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P&T Meeting – Meeting Minutes

Date and Time of Meeting: **Thursday, March 28, 2019 at 1:00 PM**

Name of Organization: **The State of Nevada, Department of Health and Human Services (DHHS), Division of Health Care Financing and Policy (DHCFP)**

Place of Meeting:

South Location:
Springs Preserve
333 S Valley View Blvd
Las Vegas, NV 89107

North Location:
Optum Office
9850 Double R Blvd
Ste 200
Reno, NV 89521

Attendees

Board Members (Present – Las Vegas)
Shamim Nagy, MD, Chair
Joseph Adashek, MD
Sapandeep Khurana, MD

Board Members (Absent)
Evelyn Chu, Pharm.D.
Mark Decerbo, Pharm.D.

Board Members (Present – Reno)
Michael Hautekeet, RPh
Steven Zuchowski, MD
Brian Passalacqua, MD
Kate Ward, Pharm.D.

Mark Crumby, Pharm.D.

DHCFP:
Holly Long, Social Services Program Specialist III
Gabriel Lither, DAG
Victoria LeGarde, Social Services Program Specialist II

DXC:
Camilla Hauck, RPh

OputmRx:
Carl Jeffery, Pharm.D.
Kevin Whittington, RPh

Public (Las Vegas)
Kenneth Barry
Georgette Dzwilewski, Indivior
Will Mullen, Indivior
Kelly Barfield, US World Meds
Patti Preston, Paratek
Eric Shaffer, Paratek
Dan Deck, Paratek
Joel Moerer, Alkermes
Deron Grothe, Teva
Don Moran, Teva
Christa Cooper, Lilly
Laura Hill, Abbvie
Lovel Robinson, Abbvie
Leon Ravin, DPBH

Public (Reno)
None

AGENDA

1. Call to Order and Roll Call

Meeting called to order at 1:00 PM

Roll Call:

Joseph Adashek, MD
Sapandeep Khurana, MD
Shamim Nagy, MD, Chair
Gabriel Lither, DAG
Holly Long, DHCFP
Kevin Whittington, OptumRx
Carl Jeffery, OptumRx
Michael Hautekeet, RPh
Mark Crumby, Pharm.D.
Kate Ward, Pharm.D.
Steven Zuchowski, MD
Brian Passalacqua, MD

2. Public Comment

No public comment.

3. Administrative

a. **For Possible Action**: Review and Approve Meeting Minutes from November 15, 2018 – Motion Carries

Motion to accept the minutes as submitted. Second. Voting: Ayes are unanimous. The motion carries.

b. Status Update by DHCFP

Holly Long – We are very fortunate to announce the appointment of Suzanne Bierman as the new Administrator for the Division of Healthcare Financing and Policy. She started with us on January 14 and her main office is located in Las Vegas. A little background on Suzanne. She was previously at The Guinn Center in Las Vegas. She has also served as the Assistant Director for the Medicaid Services for the Arkansas Department of Human Services. She earned her Doctorate and Masters in Public Health degrees from the University of Arkansas while working as a Legislative Analyst and Law Clerk for the University of Arkansas Medical Sciences. We are very excited for Susanne to be joining our team. At the January 24, 2019, DUR Board Meeting, it was asked by the board members that we send out what would be the second letter to the top 10 providers of opioids for fee-for-service Medicaid. These letters were sent out on March 15, 2019. We haven't received any feedback related to these so far. The MMIS modernization project was implemented on February 1, 2019. To provide an update on the antibiotic policy that was approved at the July 26 DUR board meeting, it was implemented on March 4, 2019. I would like to announce the resignation of Dr. Adam Zold from the P&T committee. He has been an amazing contributor to this committee. His dedication is greatly appreciated, and his participation will be missed. We are still in the process of recruiting members for the Drug Use Review Board. We are looking for two physicians and two pharmacists that are actively practicing and licensed in the state of Nevada. If you would like to nominate a provider that you think would be a good fit for this position, please feel free to provide your contact information to me.

4. Proposed New Drug Classes

a. Anti-migraine Agents – Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists

Don Moran – Pharmacist and member of the Medical Affairs Team at Teva Pharmaceutical. We manufacture one of the CGRP inhibitors that you'll be discussing today, and that product is fremanezumab marketed under the brand name Ajovy. I realize that you've got a lengthy packet of data to review today looking at the entire class as well as some deliberations to perform. What I'd like to ask you do to, first of all look at this class very critically and add the class in some fashion as an alternative to currently preventative medications and add at least one if not all the agents to your

formulary preferred status. I am very partial to the product Ajovy, of course, and would certainly ask the committee to consider it very favorably as a preferred item. The reason that I suggest that, I guess that there were some bullet points I'd like you to think about in your deliberations today.

Carl Jeffery – Let me just address the audience. What we're displaying is Optum's recommendation and on the left side is preferred products we're recommending and that's Aimovig and Ajovy. The non-preferred we're recommending is Emgality. If you feel like you want to give an overview of the Ajovy…

Don Moran – If there are questions that you might have about the product as a result of your reading the material or you wish of some perspective to balance maybe what Optum has recommended, I'm certainly willing to take a shot at answering your questions the best I can.

Carl Jeffery – This is a new class in our review the CGRPs. They are a novel product for the treatment of migraine headaches. I put a brief description of what the migraine, how they're classified. There are two basic classifications. These are used to treat the episodic migraines and the chronic migraines. The chronic migraines means that the person has 15 or more headache days per month. These are significant suffers of migraines and it's good that we finally have a product that's geared towards these more severe migraine sufferers. A lot of people don't quite meet that definition, though, so these fall into the category of the episodic migraines so that's where we get the differences of the two. There's a newer neurokinin, the CGRP neuropeptide that is thought to result in the pain caused by the migraine so what these do is inhibit the receptor, so it doesn't result in the pain. I didn't explain this well as Don could have but I'll do my best. There are three products we're going to talk about. The first one that was on the market here is the Aimovig and this has been on the market for a few months now maybe since October. Three different studies in the episodic migraines. You can see the numbers, but there are quite a few studies. All shown here, versus placebo, this one still is once a month all shown to have a reduction on migraine headache days compared to placebo. When we get into the migraine studies, it had again another 667 patients, first placebo, again for the same dosing once a month, and it also showed it was effective and reduced number of migraine days. The next one that Don was trying to talk about and we cut him off, is the Ajovy. A couple of studies here, the HALO for the episodic migraine and the chronic migraine. This one's a little bit different in that it has a monthly and a quarterly dosing, so it is kind of nice, so every 3 months they can administer this one. When they did this HALO-EM trial, they were shooting for a 1.6-day migraine headache days reduction. They didn't quite achieve that but did a 1.5 for it and the 1.3 quarterly. Although it didn't hit that significance there, it still numerically improved there. It did significantly increase the proportion of patients that achieved the reduction and the migraine headache days and also a decrease in the number of medication dates that were being used, too. It carries over with the migraine, as well. The last one we have is the Emgality. Again, a couple big studies here and quite a few patients. This one's broken

down in the EVOLVE studies, the EVOLVE 1 and the EVOLVE 2. In the EVOLVE 1, the difference is between the EVOLVE 1 was done just in North America, I think just in the U.S. EVOLVE 2 is more global but you can see again, 9.4% of patients, they looked at a different measure. This is MMHD instead of the MMD's so it's a little bit different measure, so it can't quite compare these apples to apples, but 9.4% of patients reported no headache days and then a little bit lower for the EVOLVE 2. When we get into the chronic migraine, however, though with the REGAINE study here, they had a little bit more trouble getting the significance on here. The primary endpoint was the change which favored the Emgality and it significantly increased the proportion of patients that achieved the 50% reduction but the only 0.2 and 0.8% were reporting the migraines cessation versus placebo so this wasn't statistically significant. So, we looked at the number of claims we've had so far. The Aimovig has been on the market for the longest so it has the most number of claims. The Emgality is the newest one so only two claims we've had. All the utilization numbers I'll be showing today is December, January, February of this year so we tried to get the most recent data we could for the full months. So not a whole lot of utilization of these yet. I will say that the DUR Board has addressed these and have added some prior authorization criteria that will go into effect probably May of this year, so we'll have some PA criteria. But, right now Optum recommends that the Board consider these clinically and therapeutically equivalent.

Shamim Nagy – We need a motion.

Motion to accept as clinically and therapeutically equivalent. Second. Voting: Ayes are unanimous. The motion carries.

Carl Jeffery – With this new class, this will be a new class that's included in here, so it will be under the neurological agents, anti-migraine agents and then the calcitonin gene peptide as the CGRP receptor antagonists. This follows in line with the similar, the triptans that are in there already under the anti-migraine agent system, as well, so they'll be in that same category but their own class. Optum recommends that Aimovig, Ajovy be considered preferred and Emgality be non-preferred.

Motion to accept Optum's recommendation. Second. Voting: Ayes are unanimous. The motion carries.

b. Toxicology Agents - Substance Abuse Agents - Withdrawal Agents

Shamim Nagy opened this up for public comment.

Kelly Barfield – I'm a corporate account director with US Worlds Meds. Thank you for having me today. Today I'd like to discuss the merits of Lucemyra and the impact it may have by placing it on the Nevada Fee for Service formulary. Lucemyra is the first and only FDA approved non-addictive, non-opioid medication for the mitigation of opioid withdrawal syndrome in adults. Being that

Lucemyra is the first and only nonnarcotic agent to treat opioid withdrawal, compendia has created a new therapeutic class, MediSpan, First Databank, and Elsevier, Gold Standard all have Lucemyra as or the therapeutic category agents for opioid withdrawal. I think it's important to note that the MATs fall under the class of agents for opioid use disorder. This leads me to what Lucemyra is and is not. Lucemyra is not an MAT and not a treatment for opioid use disorder. It's essential alpha 2 adrenergic agonist indicated to mitigate withdrawal symptoms in adults following the abrupt discontinuation of opioids. Lucemyra is not another maintenance therapy for patients with opioid use disorder. Lucemyra is not an opioid-based agent that would treat cravings for addictive patients suffering from opioid use disorder. So, what is Lucemyra and how could it be used based on the label? Lucemyra could be used for patients that developed a physical dependence to opioids and with the aid of their provider, have a need to mitigate their physical symptoms of withdrawal. Lucemyra is an acute 7 to 14-day therapy that may be a single treatment for dependent patients experiencing withdrawal from discontinuation of opioids. Lucemyra can be prescribed by primary care physicians that have not received additional treatment for OUD. The common theme that is continually discussed on national platform is the need to broaden the options and set a care for patients that have developed physical dependence and/or addiction to opioids. With the approval of Lucemyra, primary care physicians now have an agent that they can utilize as a frontline provider to safely treat patients they would like to mitigate the physical symptoms of withdrawal. It is important to note that the treatment of opioids role has a critical time window. Patients are highly sensitive to and fearful of opioid-withdrawal symptoms. The physical symptoms of withdrawal maybe get 8 to 12 hours following discontinuation of opioids with a peak of symptoms at days 2 through 5. For patients and providers to recognize the full utility that Lucemyra may have to offer is essential that patients have unrestricted access without having to wait 24 to 48 hours for the review and approval of a prior authorization. In closing, Lucemyra provides an opportunity to engage a broad range of providers to address and treat opioid dependence where there has been limited options in the past. Thank you.

Shamim Nagy opened up for questions.

Shamim Nagy – Is this for the use in outpatients?

Kelly Barfield – Yeah, it's a good question. This is use for outpatients. Nowhere in the label does the FDA restrict outpatient utilization. Our trials were conducted in an inpatient setting due to the control factor and that variable in recording the results of product, but we have virtually seen very, very limited outpatient utilizations all by an outpatient so far.

Sapandeep Khurana - What's the defensive mechanism of action between Lucemyra and clonidine?

Kelly Barfield – So from an MOA standpoint, there is no difference.

Shamim Nagy opened up for public comment. No public comment.

Carl Jeffery – I'm not going to spend a lot of time, just repeating what Kelly just said, so basically we've got the Lucemyra, there's a caveat with this one. We don't really see any benefit of listing this as a class and so we would be fine of the board not even accepting this class because right now basically the Lucemyra is the only approved agent for it. Clonidine is medically accepted. It doesn't have an FDA-approved indication for it, but it's medically accepted, and it's listed as common compendia so it's not a problem Medicaid covering it for the withdrawal. You can see the number of claims. We don't have any way to tease out that these are just being used for opioid withdrawal so chances are, 99% of these are being used for blood pressure and children for ADHD so three claims in the past quarter with Lucemyra; not a whole lot of utilization yet but unless there's any discussion from the board or some questions, Optum recommends the clonidine and Lucemyra be considered as clinically and therapeutically equivalent.

Shamim Nagy opened up for discussion or questions from the Board. No questions.

Motion to accept as clinically and therapeutically equivalent. Second. Voting: Ayes are unanimous. The motion carries.

Carl Jeffery – Like I said, there's really no benefit to having this class on the PDL at this time. There may be more agents in this class coming on; at that time, it may be more of a benefit but right now if the board wanted to have a class, our recommendation would be to have the clonidine and Lucemyra both listed as preferred.

Gabriel Lither – Can you explain the options a little bit more so that everybody understands. The options are to either vote with a class and vote which drugs should be in the class, where the alternative that you're putting forth is the elimination of this class with a PDL and what would it take?

Carl Jeffery – Yeah, this is a new class and so by not having this class put on there. Medicaid has an open formulary, so we cover everything that is FDA approved and rebatable so by not having this class on here, there's no restriction. We just don't advertise it as being preferred but it's not non-preferred, so we just don't add any additional restriction to it by not putting it on there. Chances are this will likely go to the DUR Board meeting where we will add some prior authorization criteria for the DUR Board. I think that's a better way to manage this medication rather than the preferred drug list.

Shamim Nagy – We already have voting on adding this as a new class.

Gabriel Lither – We just have voting for the clinical and therapeutic equivalence.

Multiple Speakers (indiscernible)

Shamim Nagy – Do we have to vote again?

Joseph Adashek – You don't have to. It's up to us if you want to vote again. It doesn't seem like it changes anything anyway so why make it more difficult if we don't have to.

Gabriel Lither – It's not a class right now. It is a proposed new class. Your options are to create new class with whichever medications you want to do, or your second option is to do nothing. And by Dr. Adashek, that you could by simply doing nothing, I was told it was helpful and clearer if you made a motion to do nothing so it's on the record that you are not adopting this new class at this time.

Joseph Adashek – Well I am pretty good at doing nothing. It doesn't change anything that we are doing in terms of this "class," we're not making it a class and it seems like it will work the same. I vote we make no changes to this non-class.

Second. Voting: Ayes are unanimous. The motion carries.

Joseph Adashek – So did we say that they're clinically and therapeutically alternatives, but we have to agree with the fact that it's preferred? Is that correct?

Carl Jeffery – Right, so you agree that they're clinically and therapeutically equivalent. We just didn't create that new class so that class will not exist on the PDL going forward with this update.

Joseph Adashek – So the DUR might decide that…

Holly Long – Right, so maybe we can clarify, too, that if it's not on here, it's not preferred or non-preferred, that's open access to it. It doesn't have to be on the PDL for Medicaid to provide coverage.

Carl Jeffery – Why was it brought forward?

Carl Jeffery – I think it was a request and then I think when this first came out, we weren't sure exactly where it would fit in with the therapies and doesn't really fit in with the other ones with like the Suboxone and those so because we have to work so far out in advance…

Gabriel Lither – I was going to say, sometimes when they're creating the agendas and they're putting together the materials so far in advance that they don't know whether something should really be on the agenda, it's too late and you guys had votes like you just did tonight.

Holly Long – And, sometimes we don't see the utilization that was supported one way or the other and then of course we always are anticipating other drugs that could possibly be coming to that class and if they don't, then we're stuck in that position.

Sapandeep Khurana – As a psychiatrist, I would say, I think would warrant a discussion but right now there's not too much to make a class.

Joseph Adashek – I would hope that DUR would make everything available possible for anything that's in the class of medication for outpatients and for all the opioids and other classes we'll talk about.

Holly Long – Sure, that's for DHCFP, they are in support of that and we're doing everything that we can make sure that the substance abuse treatment is there available for the recipients.

Shamim Nagy – That's a very important issue. We should table this to a future date.

Holly Long – Sure, and I can make note to bring it back to the next P&T meeting if the DUR Board makes any decisions one way or the other.

c. Toxicology Agents - Substance Abuse Agents - Opiate Antagonist Extended Release Injections

Shamim Nagy opened up for public comment.

Kenneth Barry – My name is Dr. Kenneth Barry, I'm from Alkermes. It's a pleasure to be here to talk to you. I want to present some clinical information and economic information about Vivitrol. We all know that Vivitrol is extended release naltrexone in injectable form and it's used and indicated for opioid use disorder and it should be part of a comprehensive management program that includes psychosocial support. Now SAMHSA government protocol recommendations for medications for OUD. OUD medication should be available to patients across all settings and at all levels of care. All patients considering treatment should be educated about effectiveness, risk, and benefits of each of the three medications used for OUD, which would include methadone, buprenorphine, and naltrexone. Medications from different pharmacological classes are available for OUD as we mentioned. Vivitrol is not associated with the development of tolerance or dependence. It does not cause disulfiram-like reactions resulting from an opiate or alcohol injections and there is no withdrawal syndrome associated with discontinuation of Vivitrol. Opiate-dependent patients including those being treatment for alcohol use disorder should be opiate free for 7 to 10 days prior to initiating Vivitrol. A few clinical studies to consider, one's published in JAMA Psychiatry in 2017. The effect of Vivitrol versus Suboxone for opiate dependence. This was a 12-week clinical trial of 232 opiate-dependent individuals to determine whether treatment with Vivitrol will be as effective as Suboxone and maintaining short-term abstinence from heroin or other illicit drugs. The study found that both drugs were equivalent in maintaining abstinence from heroin and other illicit opiates in the study. Some secondary measures with participants receiving Vivitrol received less craving and thoughts about heroin and had higher patient satisfaction compared to Suboxone patients in the trial. There were no deaths recorded in the study and the one overdose occurred in a Suboxone-treated patient. The next study was published in Lancet 2018. It was better known as XPOT or comparative effectiveness of Vivitrol versus Suboxone for opiate relapse prevention. This was a 24-week study compared to the effectiveness trial of 570

patients with opiate use disorder and had used nonprescription opiates within 30 days prior to the trial. The results show that Vivitrol was as effective as Suboxone treatment in maintaining patients relapse free among participants who were inducted. The 24-week relapse of events were similar across all study groups but the self-reported opiate cravings was initially less with Vivitrol but they did merge at 24 weeks with the Suboxone group, as well. Adverse events including overdose did not differ between the two groups. Overdose fatalities occurred in three participants in the Suboxone arm and two in the Vivitrol arm. Now recent pharmacoeconomic data that was published in the Journal of Medical Economics in 2018 was a 12-month retrospective analysis of insurance claims.

Gabriel Lither - I'm not sure exactly where you're going with the economic data, but it's important to note, this committee does not consider economic factors in its decision. So, it's beneficial for us; we're actually not supposed to hear of documented information.

Kenneth Barry – Okay, I can scratch that.

Gabriel Lither – Just a reminder that you're currently on the approved portion of the diagram up there.

Kenneth Barry – Okay, makes my job even easier, especially when I get home, I like this. So, I just wanted to thank you for your time today and your support for Vivitrol for patients with addiction. Any questions?

Sapandeep Khurana – Is it approved only for opiate disorder or alcohol and opiate abuse disorder?

Kenneth Barry – It's approved for alcohol use disorder and opiate use disorder.

Shamim Nagy opened up for public comment. There were none.

Carl Jeffery – Let me start off by saying that the Board has some decisions to make with this class, as well. This is a new class. We also have on the agenda to discuss the Suboxone, the Zubsolv, and the naloxone and the buprenorphine combinations. These two products would fit nicely into that class and so when we get down a little bit further, I actually have a couple scenarios proposed when we get to that class that this be included in there. Also, we recommended they be added as preferred in that whole class. So if the Board would like to skip this section and wait until we get down with the other buprenorphine-naloxone products, we could discuss adding those with the whole class or if the Board so desires to have this as a separate class, it's totally up to the Board. We have felt that it would fit nicely into the other ones, the buprenorphine-naloxone combination products. We heard about the Vivitrol, but I will just give my spiel about the Sublocade. It's an extended release buprenorphine product. It's dosed at 300 mg monthly for the first 2 months and then the dose is adjusted after that. You can go to 100 mg up to 300 mg dose once a month. They should be stabilized on the sublingual buprenorphine product before adjusting this, but it has been shown to be superior to placebo and achieving the more illicit opioid 3 weeks.

Gabriel Lither – I was just wondering, Carl, can you explain why you think this might feel well in a different class and what change between the time you proposed perhaps the new class and the idea now that it might be better fit in a preexisting class.

Carl Jeffery – Just to give my thunder away here, what we do is change the class so currently the other one is a mixed opioid antagonist for substance abuse agents. What we do is create a single class that would be substance abuse agents and then we would list the Sublocade and the Vivitrol as well as all the buprenorphine-naloxone products in there. What it does is simplify just the class as far as administration and also from the provider standpoint, there is less for them to review I think as far as what is on the preferred drug list. I think it would make it simpler from the provider standpoint as well as having it just under a single class so that was kind of our thought and it's indicated for the same thing. Often times these are interchangeable. As you can see, the Sublocade, they also need to be on the buprenorphine oral product, as well, during initiation.

Shamim Nagy – Should wait to discuss this again when we get to the other class?

Gabriel Lither – To make it clear, just have a motion that would be helpful, a motion to either adopt this new class now or to include these medications in the other class, so would we agree with doing that, would take it to the next class which is similar to this class next or to include it all at once, or would it be better just to make a motion to include them all in the same class, opioid antagonist?

Joseph Adashek – I think if you want to, we can just move the agenda around, as well, we can go to the other class right now, hear what we have to do about them and the class and then make a motion on this class.

Shamim Nagy – I think that would be clearer. Could we do that and move onto the next class?

Carl Jeffery – I think it's a good idea.

Kate Ward – When someone is talking, can they state their name before they make their statement because it's hard to follow you guys back and forth without wondering who's talking.

Joseph Adashek – I move that we talk about the similar class next and then we can decide to whether one category… Do we need a second for that?

Gabriel Lither – The chair controls the agenda so you can move forward with that at this time.

Carl Jeffery – Okay so, I have pulled up here the preferred and non-preferred drugs as we would propose it if the class remains the mixed opioid agonist-antagonists if we decide to update the whole class to just substance abuse agents and include the Sublocade and Vivitrol, this is our proposed class of how it would look. What brought this class back is there is a new generic for the Suboxone and so we would

include the generic as the non-preferred and just still prefer the brand name for now.

Kate Ward – I was wondering as far as the different routes and administration if combining all of them together would be more confusing and would then lead to not choosing the simplest which would be the oral form or if they advocate that it was noncompliant, they would want to (indiscernible), probably be more of a route option rather than them altogether (indiscernible).

Carl Jeffery – I think it's certainly worthy of discussion. I favor the single class and so I think it's just simpler. I think Dr. Ward has a legitimate point there. I think it would be clearer as far as a route of administration injectable versus oral. This is how I think it's simpler.

Shamim Nagy – So I see like an oral class, injectables, single, and combination agents in the same class. There are combinations there, too.

Carl Jeffery – That's why for this class, we would remove the mixed, and you can see that the previous one we have, they are the mixed opioid agonist-antagonists and so we would remove the mixed part of it and just substance abuse agents.

Sapandeep Khurana – Carl I was wondering within the class, is it possible to have orals and injectables list to categories two categories.

Carl Jeffery – It would help just to put a list after them. I'm trying to think how that would look on the preferred drug list, maybe an injectable product or oral. I'm trying to think of how that would look best.

Shamim Nagy – Okay, so you think it's okay?

Carl Jeffery – Yeah, that was our recommendation but certainly I think it's worthy of discussion. I think Dr. Ward raised a good point. I think it's worthy of the Board's consideration and discussion.

Shamim Nagy presented a motion.

Discussion of changing the name of the class to opioid dependency treatment agents.

Joseph Adashek – I move that we include this class of medications all in the same class, at this time just substance abuse agents.

Second. Voting: Ayes are unanimous. Motion carries.

Public comment opened for toxicology/substance abuse agents. There were none.

Carl Jeffery – We have what brought this back is the addition of the Suboxone generic. It's available now and I put it on the utilization statistics here. Suboxone brand is still by far the most used, almost 1000 claims in the past quarter. Optum

recommends the Board consider the medications listed here clinically and therapeutically equivalent.

Motion to accept Optum's recommendation. Second. Voting: Ayes are unanimous. The motion carries.

Carl Jeffery – Optum recommends that the Board update this class to include the Bunavail, the Sublocade, the Suboxone, Vivitrol, and Zubsolv as preferred and then the generic buprenorphine-naloxone, both the film and the tablet form as non-preferred. I think we can update renaming the classes well if that's something the Board would like.

Motion to accept Optum's recommendation. Second. Voting: Ayes are unanimous. The motion carries.

5. Established Drug Classes Being Reviewed Due to the Release of New Drugs

a. Anti-infective Agents - Antivirals - Influenza Agents

Shamim Nagy presented this class and opened up for discussion to the public. There were none.

Carl Jeffery – Xofluza is a new medication, like the Tamiflu agents. It's an endonuclease. Works kind of the same way and just a little bit different. Indicated for patients 12 years and older who have had flu symptoms no more than 48 hours, similar to the Tamiflu. Study was about 1400 patients shown and compared to placebo and Tamiflu, shown to be noninferior or actually about the same similarity between the Tamiflu and the Xofluza. What was a little bit different was the Xofluza was slightly better at not having so many of the side effects that come with the Tamiflu. I don't know when Xofluza was available on the market, but the last quarter we don't have any claims for it. It's right in the flu season so we're looking at December, January, and February so expect to see a good number of claims for these which is not huge. Amantadine I'm guessing, I don't think it's being used a whole lot this year. I've heard it's not real effective this year for the flu virus that's going around this year, so it may be used for other non-flu issues. Still not a huge number of claims here for a quarter but those are our utilization. Optum recommends the drugs in this class be considered clinically and therapeutically equivalent.

Motion to accept as clinically and therapeutically equivalent. Second. Voting: Ayes are unanimous. The motion carries.

Carl Jeffery – Optum recommends the new drug, Xofluza, be added to the preferred drug list as non-preferred and keep the rest of the class the same.

Shamim Nagy opened for questions/discussion.

Joseph Adashek – For the medication, Xofluza, what kind of antiviral is that? Is it similar to any of the other agents?

Carl Jeffery – Yeah, it is similar to the Tamiflu. It's a little bit different class but it works the same way as Tamiflu. The difference with the Xofluza as far as the dosing goes, it's just a one-time dose so you get the flu symptoms and it's a one-time dose whereas the Tamiflu 7 to 10 days therapy. It's a little bit different and a little bit easier that way.

Joseph Adashek – A one-time dose, can I ask you, who do you think honestly would be taking much more readily than Tamiflu and less likely to get influenza complications in this one-time dose? If you chose it, usually it's for economic reasons, I know we don't want to discuss that, for reasons that it could be other than the reason I just said.

Carl Jeffery – It's only approved to 12 and older whereas Tamiflu I think is down to 2 I think.

Joseph Adashek – I just don't know enough about it in terms of saying, should it be preferred or… if anyone up north, if they want to make a motion to prefer. Educate me on it other than the fact that it's a one-time dose.

Holly Long – Dr. Crumby or Kate Ward, can you speak to what Dr. Adashek is asking?

Kate Ward – Yeah, it does seem as though it has similar efficacy it obviously doesn't compare to Tamiflu but it does seem to be comparable to Tamiflu in efficacy and needs to be taken over an appropriate period of time with the diagnosis of influenza. Beyond reason, although we cannot discuss it, I believe that they would be able to be chosen interchangeably.

Sapandeep Khurana – I think with one dose, people will not get better any sooner now they're taking 10 doses to 1 dose and the second responses.

Joseph Adashek: If you don't take a full course of Tamiflu, do you have the same risk of resistance as with antibiotics?

Kate Ward – So really you want to take the most effective course and not the entire course that's written so with it, with Tamiflu, there's an amount to whether or not you really need to continue to take the entire course if you're no longer having symptoms. Again, the prescription is going to be filled for the entire course that's written so it doesn't go from a patient standpoint, they're going to get the entire course it's written for. In the form you get, the Tamiflu, you get one dose for treatment.

Joseph Adashek – I understand that, but say the patient feels better and only takes the tablet for 5 days, is there an increased risk of resistance for example than there would be for antibiotics or only takes two days of antibiotics for whatever; for a MRSA infection, there is more resistance if you want to take it two days as opposed to the entire course, would you say that is similar to Tamiflu or not necessarily?

Kate Ward – No, it wouldn't be. It wouldn't be comparable.

Joseph Adashek – My next question is, again, if Tamiflu's for 7 days or 10 days, are you taking 10 times the medication needed than if you were to take the one-time dose in Xofluza. Once you're taking 10 times the medication or say 10 days of Tamiflu, versus 1 day of Xofluza, does that impact the decision?

Kate Ward – No, when I looked at it, as far as average goes, it was well tolerated.

Joseph Adashek - I think that the medication that you take once in one pill would be beneficial, more likely to be taken, more likely tolerated, the side effects grasped, so I would make it a preferred agent. I make a motion that that it would be a preferred agent.

Gabriel Lither – Your motion is to accept the recommendations with the exception of moving Xofluza from non-preferred to preferred correct?

Joseph Adashek – I apologize and that is correct.

Second. Voting: Ayes are unanimous. The motion carries. Xofluza moves to preferred.

b. Autonomic Agents - Sympathomimetics - Self-injectable Epinephrine

Shamim Nagy opened for public comment. There were none.

Carl Jeffery – We have a new product, Symjepi. This one is a little bit different than the other ones that are available. It's a prefilled syringe and not an auto-injector like the Epi-Pens or even the generic epinephrine that's available. It looks like a Lovenox syringe. Right now, we don't have any claims for it in the past quarter. The generic epinephrine, which is our preferred agent, of course, has the bulk of the claims. You have a couple of Epi-Pens, one Epi-Pen prescription, so again seems like it is right in line with what we expected with how our preferred drug list is. We have another one that's on the market, Auvi-Q. This product does not participate in the Federal Drug Rebate Program, which is a requirement from CMS, so we have it up here, even though Medicaid can't cover it. Optum recommends that the Board consider these clinically and therapeutically equivalent.

Motion to accept as clinically and therapeutically equivalent. Second. Voting: Ayes are unanimous. The motion carries.

Carl Jeffery – Optum recommends that the new product, the Symjepi, be considered non-preferred in this class and keep the rest of the class the same.

Joseph Adashek – Why was Symjepi invented then? It's such a similar medication to the others. Is there any reason why that is even on the market?

Mark Crumby – Cheaper.

Motion to accept Optum's recommendation. Second. Voting: Ayes are unanimous. The motion carries.

c. Hormones and Hormone Modifiers – Androgens

Shamim Nagy opened this class for discussion and public comment. There was none.

Carl Jeffery – This will be a fast one, too. There are two new generic products on the market and that's what prompted us to bring this one back. There's also a new injectable product. It's called Xyosted. It's an injectable testosterone. It didn't make it to our numbers in time to really do a full review, so we may see it on again in the future but right now, we're just talking about the two new generics and that's why we're talking about this one. The testosterone gel is the generic for the AndroGel and the testosterone solution is the generic for the Axiron. Both of those are newly available. The other products with the testosterone gel have already been available for a while and those are out there in the market. You see our utilization. Not a whole lot of utilization on this one. When I show the slide, it's highlighted and the AndroGel. Optum recommends the Board consider adding the AndroGel as the non-preferred. There were 10 claims in the quarter, so I don't think it's going to impact those three members or so that they could either switch to the Androderm or we could grandfather them in with the AndroGel but shouldn't be a big problem to switch over to the Androderm. The two new products, we have one already for the Axiron and the other generic doesn't have any utilization yet. A lot of the other ones don't have utilization, either. Optum recommends the Board consider these clinically and therapeutically equivalent.

Motion to accept as clinically and therapeutically equivalent. Second. Voting: Ayes are unanimous. The motion carries.

Carl Jeffery – I think one of the bigger changes since the generics came out, it gave Optum a chance to really review these again. We are going to recommend that the brand AndroGel be removed from preferred and added as non-preferred and then the new testosterone solution and the new testosterone gel which has already been listed on there but the new solution would also be added as non-preferred.

Shamim Nagy presented motion.

Kate Ward – We'll only have a solution available and not the gel available as preferred?

Carl Jeffery – Yes that's right. The advantage of only having a single preferred agent, though, is they just to need to try that one before moving into a non-preferred agent.

Joseph Adashek – I don't prescribe this as all my patients are pregnant, is that a problem with anyone up North, AndroGel is now taken off preferred?

Motion to accept Optum's recommendation. Second. Voting: Ayes are unanimous. The motion carries.

d. Ophthalmic Agents – Antiglaucoma Agents

Shamim Nagy opened for public comment. There was no public comment.

Carl Jeffery – We have a new antiglaucoma agent, as the Board may remember, we combined all of the classes into all just one big antiglaucoma agent class a while ago. We have two new products that are on the market, one generic. We have the generic for the Cosopt-PF which is preservative-free, the dorzolamide and Timolol ophthalmic solution. It's just a new generic and nothing real special about that one. The other one is the Xelpros and it's a latanoprost emulsion and what makes it different from the Xalatan or the generic latanoprost that's currently available is that it's the benzalkonium free products. I think the result, there may be some patients who have kind of a sensitivity to the BAK product in there but they won't know that until they try it usually. It has a similar efficacy to Xalatan when it was studied. We have all of the different classes here. You can see the latanoprost generic, by far the most utilized in its class, almost 600 claims in the past quarter. All the other ones are around 100 claims for the most popular like the timolol or the Travatan-Z are 170, 164 claims respectively, so not a huge utilization for outside the latanoprost in the past quarter. This is a slide for the clinically and therapeutically equivalent. I have it broken down by class. There is another ROCK inhibitor that I think did get approved in the last couple of weeks, so we'll probably be seeing this class again, if not the next meeting but the meeting after. Optum recommends the Board consider these clinically and therapeutically equivalent.

Shamim Nagy opened up for discussion.

Motion to accept as clinically and therapeutically equivalent. Second. Voting: Ayes are unanimous. The motion carries.

Carl Jeffery – Optum recommends the new generic, the dorzolamide and the timolol be added as non-preferred as well as the new product, the Xelpros be added as non-preferred; keep the rest of the class the same.

Shamim Nagy opened up for discussion.

Motion to accept Optum's recommendation. Second. Voting: Ayes are unanimous. The motion carries.

e. Ophthalmic Agents - Ophthalmics for Dry Eye Disease

Shamim Nagy opened for public discussion. No public comment.

Carl Jeffery – Another new drug in its class, Cequa, it's another cyclosporin like the other ones. Its selling point is that it's formulated a little bit different. It's in a solution versus an emulsion with the other ones. It's formulated a little bit

different. They use micro-nano technology, but it's supposed to be absorbed in the eye a little bit better than some of the other ones. I saw and I was on the website this morning reviewing these and even on the website it said that it's not yet available so I'm not sure that the pharmacies have seen this yet but it is available from our clinical team and then for our review. But, it's indicated like the other ones to increase tear production in patients with the keratoconjunctivitis sicca. Similar to the other products, I put all the other indications up here for the Restasis and the Xiidra that are up there. We have about 1000 patients in the trial versus just the vehicle. There's no head-to-head studies versus against the Restasis or the Xiidra but after 84 days, 17% of the Cequa treated patients versus 9% of the vehicle-treated patients achieved their endpoint which is greater than 10 mm from baseline and then the smear wetting test. In my eyes, this doesn't seem all that effective anyway, and I think it's in line with the other ones but that's not great numbers in my mind. You can see the utilization. The Restasis multidose is kind of greyed out there because these numbers, if the Board remembers last time we reviewed this in November, we made the multidose file non-preferred and so the numbers here are from before the Board and it's non-preferred, so the 103 on here likely shifted over to the regular Restasis individual vials. No use for the Cequa yet. As I mentioned, it's probably not available yet and just a few for the Xiidra. Optum recommends the Board consider these clinically and therapeutically equivalent.

Motion to accept as clinically and therapeutically equivalent. Second. Voting: Ayes are unanimous. The motion carries.

Carl Jeffery – Optum recommends that the new product, the Cequa, be added as non-preferred and the rest of the class remain the same.

Motion to accept Optum's recommendation. Second. Voting: Ayes are unanimous. The motion carries.

6. Established Drug Classes

a. Toxicology Agents - Substance Abuse Agents - Mixed Opiate Agonists/Antagonists (Oral)

Carl Jeffery – I just was going to mention to the Board, it has nothing to do with the decision, there is a new drug that's another combination of buprenorphine-naloxone product that's supposed to be in the works, the Cassipa is its tradename. They just haven't released it. We may see this class again here soon, but we'll skip ahead to the next class.

b. Analgesics - Analgesic/Miscellaneous - Neuropathic Pain/Fibromyalgia Agents

Shamim Nagy opened up for public comment. No public comment.

Carl Jeffery – We have a new Lyrica-CR. I always find it amazing that these drug companies manage to come out with an extended release product about the time the regular-release product is going to come off patent, so it's incredible how

they're developing these products works. The new Lyrica-CR is once a day instead of 2 or 3 times a day and again the same indication for the Lyrica. Like I said, there's a generic that's in the pipeline, I think we should see it here soon. The other product was new; I don't know how new it is. It just popped up on our clinical review. It's a Qutenza. It's a capsaicin patch and this is the first I'd seen it, but it's indicated for the relief of pain associated with the peripheral neuropathy. It's a little bit different in that it's applied for 60 minutes at a time, up to 4 patches every 3 months and then it can only be administered by a physician or a healthcare professional. This one sounds a little bit weird as far as the administration of it. You can see our utilization, gabapentin is always one of Nevada Medicaid's population's most favorite drugs. It shows up in one of our highest utilization for the non-opioids. The numbers reflect that. The Lyrica is not quite as popular but still quite a few claims, almost 2100 claims for the Lyrica in the last quarter and only 6 claims so far with the Lyrica-CR. Optum recommends the Board consider this class clinically and therapeutically equivalent.

Shamim Nagy presented the topic for discussion. No discussion.

Motion to accept as clinically and therapeutically equivalent. Second. Voting: Ayes are unanimous. The motion carries.

Carl Jeffery – Optum recommends that the new Lyrica-CR be added as non-preferred and then since the Qutenza would only be administered in a doctor's office, there won't be any impact here but it would just be a good idea to add it as non-preferred just in case a local pharmacy tries to run it, just so it's a little bit more clearer that way, but the Qutenza be added as non-preferred, as well.

Sapandeep Khurana – Is Savella a preferred drug only for fibromyalgia as it states?

Carl Jeffery – Yes, that's right. It's only indicated for fibromyalgia. I don't think it has the neuropathic pain indication like some of the other ones do so I think that's why it has that caveat.

Motion to accept Optum's recommendation. Second. Voting: Ayes are unanimous. The motion carries.

c. Anti-infective Agents - Antivirals - Anti-hepatitis Agents - Polymerase Inhibitors/Combination Products

Shamim Nagy opened up the discussion for public comment.

Laura Hill – My name is Laura Hill. I'm with Medical Affairs and AbbVie. We're the company that manufacturers Mavyret. I just really wanted to come up in case you had any questions. Thank you.

Carl Jeffery – We have two new authorized generics from Gilead here. There's the generic for the Epclusa and the generic for Harvoni. These were just released a few months ago. The Viekira-XR and Technivie from AbbVie is voluntarily discontinued from the manufacturer. Our plan is not to remove those quite yet

from our preferred drug list, but they probably will be coming but we'll let anybody who's maybe going to continue therapy or maybe if there's some product on the shelf we don't want to be hasty about removing those products. The generics for the Epclusa and the Harvoni are the same and actually made by the same company. No problems with those. You can see the utilization numbers here for the last quarter and so the Epclusa and the Harvoni and the Mavyret actually have quite a few claims on there. Optum makes the recommendation the Board consider this class clinically and therapeutically equivalent.

Shamim Nagy opened up for discussion. No discussion was heard.

Motion to accept as clinically and therapeutically equivalent. Second. Voting: Ayes are unanimous. The motion carries.

Carl Jeffery – With the new generics on the market, Optum recommends the new generic for Epclusa and generic for Harvoni be added as preferred and the rest of the class remain the same.

Motion to accept Optum's recommendation. Second. Voting: Ayes are unanimous. The motion carries.

d. Dermatological Agents - Topical Anti-Infectives - Topical Antifungals (Onychomycosis)

Shamim Nagy opened the class for public discussion. No public comment.

Carl Jeffery – We brought this back a couple of times because we're trying to figure out what the class should be. This is the last class. The antifungal so, onychomycosis agents, these are only agents that are used to treat toenail fungus. It's generally what they are on infrequently for fingernail fungus. Optum sees no benefit to managing this class on the preferred drug list and so Optum's recommendation is just to eliminate this class from the preferred drug list and as we discussed with the Lucemyra is that it just creates open access. There is prior authorization requirements for a lot of these agents already for like the Jublia and some of the other medications of the topical medications, so it's not like they wouldn't just be uncontrolled but they would be still limited to those who should be best getting them. You can see the utilization of these. The therapy of these agents is a long time for not a whole lot of success rate with these, so still pretty low success and you can see people have to be on these for 48 weeks before they have a moderate reduction or moderate control of their toenail fungus. With the oral agents and I think some of the confusion is because we have it listed as a topical antifungal, I think our intention was that the fungus is topical and not everything is applied topical and I think it was creating some of the confusion because there are oral agents included in there. You can see that the oral agents are proven successful. They're a little bit more successful in treating this than the topical agents but then there are side effects with them, as well. We look at the utilization, the terbinafine can be used for other things, too, although it's probably mostly being used for the toenail fungus and then the ciclopirox is the number one

utilizer as far as the topical treatments go. There's no benefit to having this as a managed class because everything we have on here is generic and so our generic first program would kind of take over from not having this class on there.

Joseph Adashek – I would agree with Optum's recommendations that this is no longer considered a class.

Motion to accept Optum's recommendation. Second. Voting: Ayes are unanimous. The motion carries.

7. Report by OptumRx on New Drugs to Market, New Generic Drugs to Market, and New Line Extensions

Carl Jeffery – We've got a couple new nasal spray. I'm sure this is getting a lot of press coverage, the esketamine, the Spravato nasal spray. I don't know if this is going to be on our preferred drug list. Eventually, it is pretty unique on where it fits in and the therapy is really only for treatment-resistant major depressive disorders. From what I hear, it works very rapidly and has been successful for the relatively small group of people and this is really geared towards. It doses twice a week during the induction and then once a week for the maintenance phase. The other two new products are both ADHD medications. I'm not sure why we need more, another methylphenidate product, another amphetamine product, so we'll probably be seeing those in the future. Again, a couple new generics, Advair Diskus is now approved as generic and we'll be seeing those coming up here as well as the Proair, the Ventolin, and I believe the third new one coming out, too, and the Renagel as well as a new generic so these will all be a little foreshadowing where we'll be coming for future meetings.

Joseph Adashek – There's a new postpartum depression, over 60 hours, we'll have to discuss that correct?

Carl Jeffery – Physician-administered drug claims, we call them PAD claims, they're not bound by our preferred drug list and so that one would be given through a physician-administered drug. It's usually given right after the baby is born right?

Joseph Adashek – Well, it's best given for postpartum depression when diagnosed. It could be a couple weeks later, a month later.

Kate Ward – It requires the healthcare facility to administer because of the adverse effects that we're seeing so, it is given in the hospital.

Joseph Adashek – If there's 2 people out of 250, they got out of bed too fast to go to the bathroom, I read those where to the two adverse events. That was the reason it is given in a healthcare facility.

Sapandeep Khurana – For the esketamine, if the pharmacy has claimed now, what's the status that it would go through?

Carl Jeffery – Yeah, this is not restricted right now so you have to take out a claim for it. I can't think of anything that would stop it. I don't know that it's been loaded yet, though, I don't know if it's in the system yet.

Sapandeep Khurana – So would it come through or not?

Carl Jeffery – There wouldn't be any approval. The claim would just go through without any kind of restrictions so there is no approval process. It is on our list. We will bring it to the DUR Board. I think it merits restriction. I don't think it should be open access to everybody. There's some monitoring that needs to go along with it, and not everybody has treatment for major depressive disorder, so I think from what they're saying, there's certainly a limited number of people who have tried and failed other more traditional therapies before they moved to this product.

Sapandeep Khurana – You are correct, treatment is the definition of TRD and this is the study of indication of failure of two antidepressants.

Carl Jeffery – And so, two SSRI failures, probably a lot of people. A couple of new drugs coming out of the pipeline. I don't know what's with the nasal spray focus but metoclopramide nasal spray, this is interesting as it is only for adult women for acute and recurrent diabetic gastroparesis, so it would be interesting to see how this one comes out and if we'll address it. Dosed at 4 times a day so still frequent with this one. New medication that's coming out for the plaque psoriasis. I thought this one looked promising. It's a new subQ IL-23. This one is dosed every 12 weeks, so I think it's promising that it's not having to be given very frequently. Superior to Humira and Stelara which may have some promise to and then this other new one, the last one on here, is a new one for the SMA, which is muscular atrophy type 1. We've got a couple of other products that are on the market. It's a novel gene therapy which I think this one looks promising. A one-time infusion and I think we can discuss cost with this one since we're not deciding about covering it or not but 2 million dollars for the administration of this one-time infusion. A lot of money with this one coming out but I think if it's effective, and so they studied it in 12 patients, all 12 of them after 2 years, haven't declined at all, so I think it shows a lot of promise and if we're going to get that much effect out of it, maybe it's worthwhile, but I think we're just getting the tip of this new gene therapy with these other medications coming out.

Shamim Nagy opened for public comment.

Daniel Deck – Hello my name is Daniel Deck. I'm a clinical pharmacist by training. I work with the medical affairs division at Paratek Pharmaceuticals and I just wanted to take 2 or 3 minutes of your time to introduce you to a new antibiotic that helps address the challenge of antibiotic resistance. Omadacycline is a modernized tetracycline antibiotic that is FDA approved for the treatment of adult patients with community-acquired pneumonia and acute bacterial skin and skin structure infections. It's available in both an IV and oral formulation which will help facilitate discharge from the hospital on the same antibiotic and really focused on the resistance piece. It's structurally distinct from other tetracyclines and allows it to

overcome the common tetracycline-resistant mechanisms that we see that affect the older tetracycline antibiotics. As we know in the disease states of skin and soft tissue infection and community-acquired pneumonia, resistance is a growing challenger and as we know, some of the other options there are growing safety concerns with the fluoroquinolones and the black box warning. Omadacycline has activity against all the common community-acquired pneumonia pathogens including strep pneumo, Haemophilus, including islets that are resistant to other antibiotics and in the skin and soft tissue infection world, we're active against MRSA and group A strep. Notably older tetracyclines are not active against many islets of strep. We also have invitro activity against E coli including islets that are multidrug resistant. What those produce, extend the spectrum beta-lactomases, VRE, the safety and efficacy of omadacycline against these microorganisms has not been established. The tetracycline class also has a much lower incidence of C. diff which is a growing problem. It contributes the burden of cost in the hospital and so we look forward to coming back at some point when we're being considered for review to talk to you at greater length about that.

8. Closing Discussion

a. Public comments on any subject. There were none.
b. Date and location of the next meeting –

Carl Jeffery - June 27, 2019, and you can provide some feedback on how the meeting room was up there and if there's something we can improve.

c. Adjournment

Meeting adjourned at 2:36 PM