side, scroll down into the MCOs and we can address those, too. I broke it down by age group so we can see what ages and under one methadone as our highest one and those are probably babies who are born to addicted mothers and then just a couple of claims, and we're talking about a couple of claims with less than 1. If you get to the 1 to 4-year olds, we're still looking at the total claim count not over 15 claims for any of those. We're not talking about very many claims that these are going to be impacting. All of these claim numbers climb from ages 5 to 9. From 10 to 17, and even in the past year, we've seen a pretty good decline in the amount of hydrocodone that has been prescribed, too. That tells a good story, too.

Paul Oesterman: I say looking at all the graphs, there's a general trending down. Excellent. We have in front of us, the proposed prior authorization criteria for the opioids prescribed to patients under the age of 18, mirrors the over 18 with the exception of changing from a 7-day prescription for initial prescriptions to 3 days and total of 13 3-day prescriptions in any rolling 12 month period.

Motion to accept criteria as presented. Second. Voting: Ayes are unanimous, the motion carries.

c. **For Possible Action**: Discussion and possible adoption of prior authorization criteria and/or quantity limits for CGRP (Calcitonin Gene-Related Peptide Receptor) Inhibitors.

Don Moran: I'm a pharmacist and also a member of the medical affairs team. Our company is the manufacturer of one of these CGRP products. We were the second drug to be approved on September 14 by the FDA for episodic and chronic migraine, essentially preventative therapy. The drug does not appear in the agenda materials because I think the materials were prepared prior to our launch so I just wanted to say that on behalf of the company, we are hoping that you will consider this as part of the CGRP class. Now, what makes our molecule unique, especially compared to oral preventative agents which have been standard of therapy for many years, it's an injectable product and unlike others, it can be injected once a month subcutaneously or injected once every 3 months. So, issues of compliance can really be controlled by the clinician who chooses to administer the product in his or her office or in a patient who can self-administer the product at home, having some flexibility treating the disease, and also flexibility by monthly or quarterly dosing should improve patient compliance with therapy. In looking at the DUR class review that you were given, the thing that caught my attention was probably the second to the last paragraph in the entire document. It's the conclusion that the CGRP have a role in the subset of patients with migraine, unable to tolerate and establish oral prophylactic therapy. It goes so far as to say that these agents have been specifically designed to treat migraines. Their value is not in just patients who can't tolerate oral therapies but those patients who failed to respond to oral therapies, so take a look at the universe of patients with migraines who have disease severe enough who need preventative therapy, about 35%, 1/3 of migraine patients suffering migraines are candidates for an oral or some kind of preventative therapy. Of that third of the population, 25%, 1 of 4 patients who are eligible for preventative therapy actually seek care or continue to use it. Why is that? The number one reason for not using preventative therapy, 43% of the patients, inadequate response; 43% of the patients can't tolerate therapy side effects which means that over a period of time, probably by the end of the year, fewer than 10% of those eligible for therapy actually are using as preventative so this class actually offers an alternative and an innovation for the treatment. What I've seen in your DUR, unlike your colleagues, at United Healthcare, you put one more step in the road before the patient can have access to this medication, so physicians prescribing on behalf of Blue Cross patients, on behalf of the UHC patients, they have to demonstrate patients had at least 2 trials of prophylactic therapy, you're actually asking patients to demonstrate through the clinician, they've had at least 3 different trials over a 6-month period of time. So, you're a little more delayed compared to other clinicians in the state of Nevada. One other thing to think about is if I look at your population of 460,000 people. There's probably 2000 patients who have criteria that were going to run up against your prior authorizations. There's 125 pain specialists who are part of the criteria, there's 325 neurologists dividing 2000 prescriptions by your population of neurologists. That's between 7 and 17 new prior authorizations every 6 months with clinicians that evaluate these patients. I ask today that one, Ajovy be included in your DUR criteria in your prior authorization criteria. Two, consider aligning criteria to more consistent with that of Amerigroup and the United Healthcare providers and various clinicians are following uniformity. Those prior authorizations could use leverage to power some of your primary care doctors who can make a diagnosis and maybe take on a decision. Then you can think about automating your prior authorization process so that your processes, looking at the prescription history and background, you're looking to see if patients have a history of preventative use and then based on that preventative use, you have a profile for a patient who should in fact manually trigger a prior authorization. Are there any questions?

Paul Oesterman: I think one thing that you mentioned is something that we've been trying to do is focus on drug classes more than specific products. Otherwise, we end up going through the same class every single time.

Carl Jeffery: You mentioned you are not in favor of the specialist requirement. Is there another one outside of a neurologist or pain specialist that would be best to limit these to?

Don Moran: I'm sensitive for two reasons. I'm familiar with the recent American Medical Association survey doctors who are reporting that performed about 29 prior authorizations per week in their office, about 14 hours of time, imaging studies, diagnostic studies, access to medications. This is now incremental to that. I understand the need for a neurologist to be involved but I think primary care docs, certainly have the power to diagnose a migraine and they can certainly prescribe every other migraine treatments to date other than this for your prior authorization. I'm sensitive to prior authorization requesting physicians, nurse practitioners who have now discovered that they can't continue to care for their patients with migraines with this therapy because they now must involve a neurologist in the patient's care and in the state of Nevada, I don't know how easy patient access is to neurologists across the entire spectrum. So my request is just being sensitive to primary care doctors who might be able to leverage, might be able to simplify the process and use prescription claims history, and you know your community has 325 neurologists and if they will welcome an additional number of prior authorizations.

Holly Long: What is the reason for the 14 headache days per month?

Carl Jeffery: This is the standard criteria for the diagnosis of episodic migraines. This just confirms that yes, they have episodic migraines and its similar criteria for the chronic migraine. It has 15 headaches per month and at least 8 must be migraines. As Paul had eluded to, we're not calling out just any single agent in there because there are, as Don mentioned, there's three products now. Don's exactly right, the other two products came out after we had our clinical review done so the next, future reviews will include those but we're not making any distinction about which product has which criteria so I think it's fair to add some criteria for the general class and include all three agents in that criteria.

Paul Oesterman: I guess I need to make one comment. I appreciate your concern for the neurologists and pain specialists and the potential for work load; however, in the past, we have, as you can imagine, seen inappropriate prescribing and one of our duties as the DUR board is to make sure that the prescriptions that are dispensed are appropriate. When something like this is new and available, there is a very good potential for multiple primary care practitioners to be detailed on these products and all the sudden we see a spike where it may not always be appropriate, so I see both sides.

James Marx: The vast majority of headaches are treated at the primary care level, and I know that particularly the family practitioners that really done a good job and they incorporated it into their certification and maintenance. The average time to get a patient to a neurologist in Las Vegas is 3 to 4 months and most of the pain specialists really don't do much in the way of headaches, it is pretty limited to Botox. In this day and age, I don't think there's any need for neurologists to see patients for migraines. Migraines have become such a well described, well included in all the residencies. I don't see any reason to require pain specialists or neurologists who would be responsible for this, and I think we just need to take a look at the utilization. I don't think that will be that much of a problem because I hope that the Pharma would do a good job in detailing this. Migraine headache is a real problem and it's a tremendous deterrent to productivity and quality of life and I think that it's really important that we get, this is really a very dramatic improvement in the lifestyles because basically other than Botox perhaps, there really hasn't been anything. I think this is going to be more effective than Botox, but there's really very little that's really giving these

patients any sort of quality of life. And to deny this medication for a neurology consult I think is detrimental. I don't see it as being reasonable to include in the criteria.

Holly Long: So I looked up quite a few other states are jumping right on board with this, and they were drug-specific. They're obviously already talking updating to do a class instead but the little bit of difference that I saw, they did say that the prescriber has to be a specialist or consulted with a specialist such as a neurologist, and they just did a blank statement instead of putting in an exact age, I kind of liked it. They did a patient is within the age range as recommended by the FDA label so we don't have to go back in and change it when they change the age later as that's a good possibility. As far as the number of migraines, they said the patient is experiencing at least 4 migraines a day per month requiring acute pharmacological management so they didn't go specific into the differences between acute and chronic, and they didn't limit it with the definitions like you're explaining it, they just did 4. Another one that they put was the failure statement. They did a 3-month trial of at least one agent from each of the following classes and they gave the list of beta-blockers and antidepressants or anticonvulsants.

Carl Jeffery: Right and this is what Don was talking about. We've got the 3 different classes so either Elavil or Effexor or Depakote or Topamax or a beta-blocker.

Holly Long: They limited the initial approval to 3 months.

David England: Even though we may not use a neurologist initially, could we amend the criteria that states within a year, they would have to see a neurologist?

Holly Long: So do like a continuation to continue therapy after a certain amount of time and it would require that?

Paul Oesterman: Initial prescription doesn't require…

Beth Slamowitz: I would say after the initial prior auth. If the initial prior auth was for six months, then after the initial prior auth and then would have to be in consult or by a neurologist.

Michael Owens: I think when you start using injection medications, I really like the opinion of a specialist. Because if things go wrong, I always imagine myself in a courtroom, are you specialized enough to be giving this medication and then it goes back to standard care and what's expected in your community. Medications like Prolia, but it has taken me a long time to get there. It's one of those things where I think if a patient has failed everything else, then if it's my patient, I would have said, well, with migraine medication is not working, we'll just have to keep chugging away and I'll get you in to see a neurologist. My usual spiel is if the neurologist said that this is okay and they're on board with this, and I have their blessing, you don't need to see the neurologist ever again. I want that stamp of approval. My practice is varied enough that so that if there's anything new that I'm looking at introducing, then I typically will have a consult on this.

Beth Slamowitz: This isn't first-line therapy. You have to fail other oral therapies. If they got to the point where those are not working, then at that point those primary care prescribers would have some consultation with a specialist, does this make sense. Maybe it isn't a migraine.

James Marx: I can speak from a legal perspective, if you have gone through those other medications, that you met the standard of care. I am much more concerned with triptans than I am

with CGRP's. I would take the opposite, I would put someone on this before starting Imitrex injections. We all are very cognoscente of the risks and benefits we have to practice, but I think if you go through the algorithm of care, basically you are going to meet the standard of care and there's going to be a lot of doctors that are in situations who really can't get a neurological consultation. I don't think we should design the criteria because of that. You don't want to make those prior authorizations so hard that they won't actually do it. Our prior authorization criteria is so difficult because when you have to go to a neurologist or a pain specialist, you know what do you need, you want an okay for someone else to give a medication. That isn't going to make a real impact in terms of moving that patient in the priority of being seen. I think we are going to make it unreasonably difficult to get this medication.

Beth Slamowitz: Remember a consultation can be a phone call or chart review. It isn't always that a patient needs to be seen at an appointment. There is difficulty with the number of specialists, that is why the consultation is not meant to be in person.

James Marx: Again, speaking from an insurance standpoint, I can tell you that if you call a neurologist and say we have this patient, even though it's just a phone call, that's considered a consultation and there's a much higher level. It doesn't meet the standard of care. They are called "Curb-side consult" and they're very dangerous and you're not going to find a neurologist who is wanting to give you a phone okay.

Yvette Kaunismaki: I agree. I mean, as a specialist myself, if somebody calls me and asks about this, I would say I need to see the patient.

Beth Slamowitz: A consult doesn't necessarily mean I'm calling you up, I have this patient with this, what should I give them? I would hope the provider on the line would want to see a chart or medical record or see that person.

Yvette Kaunismaki: Just a note on that consultation, they still need to get on the schedule.

Michael Owens: It is the same with pain consult. By the time a patient has failed other migraine treatments, you can see that coming down the road. It is one of those things you can tell they are not doing well. If you have a patient with diabetes and their A1c keeps climbing to 11 or 12, no matter what you're doing, I'm going to send them to an endocrinologist. You see those scenarios coming. It is the same with getting patients into pain management. It sometimes takes two or three months. That is one of those things you are aware of. I don't think you are putting the patient through a lot of undue pain and suffering by having them wait to see a neurologist. That is the way I practice and it my comfort level with introducing new medications, it just takes a while.

Paul Oesterman: What I'm hearing, you have this proposed criteria in front of us and the primary question revolves around bullet point number 4, the episodic migraine, as to whether these products need to be prescribed by or in consultation with one of the following specialists, either a neurologist or pain specialist. Ignoring that point for the moment, are there any other concerns with the criteria of that as presented?

Netochi Adeolokun: The criteria from other states, does the criteria require three step therapies or two?

Holly Long: The patient has failed a 3-month trial of at least one agent from each of the following classes of preventative medications and they have in parenthesis unless contraindicated and they have listed beta-blockers with a list of examples, antidepressants and a list of examples, and anticonvulsants.

Paul Oesterman: They have had to fail one from each class, similar to the criteria here.

Ryan Bitton: For HPN, we have a failure of two agents, it is just a matter of how you write it. We have an initial authorization for three months like those other states. Some of the trials were built around a three-month endpoint to see efficacy. Some others have six months. HPN proposes three months and then 12 months after that.

Holly Long: Virginia said additional approval will be for 3 months. Additional therapy may be approved only with the clinical documentation showing a 50% reduction in either the number of headaches per month or the overall symptom severity as measured by MIDIS or HIT-6 compared to baseline.

Ryan Bitton: We are not as prescriptive as the percentage of decrease.

Paul Oesterman: Hearing everything, it sounds like there could be a compromise here where we make our initial approval for 3 months not requiring a specialist and then if it appears to be effective for the patient that for the next year, prior authorization would require.

Carl Jeffery: Are there primary care doctors who have specialized in migraine who maybe would have an advantage of treating that over another primary care who focuses on lipids or is that worth including in there?

James Marx: There are a few. One of the things that will chill your enthusiasm a little, the fact that these are injectable, not a lot of patients are going to be gung ho about this. I think only the most severe patients are going to be willing to do the injections. There is a tremendous resistance to injections. The next step of this therapy will be an oral or nasal delivery.

Paul Oesterman: I agree with your point there and I think that's one factor that I don't think the neurologists and pain specialists are going to get hit with, 2000 patients or something like that, there's that many that don't want to self-inject but it's not going to be as big a burden as potentially could be.

Holly Long: Could we maybe be a little bit more general with the specialists. Instead of saying that it has to be prescribed by or in consultation with one of the following neurology or pain specialists if we said something along the lines of the prescriber is a specialist or has consulted a specialists such as a neurologist so that it leaves it more open or should it just be a neurologist or pain specialist?

Beth Slamowitz: I think it should probably be one way or the other, but I also want to caution, it sounds like a good compromise to say that you agree with a three month prior auth and then you would switch to allow them to have a consultation or have a specialist write it at that time but you have a risk of that individual having access to care if that provider is giving them the initial prescription and they have a 3-month or 6-month prior authorization is not a good communicator and doesn't indicate to them that this is the only time you're going to get from me and you're going

to have to go get an appointment with a specialist at that time. There could be a break in treatment and you could have recurrence or it could get worse or who knows and they're still going to have to go see that specialist as an initial patient and they're still going to have to go through a workup. I can't imagine any specialist will take it at face value at that point even if they have already been on this medication. I just want to caution that it should be one way or another for continuity of care.

James Marx: Personally, for a patient like that, after three or six months, they tell me it is successful, I would wonder why I'm seeing them. Not realizing there was prior authorization criteria. Where is the meat? What is the consultation about? It is for pro-active treatment not looking back.

Beth Slamowitz: So maybe if you want to take out that requirement in the criteria, and we can bring this back with some utilization to see who is prescribing it and how much is being used and then we can determine at that time if it makes sense to go another route.

James Marx: I think that is the way to go.

David England: I did a quick search, most recommendations state to refer to a neurologist or pain specialist to assess comorbidities.

Ryan Bitton: Once we let the cat out of the bag, it is going to be difficult to reign back in. These are great therapies, these are block-buster good quality drugs. I'm concerned with opening them to everyone.

Beth Slamowitz: You have the failure criteria, so it won't be used first-line.

Paul Oesterman: In the interest of time, I'm going to do a couple of things here. I'm going to ask for a motion to approve the criteria as it has been presented. Hearing none and seeing none, secondarily ask for a motion to approve the criteria with the elimination of bullet point 4 under episodic migraine and bullet point 5 under chronic migraine with the understanding that we will bring this back in 2 meetings and look at utilization numbers.

Carl Jeffery: Also, change the initial approval to 3 months?

Paul Oesterman: I'm not familiar with these products. What's the usual onset for determination of efficacy?

Beth Slamowitz: Some are 3 months and some are 6 months to see if there's any improvement over that time period.

Carl Jeffery: I think they started seeing effects almost immediately.

Paul Oesterman: I say the approval length to be 3 months. We'll make a formal motion to approve the presented criteria with the elimination of bullet point 4 for episodic migraines, bullet point 5 for chronic migraines, and the approval length would be for initial 3-month period and then in 2 meetings, we will look at the utilization criteria.

Carl Jeffery: Under the reauthorization criteria, it does have a requirement for the specialist.

Paul Oesterman: Do we have a motion to approve that criteria?

Motion to approve. Second. Voting: Ayes are unanimous, the motion carries as amended.

5. Public Comment on any DUR Board Requested Report

James Marx: I have encountered this recently with management care organizations where we have initial requests for prior authorization for Suboxone for medication-assisted treatment and I know that the pharmacies theoretically are supposed to give you a 3-day fill on them but apparently they're not. I'm not even sure why we need a prior authorization for Suboxone or any of the other Suboxone variants. It seems to me, when the patient presents and they need medication-assisted treatment that prior authorization should be pretty obvious. I can see where you have to prove that they actually were abusing it. I'm not sure why there would be a prior authorization criteria. I think it's really a deterrent to therapy.

Ryan Bitton: HPN doesn't have prior authorization criteria.

James Marx: Right, it wasn't HPN.

Ryan Bitton: We used to, but it has been removed.

James Marx: I think we need to get the word out, it is a deterrent to therapy. There is one manufacture that has voucher for 15 days supply, but I don't know how long those are going to last.

Carl Jeffery: Your request is for us to bring this back to future meetings?

Beth Slamowitz: It would help to know which MCO you're referring to.

James Marx: It was Amerigroup.

Beth Slamowitz: I know that for fee for service, we allow seven days' worth without prior authorization.

Holly Long: So, do you want to email me that information and I will get in communication with Eric Sanchez and Jeanine Murray and we kind of clarify exactly what it was. Will that help?

James Marx: Well, what is the.. Is there a prior authorization criteria now? Do we have that? Fee for service doesn't.

Carl Jeffery: Yeah, after the 7 days we have a prior authorization criteria.

James Marx: So what are the rules?

Carl Jeffery: I don't remember all the rules off the top of my head, but basically they're not finding any other opioids, and they're under treatment for…

Beth Slamowitz: So if there are specific criteria or specific issues or components, you can certainly bring it to Holly or myself and we can see if maybe at a future meeting we can bring that back and have the MCOs address the criteria that they have and see if we have that conversation.

6. DUR Board Requested Reports

a. Prior Authorizations on High Dollar Claims

Carl Jeffery: This was just put into place August 6. We don't have very much data. For fee for service, anyway. The MCOs had some form of a limit on before that, so just for fee for service. What you have in your binders there is the number of PAs that are approved or rejected based on what was requested. There's a foreshadowing on what's to come. We've got a lot of oncology drugs on here, too, so those have a 10,000 dollar limit. We don't apply the 10,000-dollar limit to physician-administered drug claims. This is only POS.

Paul Oesterman: On the second one, the aminoglycoside antibiotic, Tobi Podhaler capsules, there are alternatives to that particular product.

Carl Jeffery: The P&T has addressed these and they've got the class of tobramycin inhaled for CF and I think the Tobi is preferred. We work with the manufacturer on that one.

Paul Oesterman: There's a lot more rejected than are approved.

Carl Jeffery: What's kind of interesting going through some of these claims, I can't just look at the PA requests, I have to look at the claims that were submitted for over 10,000 dollars to see because sometimes they'll get that reject and they'll never submit a PA for it, and so we'll never see it in our PA system because they never submitted it because they know they don't meet criteria. Trying to track those down is a challenge.

Paul Oesterman: I think this is a good report and it's providing the information that we were interested in. Is there anybody on the board who wants any drilled down information on anything in this report? This is a 60-day almost…

Carl Jeffery: Yes, from October 3.

b. Opioid Utilization – top prescribers and members

Carl Jeffery: This is a running report we've been watching for a long time so it is kind of our standard. We've got the fee for service side and I'll let the MCOs speak in turn for their own reports but for the fee for service side, we've got the top utilizing by member, by different claims. I think we've seen this member in here before.

Paul Oesterman: The first encrypted member 747. Again, caution is the amount of acetaminophen that the patient may be ingesting.

Carl Jeffery: This is over the course of a year. A lot of these members have a lot of quantity and a lot of claims. It's deceptive and I didn't tease it out, but some of them may be long-term care where they're getting like 7 days at a time and so there would be a claim every 7 days so it's a little deceptive.

Paul Oesterman: Okay, so instead of looking at the count of claims, look at the sum of quantity. Is there a correlation between these top 15 members and the top prescribers?

Carl Jeffery: I didn't match those up.

Paul Oesterman: For the next meeting, can we take a look and see if there is any correlation between the top opioid member utilization and the top prescriber? It's not to say it's necessarily inappropriate to have an oncologist or pain specialist who is the prescriber. It has been known that patients will seek out those people who are willing to write prescriptions more leniently than others.

Carl Jeffery: When you look at the general trends starting on page 470, the general trends here, and again tells a good story about the numbers decreasing, I think. Even by count of, almost in all metrics, count of members, count of claims decreasing, quantities decreasing, the supply is decreasing so I think the message is getting out.

Paul Oesterman: One more calculation to add to this would be number of doses per member. Quantity divided by the number of members.

James Marx: One thing that catches my eye is the Methadone.

Paul Oesterman: We have on page 472, the top 10 prescribers by count of claims for the fee for service model.

Carl Jeffery: It was kind of the same, our number one nurse practitioner that we got the letter of response to and moved down to number 2 a while ago and now it's got a new number 1 anesthesiologist in Henderson and is eclipsing everybody else by quite a bit.

Paul Oesterman: We have a similar-type letter to what we sent in the past, it might be worth sending.

Carl Jeffery: Yeah, I'll have to check to see if they got one before, because they've been in the top 10 here for a while. They probably got one but kind of wanted to give some updated standings. Maybe they are proud of that.

Paul Oesterman: Anthem, what do we have here?

Jeanine Murray: These are the top 10 prescribers for the opioid utilization and then the top 10 members.

Paul Oesterman: Is it at all possible to see if the top 10 prescribers for the different MCOs are one in the same?

Carl Jeffery: We looked at that at the last meeting and there was one prescriber that crossed over but it wasn't real big. We can do that again. It just takes some coordination. We need the real NPIs and we'd have to disguise that.

Jeanine Murray: But we can share that on the pre-DUR meeting that we have right?

Carl Jeffery: Right.

Ryan Bitton: I don't have much to say, that is the data. It is broken down by member count by quarter.

Paul Oesterman: What happened to prescriber ID A who's number 1 in the third quarter of 2017 dropped to second and then disappeared completely off the list?

Ryan Bitton: I'm not sure. I can look into that.

Paul Oesterman: Silver Summit?

Thomas Beranek: I don't have any additional comments. We will try to get everything in the same format for the next meeting.

c. Antibiotic Utilization

Holly Long: I just wanted to give everybody an update as far as where we're at with the antibiotic policy that was recommended to the state at the last meeting in July. We asked for letters to go out with provider education regarding the antibiotic policy. Those went out starting September 18 and there were a few different avenues that were used. We were faxing, we were mailing, we were e-mailing. We had it provided to the board of pharmacy and to the board of medical examiners for them to turn around and provide to whomever they deemed necessary. I also provided it to Dr. Capurro, the Nevada State Dental Health Officer and she is over the DPBH oral health program and she agreed to assist us with providing it as far as outreach to the dental providers. We also did a lot of mailing and emailing to directors of pharmacy, anybody that we can pretty much Google and find. We tried to make sure that we got to everybody. We were more specific with rural areas when we were sending that out. We also attended a tribal consultation in order to do some outreach to the tribal community, and I got a lot of feedback with the consultation. The letter was provided to them and they had information about what the policy included. We have an initial web announcement that is going to be going out but hasn't been posted yet. We also have a flyer or sort of like a newsletter that we're creating that is going to have almost like a fact sheet specific to the policy. A lot of the feedback that we've been getting so far pretty much is telling us that people don't understand that it's specific to the fluoroquinolones and third generation cephalosporins so we're being specific to what antibiotics it is and then to the exception criteria that was approved, as well. We were going over that and the fact sheet or newsletter. That should be provided I think within the next week. We'll start posting that and we'll have numerous locations where we're going to try to post that as far as the DHCFP's pharmacy site, Medicaid site, and then all the outreach that I did as far as the Board of Medical Examiners and the Board of Pharmacy again doing all that again. We're doing a project kickoff which will be internal for the state so that we can develop a list of who is going forward with workshop or work group, and we're going to do a webinar with Dr. James Wilson that was here that presented when we were at the July DUR Board Meeting. We're looking the earliest it would possibly be would be early February but because of what we're doing, we're actually seeing that that might get pushed out. It will be a while but eventually after implementation, we can definitely look at utilization.

Paul Oesterman: In anticipation of that, word of mouth is getting out. I would really be interested like Dr. Marx has asked, just look at our utilization knowing that it hasn't been fully implemented.

Carl Jeffery: There's some utilization numbers in the binder here and so you can see, even in the top 10, we've got several products in there so we've got some high utilization of the classes that we're first addressing here. These include some of the physician-administered drug claims, too, so some of the ceftriaxone, those won't be impacted and actually they're exempt anyway. Some of these won't be included in here but a lot of the Cipro, Cefdinir, the levofloxacin. There's some pretty big numbers for the last year so this will be a pretty big impact.

Holly Long: One of the major concerns that came up that I'm looking for help with is that people were concerned since we are requiring culture and sensitivity wondering if that would be paid for by Medicaid and yes it will be. The other is if that's going to have a hold-up or other issues and so really what I'm looking for is information, if anybody has any contacts with the major lab corporations in Nevada? I don't have that so Lab Corps or Quest or any of those that would be good contacts in order for me just to get into communication with them and give them a heads up of what we're looking at implementing so that I can get information from them to be able to provide to the community.

Paul Oesterman: Okay, so we'll get some utilization from this and this report is complete antibiotic utilization. If we can just limit it to the targeted fluoroquinolones and the third generation cephalosporins, I think that would be helpful.

d. Oncology Medication Utilization

Carl Jeffery: The Board may not have asked for this one; this may be one we prompted trying to prime you guys because I think where we're going is probably some utilization management for some oncology medications. We've got the list of drugs on here listed by claim count. The Avastin is a little deceptive because they also use the injection into the eye for macular degeneration so that one is probably a bit skewed but the other ones… With the oncology drugs, I saw a TV commercial and I think half the commercial was listing the indication. The indications are so specific and right now without any kind of controls on them, you never know if they're being used off label. I don't think Medicaid should be responsible for footing the bill for the drugs studies. If they are off label, then Medicaid shouldn't be reimbursing for them.

Paul Oesterman: So, the proposal would be to bring back some PA criteria that is maybe simple as FDA approved indications?

Carl Jeffery: Yeah, we're working on some options.

Ryan Bitton: HPN has criteria that states it has to be FDA approved indication or reference recommendations that are 2B or above. So, no experimental treatment is covered. We have a lot of specific criteria in place.

7. Public Comment on any Standard DUR Report

Holly Long: I have one more thing to talk about. There is a form that we're going to use, it's my consolidation proposition going forward. I'll talk about that after the report review.

8. Standard DUR Reports

a. Review of Prescribing/Program Trends.

i. Top 10 Therapeutic Classes for Q4 2017, Q1 2018 and Q2 2018 (by Payment and by Claims).
ii. Top 50 Drugs of Q4 2017, Q1 2018 and Q2 2018 (by Payment and by Claims).

Carl Jeffery: Nothing outstanding here. As we've seen the trends, the hep-C antivirals just keep ticking down. It seems like to me that we've treated most of the people in Nevada that have hepatitis-C so I think that's a good trend, as well, and nothing else. We have the antihaemophilia products that are always number 1 on here. We've approved some criteria for those so I think it's not implemented yet but I think there may be some trend with that eventually.

Ryan Bitton: Our utilization is also included.

Carl Jeffery: It looks like HPN has antivirals are increasing.

Ryan Bitton: That includes flu treatments as well, so there was a spike for flu season.

Carl Jeffery: We also have the top 50 in here and nothing to write home about with those, either. Pretty standard. Another primer for what we're thinking about for the next meeting is some criteria around albuterol utilization so get your mind thinking about how maybe we can control some of that utilization. On page 550 here, it's our standard report. This is the updated report for ProDUR.

Paul Oesterman: If we're going to be looking at albuterol at our next meeting, then we should get some stats in terms of all the asthma and COPD medications. Does anyone on the board have other requests for the next meeting?

Holly Long: I'd like to recommend that we bring compounds back. I know we just reviewed that and made a decision in July.

Beth Slamowitz: I attended a conference in DC with the FDA to go over the final rules for compounds. There was a lot of interesting information and I'll bring some of that forward, as well, so you can kind of see. There were representatives from every state.

b. Concurrent Drug Utilization Review (ProDUR)

i. Review of Q2 2018.
ii. Review of Top Encounters by Problem Type.

c. Retrospective Drug Utilization Review (RetroDUR)

i. Status of previous quarter.
ii. Status of current quarter.
iii. Review and discussion of responses.

Holly Long: Instead of asking everyone to submit prior authorization criteria, we're proposing that we use this form instead. So, this would be provided by myself and Optum to each of the MCOs when we're developing the DUR binder. In lieu of providing pages and pages of prior

authorization criteria and asking everyone to hurry up and go through all that, we're going to do the forms. In the past, I've tried to go through and provide a spreadsheet of comparisons and it's too difficult to be able to do that so we're hoping this will work. I thought we would try this. It's very a simple form and if anybody has any suggestions for changes that we need to make. This will take the place of all the prior authorization criteria from each of the MCOs, what we would do is provide the criteria of what Optum is proposing or proposed changes to what exists, ask them to review it, compare it to what they have, and then provide this back. This will go in the binder with any comments or suggested changes or approve whatever is proposed and this will go in the binder instead of all the pages and pages of criteria. Where it says managed care organization, that is a drop-down in the form. I'll put what the prior authorization criteria being reviewed is and then provide one for each of the drugs or drug classes that we're looking at.

Beth Slamowitz: All the board will see in the binder is the exceptions. It will state they either approve of the Optum proposed criteria or they will provide what changes they would like to see.

Holly Long: So, for example, if everybody is looking at HPN and we really, really like that one and we would have those documents supplied as attachments with it but otherwise it will just be this form.

James Marx: How much notice are they going to get with this?

Holly Long: It is a few months out from when we request the information from them. We provide them with information and Carl has developed this spreadsheet in order to make the binders as efficient as possible in getting that information from each of the MCOs. We'll provide the criteria and the template and spreadsheet for them, and when they provide it back to us, this will be in place of all their prior authorization criteria including all their reports and it will go into the binder.

Paul Oesterman: I like it.

Beth Slamowitz: We are hoping to eliminate the 600 page binders.

Holly Long: Let me know if there are any comments or changes.

Ryan Bitton: I think getting the reports consistent is the biggest benefit. Making the reports more meaningful.

Paul Oesterman: Do you want the date on this?

Beth Slamowitz: Sure, we'll add the meeting date. It will be part of the binder going forward.

9. Closing Discussion

a. Public comments on any subject.

b. Date and location of the next meeting.

i. Discussion of the time of the next meeting.

Paul Oesterman: Our next meeting is January 24 back at the Hyatt.

c. Adjournment.

Meeting adjourned at 7:06 PM