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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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DRUG USE REVIEW BOARD

Draft Meeting Minutes

Date of Meeting:	**Thursday, November 5, 2015 at 5:15 PM**
Name of Organization:	**The State of Nevada, Department of Health and Human Services, Division of Health Care Financing and Policy (DHCFP), Drug Use Review Board (DUR).**
Place of Meeting:	**Best Western Plus Airport Plaza Hotel** **1981 Terminal Way** **Reno, NV 89502** **Phone: (775) 348-6370**

AGENDA

Committee Members Present: James Marx, MD; Jeffrey Zollinger, DO; Paul Oesterman, Pharm.D.; Chris Shea, Pharm.D.; David England, Pharm.D.

Committee Members Absent: Michael Owens, MD

Others Present:

DHCFP: Coleen Lawrence, Chief, Program Services; Mary Griffith, RN, Pharmacy Services Specialist; Darrell Faircloth, Deputy Attorney General

HPES: Beth Slamowitz, Pharm.D.

OptumRx: Carl Jeffery, Pharm.D.; Rob Earnest, Pharm.D., JD; Daniel Medina

Others: R. Karim, Abbvie; S. Johnson, Otsuka; C. Holtzer, Abbvie; L. Robinson, Abbvie; Jennifer Lauper, BMS; Sarah Swan, BMS; Charissa Anne, J&J; Marykay Queener, J&J; Bonnie Romero, Alkemes; Charles Krasner, Unsom; Sonia Buchecha, Renown; Sergio Gonzalez, Takeda; Tom O'Connor, Novartis; Melissa Walsh, Novartis; Ketul Patel, Vertex; Ann Nelson, Vertex; Daniel Fry, HPE; Joshua Livernois, NNHOPES; Abigail Polus, NNHOPES; Julia Efistoff, Consumer; Isabel Deane, HOPES, Mark C, HOPES; Kerry Kostman Bonilla, AZ; Andrea Schershel, BMS

Others via telephone/Web: Aimee Redhair, UCB; Brad Willie, Novartis; Becky Gonzales; Rob Bigha, Shire; Mark Schwartz, GSK; Lori Howarth, Bayer; CAF Fay; Christopher DiSimone, Aegerion; Kevin Whittington, Optum

1. Call to Order and Roll Call

Called to order 5:21PM

Roll Call:

Coleen Lawrence, Chief Program Services, DHCFP

Mary Griffith, RN, Pharmacy Services Specialist, DHCFP

Chris Shea, Pharm.D.

Jeffrey Zollinger, DO

David England, Pharm.D.

Paul Oesterman, Chairman, Pharm.D.

Darrell Faircloth, Senior Deputy Attorney General, DHCFP

James Marx, MD

Carl Jeffery, Pharm.D., Optum

Rob Earnest, Pharm.D., JD, Optum

2. Public Comment on Any Matter on the Agenda

Paul Oesterman, Chairman: Any public comment on any matter on the agenda? None

3. Administrative

a. **For Possible Action:** Review and Approve Meeting Minutes from September 3, 2015.

Review and approve the meeting minutes from the September 3, 2015 meeting. The Chair asked for a motion and a second to approve the minutes.

James Marx: I move to accept the minutes as submitted.

David England: Second.

Voting: Aye's across the Board

b. Status Update by DHCFP

Coleen Lawrence: November 1 we implemented the NADAC pricing. We have had some bumps with it, but if you hear anything, please direct them back to Optum or ourselves and we will work through them. This lead to a dispensing fee survey, it decreased our long term care dispensing fee because we went to one fee. Overall, this will benefit the pharmacies. The second thing is, we are working on a pharmacy tool kit in the office. For supplemental rebate or federal rebates, we want to put out a pharmacy tool kit for the stake holders, to have the tools to know how to work with us. We hope to have it out within the next few months after it goes through our internal review. If you have those popular questions that you would like to see in the tool kit, let us know and we will be sure to include it. It is for all programs and we want it to be educational.

4. Board Action

a. **For Possible Action**: Discussion on Lock-in Program proposed changes to criteria

Paul Oesterman, Chairman: Now we are going to move to the discussion of the lock-in program and some proposed criteria changes. Is there any public comment on the phone or in person? There doesn't appear to be any. What are the proposed changes?

Mary Griffith: I help with the lock-in program that's managed in the SURS department. We don't necessarily need any changes, but we want some clarification for certain situations. We have recipients that change pharmacies frequently and we don't have policy to limit this. The other issue is we don't have any way to get people off the program. We have criteria to run the report to put them on and we have been doing this since 2008 and we have about 800 people on the program now. We want to make sure we are doing what we should be doing. We have talked about the holy trinity, opioid, muscle relaxant and an antianxiety. There is talk about locking people in with these drugs only.

Coleen Lawrence: As a reminder, to get locked in as a best practice, we use the data in a responsible way. We work with the Board of Pharmacy and the claims history. We only look at controlled substances. So question one, should we stay with controlled substances? The next with the Governor's task force, are they receiving any follow up care, behavior health services? We looked at this, and there are several recipients in the lock in program that are getting behavior health treatment. We are also working with our behavior health program to work with messaging. The other issue Mary is looking at is changing pharmacy policy, and should we reevaluate after a year? Or should we have an evaluation from the prescriber?

Carl Jeffery: Some other challenges, should we lock in people with Medicare D? And another issue is people going into a long term care facility that are locked in to an outpatient pharmacy, making it difficult to get their medications filled.

Coleen Lawrence: Don't we exempt the dual eligible recipients?

Carl Jeffery: We have been, but they still show in the report.

Mary Griffith: We also have an issue with people moving from fee for service to the MCOs.

Coleen Lawrence: We are working with the MCOs to create their lock-in programs.

James Marx: I still have one patient that is lock in, and I can't figure out why. She does have multiple medical issues. The changing in pharmacies is being driven by the supply issue, we see recipients going to a pharmacy and not being able to get their medication filled and having to go to another pharmacy. We have patients on a long acting and an intermediate and they are not always in sync and then the pharmacy may impose some other restrictions.

Mary Griffith: There is an override so they can go to a non-participating pharmacy.

David England: We probably need some criteria for changing pharmacies, but it needs to be the same for the MCOs. Maybe every one or two years to reevaluate their lock-in. It seems the purpose is to change the drug use habits.

Coleen Lawrence: Asking the Board, what would be an appropriate time period?

Carl Jeffery: We run a report for a cost summary, it includes all drugs, not just controlled substances.

Coleen Lawrence: How would the Board like to update this? If we come back with some review criteria.

Paul Oesterman, Chairman: I would say a six month period would be enough to comply with lock in behavior. If they can demonstrate their compliance, then after six months unlock them and then review them again in six months.

James Marx: What is it we would be evaluating?

Paul Oesterman, Chairman: We would be looking for drug seeking behavior. Through PMP and emergency room data. Do you know if the number of emergency room visits has decreased?

Coleen Lawrence: I don't have that now.

David England: For the people who have come off the program, how are they doing?

Carl Jeffery: Those people on the report are no longer eligible for Medicaid, no one has been removed from Lock-in.

Paul Oesterman, Chairman: Going back with patient having to go to multiple pharmacies, I think the shortage issues seem to be resolving from what I hear.

James Marx: Not in Las Vegas, they are getting better. Some pharmacies won't order the medication.

Coleen Lawrence: The pharmacies are told before the recipient is locked in to their pharmacy.

Jeffrey Zollinger: The policy does have an exception if the pharmacy is out of stock. So there is an option of finding another pharmacy.

David England: In the event of that happening, it may take a few days to get a CII in. Could the pharmacy get the medication in in time if the patient is completely out? I'm curious about these shortages.

Chris Shea: If they are filling a 30 day supply, when can they come in for a refill?

Carl Jeffery: It is 90% use before they can get a refill.

James Marx: Some pharmacies impose their own, more strict days.

David England: If we have facilities or individuals imposing their own rules on the recipients, we need to have a discussion with the provider.

Coleen Lawrence: I did, I asked some large chain pharmacies, but did not get any information. If you find that, let me know because we need some examples.

James Marx: I can give you plenty of examples.

Coleen Lawrence: Then please pass those along so we can work with these corporations to make sure we are all in line

James Marx: We probably see it more on the commercial side.

David England: If they get an override, can they get the medication again?

Mary Griffith: No, it will hit a duplicate edit and it is a one-time override.

Paul Oesterman, Chairman: Going back, looking at the criteria, I can see a potential to alleviate some. The criteria for more than one pharmacy, if that is relaxed so they can go to a second pharmacy if necessary. I think making it so it is more than two pharmacies. For the ones locked in now, we have to find a way to get out. And looking at the number of controlled substances in 60 days, by the time you add a long and short-acting opioid and maybe something for adjunctive treatment, you're up to 6 controls in 60 days.

James Marx: If you add a benzo, and an anti-epileptic for seizure, then it can creep up there.

Paul Oesterman, Chairman: Any patient with more than 10 in a 60 day period, they are either very willing to work with the pharmacy or are exhibiting drug seeking behavior.

Coleen Lawrence: We have only had a few appeals, so the criteria is pretty solid. The criteria is working to target the appropriate population.

Chris Shea: So they are not asking to get out of the program?

Coleen Lawrence: No, we have been doing this since 2008, and only about 5 appeals. I think we want to know if people can get out of the program.

Carl Jeffery: We send the report to a nurse at the State, and she will pick out about 10 members from that report. She looks at the diagnosis and makes a clinical decision.

David England: So you want to know how long they should be locked in before they are reviewed? So if we increase the pharmacy to two, and then after 6 months, review the recipient, and then take them off lock in and follow up in 6 months again. Then they can be put back on the program again.

Jeffrey Zollinger: The physicians should be checking the PMP now with the law change. I think if we raise enough red flags with physicians and care takers for 6 months, all eyes on the patient, then they can be taken care of.

David England: And then if you go to a medication reconciliation, then you would be able to see trends of possible abuse.

Mary Griffith: We do send letters to their physicians.

James Marx: How often does that letter go out?

Mary Griffith: When they are locked in, it goes to the doctors in their profile.

James Marx: This one recipient I have, I haven't received a letter in five years.

David England: Should we review every six months and send a letter out when they are off and then if they go back on, they send out a status update.

James Marx: It would also give you an opportunity to review if they should be on lock in. There haven't' been any appeals, I would be shocked if there were a lot of appeals. Sending out a letter every six months and remove some of these recipients, then it would reduce the burden.

Coleen Lawrence: We are not looking to decrease the number of recipients, we are looking for the best care of the members. We want them to be compliant and healthy. We are looking to increase education for the providers and link it to the PMP.

James Marx: If you send letters out to prescribers and ask for their input to allow them to be removed, otherwise it will be a growing snowball.

David England: Do people have to move that much, is their housing that unstable?

Mary Griffith: I don't think that is the majority, there are some like that, but most requests are coming from people that want to keep changing for various reasons. Maybe a limit of three changes per year.

Paul Oesterman, Chairman: Maybe under bullet point 4 where pharmacies may call for an override, you have three criteria, maybe add another reason the member has had a permanent

change in address. I think we have had some good discussion, and we have some recommendations to change 1.A to utilizing more than two pharmacies in the past 60 day period, then six month follow-up and then assess to see if they should be removed, and then a six month follow-up after that. A follow-up letter to the physician to check their status and then the final change would be to add a permanent address change to the reason for change.

David England: Motion to accept as amended.

James Marx: Second.

Paul Oesterman, Chairman: My only point of clarification would be how that six month period is processed.

Mary Griffith: We will work that out.

Voting: Ayes across the Board, motion carries.

5. Clinical Presentations

a. For Possible Action: Discussion and possible adoption of updated prior authorization criteria for the addition of daclatasivir (Daklinza®) and ombitasvir/paritaprevir/ritonavir (Technivie®) to the current Hepatitis C criteria.

Paul Oesterman, Chairman: Discussion of Daklinza and Technivie prior authorization criteria adoption. Any public comments?

Andrea Schershel – MSL for BMS – speaking on daclatasivir. She gave overview of cure rates and duration of treatment according to the recommendations from AASLD.

David England: Do you have a copy of the criteria we are looking at?

Andrea Schershel: I have the information from the web.

Carl Jeffery: That doesn't sound like you are looking at the same page we are reviewing.

Jennifer Lauper: It is page 161 from the website. I can show you.

Paul Oesterman, Chairman: Ok, it is on the proposed criteria, not on the existing criteria.

David England: Are you making any changes to this page?

Andrea Schershel: I would propose that cirrhotic patients with F4 be treated with daclatasivir, plus sofosbuvir and ribavirin for 12 weeks, or 24 weeks with daclatasivir and sofosbuvir.

David England: Ok, that is 1F.

Andrea Schershel: Also, patients that are post-transplant be treated per the AASLD guidelines with daclatasivir and sofosbuvir for 12 weeks in the non-cirrhotic patient and 24 weeks in the cirrhotic patient.

David England: other than that, any other concerns on the proposed criteria?

Andrea Schershel: No, just that.

David England: Can we validate that?

Carl Jeffery: Sure, it will be part of our discussion.

Paul Oesterman, Chairman: Any other comments? None.

Carl Jeffery: As you just heard, there are two more products on the market now, they are expanding the indications to cover the other genotypes. The AASLD is the highly reputable society that creates these guidelines and updates the guidelines very frequently. But with our process, we can't keep up with them. If there is some way to write in that we follow the AASLD guidelines because they change so frequently. I don't know how the Board feels about adding language to the policy. There is also some new information from CMS that Rob was telling me about.

Rob Earnest: Yes, CMS released some information expressing some concern about what states are doing with Hep C with utilization management. The gist was to take it slow and be sure we are being appropriate. They called out some examples for states having abstinence from alcohol or drug use. They didn't come out specifically, as a heads-up that they are looking at the criteria. I can provide the release to the Board, it just came out today. They want the fee for service and the MCOs to follow the guidelines.

David England: I don't feel we need to be on the cutting edge, but we should be on the wave so we can be in compliance with the Medicaid rules. Can we put criteria that we would follow the association recommendations after 30 or 60 days after being published, that we would implement it into our prior authorization request information, but give it time to shake out?

Andrea Schershel: I understand your point. Right now, the guidelines have been out for 2 months. If the issue is the cost of the 24 weeks of the daclatasivir and you are waiting for the guidelines update that will probably happen in about a month at the next AASLD conference. You will pick that up when they discuss the ALLY 3 trial. This trial is daclatasivir, sofosbuvir plus ribavirin for 12 or 16 weeks of therapy. The results are not published yet, but if you add ribavirin to the therapy, you will a comparable SVR. So to be fair, if you wanted to wait for the new guidelines, they will reference this therapy for the cirrhotic patients.

Paul Oesterman, Chairman: We will have to wait until that data comes out.

Abigail Polus: My name is Abigail Polus and I am with Northern Nevada HOPES as a patient advocate. I have been speaking with Mary Griffith via email. We're having some issues with getting PAs through and not getting the ability to obtain treatment for hepatitis C.

Paul Oesterman, Chairman: Let's have this discussion and then we will call you forward. Carl, can you give your information?

Carl Jeffery: You have the proposed criteria that was put together with the guidelines that were available at the time. We can update for transplant and cirrhosis status. The clinical call center is good about approving if the request is medically accepted and included in the current guidelines.

David England: I don't see the thing about CMS guidelines about abusing drugs or alcohol.

Rob Earnest: Let me be clear, those were not CMS guidelines, they just use as example some more aggressive criteria.

Carl Jeffery: CMS did NOT want states to do this, they said the State may be putting themselves at risk. The criteria for the Technivie is also included.

David England: Does the AASLD have criteria for the other things as well?

Carl Jeffery: The guidelines are pretty extensive.

David England: Do we want to say we will accept guidelines from national groups after release so we don't have to update the criteria.

Carl Jeffery: I don't think we need to cut and paste the guidelines into chapter 1200, we would just have a statement that we would use the guidelines in the background for requests.

David England: These are changing so quickly. If these are the best practices, rather than rehash it, we may have to say specifically which groups we are accepting this data from. It would have to be from peer-reviewed professional journals.

Coleen Lawrence: Peer-reviewed is already built into the process. You have a combination of the guidelines here, as a Board, you may not always agree with the major association's guidelines.

David England: Would we want those criteria to be used until the Board reviews or after the Board reviews? If something new and great comes out, but it takes so long for us to approve the criteria, I would hate to not have that criteria available.

Coleen Lawrence: We can always use administrative approval if necessary for emergencies.

David England: That's why I think we could list specific organizations.

Coleen Lawrence: I think this would be an exception to our normal process.

Mary Griffith: For hearings, we need to have a specific reason for why it was rejected.

Coleen Lawrence: So we would need to go find the literature at that time the decision was made. The other thing we can do is meet sooner than later on this.

Darrell Faircloth: What the committee is doing is using your clinical knowledge to recommend policy to DHCFP. There is a timeline involved, but it isn't something you should do is advocate

policy from an external organization. They may have a different approach to what is clinically appropriate.

David England: We want to keep on top of new guidelines, but we don't need to go line-by-line.

Darrell Faircloth: And we don't have those criteria in place or in front of us.

Coleen Lawrence: If the guidelines will be posted in peer reviewed literature, Chapter 1200 already says the prior authorization is based on peer reviewed literature. It is on the behalf of the prescriber to state what peer-reviewed literature they are using. I think we should put the most current criteria in the chapter, and then we can use peer-reviewed literature when it is updated.

Paul Oesterman, Chairman: We have this class of drugs that will be coming back up due to the continuous changes to the guidelines. We have suggestions to adopt a blanket statement of approving the guidelines as they are published, or review and adopt the guidelines during our meeting. I'll ask the Board if we should relinquish control and use the guidelines or should we maintain control and review the criteria from the guidelines before being used for prior authorizations.

James Marx: I can't imagine a scenario where this Board will ever disagree with the guidelines. I think we should reserve the right to review the guidelines.

David England: I think it is a matter of timing, we should continue with the current process and review the guidelines as criteria as they are proposed to use from Optum. We have used guidelines like this in the past.

Paul Oesterman, Chairman: We do agree with the concept that Optum uses the guidelines to put together the proposed criteria and we often approve them. I don't think we want to tie ourselves to one organization, we should use a nationally recognized organization.

David England: I think we need to stick with peer-reviewed journals.

Paul Oesterman, Chairman: We have a couple things. One, we need to decide how to proceed with the established proposed criteria, if we want to accept what we get from the FDA or nationally recognized organizations and two, if we want to amend the proposed criteria based on what we have heard tonight.

Carl Jeffery: The only thing on the agenda tonight is the Daklinza and Technivie.

Chris Shea: Carl, do you know if the transplant data is in the guidelines and cirrhosis guidelines are listed?

Carl Jeffery: I think they have been updated, I'll pull them up and compare them.

David England: Do we need to amend the proposed criteria based on what we have heard from the speakers tonight?

Paul Oesterman, Chairman: To back step, we have two products where we have proposed criteria. The first one we have the possibility to amend it based on what we have heard. The second product we have the proposed criteria. Is there any more public comment?

Jeffrey Zollinger: Can we adopt the criteria now with an exception to account for the new clinical literature?

Coleen Lawrence: That is already in the Chapter, the new literature can be used to evaluate.

Paul Oesterman, Chairman: But if we can get the guidelines updated.

Carl Jeffery: I don't think I am comfortable updating the proposed criteria on the fly right now. There are several pages of guidelines.

Paul Oesterman, Chairman: We have the proposed criteria here. We can put in a provision to utilize updated literature as it becomes available.

David England: I will make a motion for that.

James Marx: Second

Paul Oesterman, Chairman: So we have a motion to approve the proposed criteria for the Daklinza as it has been presented with the inclusion of the use of current clinical peer-reviewed literature. Any further discussion. All those in favor?

Votes: Ayes across the Board.

Paul Oesterman, Chairman: The second in this class is for Technivie. Is there anybody in the audience or on the phone wish to give comment? We have someone here

Chris Holtzer: Chris Holtzer with Abbvie. I am here for questions about Technivie.

Paul Oesterman, Chairman: Have there been any changes in the criteria?

Chris Holtzer: The proposed criteria fit the drug label as well as the AASLD guidelines.

Paul Oesterman, Chairman: Great, thank you. We have the criteria in front of us.

Carl Jeffery: I don't have anything to add.

Paul Oesterman, Chairman: Any discussion? No discussion, can we get a motion to approve the criteria as proposed?

David England: Moved.

James Marx: Second.

Votes: Ayes across the Board – motion carries.

Paul Oesterman, Chairman: We have someone in the audience that wishes to address the Board, please come forward.

Abigail Polus: My name is Abigail Polus with Northern Nevada Hopes. I want to convey some concerns we are seeing with some of our patients. Reads letter outlining concerns with criteria. Concerned with stage of liver disease, difficulty getting paperwork and drug testing done timely, patients required to try some agents before others. She stated Medicaid is not in compliance with AASLD guidelines. Staff unable to treat Nevada Medicaid recipients to the best of their ability because of these rules.

Coleen Lawrence: Mary did talk to Ms. Polus. We have multiple plans within Medicaid, Fee for Service and Managed Care. Mary has been working with our two managed care plans to determine their coverage of hepatitis C policy. Our policy is here and does align with the national organizations and standard. We will continue to work with managed care. We can't discuss their coverage policy, but we are researching.

David England: As far as time-frames, what do you think it is appropriate for a time-period?

Abigail Polus: We have members from our staff that help with prior authorizations that may be able to help answer that question.

David England: Another thing you mention is Specialty Pharmacies, some manufacturers have to have specialty pharmacies, and that is usually out of our hands.

Mark – Pharmacy director from Northern Nevada Hopes – I have a follow up question regarding specialty pharmacies. Is Medicaid, do they have anything to do with pushing medications out to specialty pharmacies?

Coleen Lawrence: We are an open network, so any qualified provider on FFS is allowed to provide services. If the manufacturer only provides their drug to a certain pharmacy, we don't have control over that.

Mark: A lot of drugs we are talking about are widely available through our distributor, so I do believe it could be the MCO that is mandating this.

Coleen Lawrence: This Board is only responsible for FFS. The MCOs to have the ability to manage their pharmacy networks. We are researching this.

b. For Possible Action: Discussion and possible adoption of prior authorization criteria for paliperidone palmitate (Invega Trinza®).

Paul Oesterman, Chairman: The next agenda item is the Invega, or Paliperidone palmitate. Any public comment?

Marykay Queener: My name is Marykay Queener, I am a medical science liaison with Janssen Pharmaceutics. I don't have any comments with the proposed criteria, I would endorse their adoption, but I am here for any questions.

Carl Jeffery: Invega Trinza, the extended release form, given every three months. There are specific criteria for this, they need to be stabilized on the monthly form for four months. The proposed criteria is presented and follows the drug label for diagnosis and prior treatment requirements.

Paul Oesterman, Chairman: One question, it says the two most recent doses of the monthly injectable product were the same strength. Would the patient start on the corresponding dose or could it be changed?

Marykay Queener: The recommendation to have the last two doses the same is because of the long duration. It would not be recommended with the first Trinza dose, but could be done if there are adverse events or not having control. Going up, if there is a gap in therapy, you may need to have an immediate acting dose to get coverage. But normally, the dose should be stabilized on Sustenna before going to Trinza.

Paul Oesterman, Chairman: The proposed criteria are here. We need a motion to approve.

David England: Motion.

James Marx: Second.

Paul Oesterman, Chairman: We have a motion and second to approve the criteria as proposed

Voting: Ayes across the Board.

c. For Possible Action: Discussion and possible adoption of prior authorization criteria for alirocumab (Praluent®).

Paul Oesterman, Chairman: The next item on the agenda is for Praluent, is there any public comment? Seeing none.

Carl Jeffery: This is a new class of medications, the PCSK9's. It is a unique mechanism of action for high cholesterol. Covers mechanism of action in detail and clinical study results. There is another agent in the class that we will review next time, Repatha. I think it is worth adding some guidelines to make sure the utilization is appropriate. There isn't really any long-term morbidity and mortality studies.

Paul Oesterman, Chairman: Are you aware of any studies that looked at patients with rhabdomyolisis?

Carl Jeffery: Muscle pain and weakness is one of the side effects, and they are looking further into it, but I'm not aware if there is anything in the guidelines. I know we talked about setting this in the class as the PSCK9's.

David England: In 1B, where it is prescribed by a cardiologist or lipid specialist, could it be renewed by their primary care physician?

Carl Jeffery: Yes, I think it could be renewed after the initial evaluation.

James Marx: Is there any lab monitoring required?

Carl Jeffery: Not that I recall reading.

Paul Oesterman, Chairman: As much as we would like to make this a class authorization criteria, it is not on the agenda that way. For the next meeting, we can agendize this as the class and review the quantity limitations because they are dosed differently. We need a motion to approve the criteria as presented.

James Marx: Motion.

Jeffrey Zollinger: Second.

Voting: Ayes across the Board, the motion carries.

d. For Possible Action: Discussion and possible adoption of prior authorization criteria for lumacaftor/ivacaftor (Orkambi®)

Paul Oesterman, Chairman: Our next drug is a combination product, Orkambi, for cystic fibrosis. Is there any public comment?

Ketul Patell: I'm Ketul Patell, a medical science liaison with Vertex pharmaceuticals. I am here for questions you might have.

Sonia: I am the Medical Director of the local cystic fibrosis center in Northern Nevada and I'm here for questions if you have any.

Paul Oesterman, Chairman: We do have a letter from the Cystic Fibrosis Organization, the Board can review that.

Carl Jeffery: Orkambi is a combination product. Gave an overview of medication. The proposed criteria follows the FDA approved label.

Paul Oesterman, Chairman: Is there a duration, or is it for life.

Ketul Patell: It is a chronic medication.

Carl Jeffery: I think the only thing we talked about is if the dose needs to be reduced with severe hepatic impairment. It would be D, if you could amend for the appropriate dose.

Paul Oesterman, Chairman: I think we should add an "E" so they don't get sub-therapeutic dose, the dose is one tablet every 12 hours with severe hepatic impairment. The proposed criteria with the addition of "E" for "the requested dose is one tablet every 12 hour in the presence of severe hepatic impairment." "E" would be an "or".

James Marx: I move for approval as amended.

David England: Second.

Votes: Ayes across the Board.

e. For Possible Action: Discussion and possible adoption of updated prior authorization criteria for the addition of rilonacept (Arcalyst®), secukinumab (Cosntyx®) and Canakinumab (Ilaris®) to the current immunomodulator criteria.

Paul Oesterman, Chairman: Our next action is the possible adoption of criteria for Arcalyst, Cosntyx and Ilaris to the immunomodulator class.

Carl Jeffery: We have three new products on the market now that fall into this class. These have some unique indications compared to some of the others currently available. Discusses indications for each and how the products are used. The updated criteria, they have been updated to add the age of 18 because we also have the juvenile indications to include the indications for the kids. The last time we reviewed these, we pulled the drug names out of the criteria so we can include the indications as they come out.

Paul Oesterman, Chairman: Have we had any usage to date for these new products?

Carl Jeffery: You will see the usage in the front, there are a few claims.

Paul Oesterman, Chairman: We have the updated proposed criteria; we need a motion to approve as presented.

David England: Moved.

James Marx: Second.

Voting: Ayes across the Board, the motion carries.

f. For Possible Action: Discussion and possible adoption of prior authorization criteria for sacubitril/valsartan (Entresto®)

Paul Oesterman, Chairman: The next topic is the discussion and possible adoption of prior authorization criteria for Entresto, used for heart failure. Do we have any public comment?

Melissa Walsh: Melissa Walsh, Medical Science Liaison with Novartis. There are some requirements that do not align with the label. First, 1b, asking for a left ventricular ejection fraction of less than or equal to 35. The indication from the FDA states heart failure with reduced rejection fraction, there is not a specific EF listed. If you do look at the guidelines the 2013 American Cardiology Association guidelines, they consider heart failure to be ejection fraction of less than 40. The first change I would like to suggest is either get rid of the number or align with the indication. The next, 1d, the prescriber is the cardiologist. There is nothing in the label that suggests this. If you look at the trial, it was not required. My concern is that these patients in more rural areas may not be able to access a cardiologist. The next, 1e, patient has been stabilized on an ACE or ARB. There is nothing in the indication that requires this. The indication does state it is given with other agents. The last would be 1g, the maximally tolerated dose of a beta blocker. The indication does not state the patient needs to be on a beta blocker. The trial did state they needed to be on a beta blocker, it was an individually optimized dose.

Carl Jeffery: This is a new product on the market, I think we have two patients on it now. The criteria comes from the Paradigm study. The cardiologist comes from heart failure likely being diagnosed by a cardiologist.

David England: In the past, many of the medications are not first line, then we prefer to go through a specialist with at least a consult. In the rural areas, they can at least get a conference set up.

Carl Jeffery: The maximally tolerated beta blocker came from the guidelines for the treatment of heart failure.

Melissa Walsh: The beta blocker had no difference in the outcome.

David England: On section E, if this is a new class, where does this come in to play in the guidelines?

Melissa Walsh: You definitely don't want to use with and ACE. The paradigm study was head-to-head with another ACE. The guidelines are not done yet and this has not been incorporated.

Jeffrey Zollinger: Is there any morbidity and mortality data on this?

Carl Jeffery: Yes, there was a 20% reduction in the endpoint of hospitalization compared to enalapril.

Paul Oesterman, Chairman: In reference in 1b, there is no number for ejection fraction?

Melissa Walsh: There is no number in the indication. The Paradigm trial started with a 40% ejection fraction and then moved to a 35% to capture the sickest possible population. But the indication itself does not list a number. My concern was that this is confused with the product you reviewed last time that does list ejection fraction of 35 in the label.

James Marx: My biggest concern is, what is heart failure? Getting the proper diagnosis is important for this medication. Even in the rural areas, the ejection fraction can be done.

Jeffrey Zollinger: I think if a patient has an ejection fraction of 40, it may be best to let the cardiologist to decide if they want to use this drug.

James Marx: If we can remove the ejection fraction, but leave the cardiologist, and let them decide when to use this medication.

Paul Oesterman, Chairman: What do we want to do with the beta blocker? I was reading about post MI patients.

David England: That is where I'm a little confused about it too. We may need to change the verbiage around a little so it isn't, "maximally tolerated beta blocker." For the ACE, can we say a "trial of an ACE inhibitor?"

Chris Shea: This verbiage for not getting an ACE inhibitor is a safety thing, so they don't get both.

Carl Jeffery: Until we get some updated guidelines, we are not going to know for sure how these are placed.

Paul Oesterman, Chairman: To recap what we have so far, no change on A, for B we are saying "reduced left ventricular ejection fraction", with no number. C and D remain the same. E would read as, "Recipient has had a trial of an ACE or an ARB for at least 4 week prior to the initiation of therapy." F would remain the same. G says, "The recipient is on an individualized dose of a beta blocker, or the recipient has a contraindication to beta blocker use."

David England: I will move the amended criteria.

Jeffrey Zollinger: Second.

Voting: Ayes across the Board, the motion carries.

6. Public Comment on any DUR Board Requested Report

Paul Oesterman, Chairman: We now have any public comment on any of the drug use review Board requested reports. Hearing none, we will go through the reports.

7. DUR Board Requested Reports

a. Report on diabetic patient compliance for blood glucose monitoring receiving insulin and possible hospitalizations due to lack of monitoring.

Carl Jeffery: The first thing is the diabetic supply. We talked about the test strip use for recipients getting insulin. We have 1000 member with insulin and test strips and 1000 members with insulin without test strips and compared their emergency room visits. I don't think the numbers were significantly different. The report breaks it down by diagnosis, and then there is a summary of a diagnosis. The summary of this one shows that not getting test strips does not result in higher admissions.

Paul Oesterman, Chairman: It would be interesting to see if these members are getting test strips somewhere.

Mary Griffith: It was a pretty high number around 60% have received an A1c at least in the past year. But only about 6% are getting the diabetic teaching.

Coleen Lawrence: I think this may be because the way we reimburse. Everything is paid through the physician model. We are in the process of getting that updated and looking at that policy. The second thing we are looking at is test strips we pay for vs. managed care. We are looking at some possible alignment.

Carl Jeffery: As Coleen mentioned, the ICD-10 needs to be submitted by the pharmacy to get these to go through without a PA. Our concern is that we might have some members that get 400 test strips and then sell them at the flea market. Instead we can do a look back to see if they have an order for a drug that causes hypoglycemia.

Mary Griffith: We would still need to change the policy because it says ICD-10.

Paul Oesterman, Chairman: Maybe look at an A1c correlation to insulin dependent patients vs. oral hypoglycemic agents.

b. Brand products dispensed where a generic is available

Paul Oesterman, Chairman: Our next report is brand products where a generic is available.

Carl Jeffery: The report is listed by cost. The top drugs make sense since they are preferred. All the rest are the recipient states the generic doesn't work. The Xanax caught our eye last time. Some may be justified because of short supply of the generic or the generic was just released. It is broken out by point of sale claims and physician administered drug claims. Zometa and Lovenox are at the top. We are relying on the person in the office that gives the dose to give the NDC to the billing department and this doesn't always happen.

Paul Oesterman, Chairman: A lot of the office administered drugs, there have been shortages of the generics. Anybody on the Board want to see something to dig into? The inadvertent of information being entered, and I would guess a fair number of these is because of this.

Rob Earnest: Most of our disputes in the rebate program are related to physician office claims.

Chris Shea: I highly doubt it is intentional, but there is a lot of money being paid that could be reduced.

Carl Jeffery: One option is to start rejecting brand medications where there is a generic available.

Extended discussion on billing process for physician administered drug claims.

Paul Oesterman, Chairman: Great discussion. Maybe a future topic would be to tell us what else you have learned and what has been done.

c. Midazolam Syrup utilization

Paul Oesterman, Chairman: Next is Midazolam syrup. Utilization of one, I think this is a moot point.

James Marx: I think we were looking at the syrup for pediatric use.

d. Hydrocodone Product utilization

Paul Oesterman, Chairman: Hydrocodone products, we have the utilization now.

Carl Jeffery: I think as you would expect the popular combos are at the top.

Paul Oesterman, Chairman: Have we done any kind of study with acetaminophen cumulative dosing?

Carl Jeffery: We put the quantity limits in about two years ago.

Paul Oesterman, Chairman: What is interesting is the three top ones, the trends are consistent. At least they are not climbing. Has our membership increased?

Carl Jeffery: It has modestly over this period.

Paul Oesterman, Chairman: So given that and our numbers are steady, that is a good thing.

8. Public Comment on any Standard DUR Report

None

9. Standard DUR Reports

Paul Oesterman, Chairman: The next topic is the standard DUR reports. Carl do you want to run over the standard reports?

Carl Jeffery: You have the top 10 therapeutics classes by cost and claim count.

Discussion of anticonvulsant utilization trends.

Paul Oesterman, Chairman: The count of claims for the anticonvulsants is up, cost wise, has it changed over the years?

Carl Jeffery: We can look back over the years to see how it trends. The hepatitis C trends seem to be going down, which might be a good thing. The next report is the top 50 by quarter. The same story with hemophilia and Abilify.

Paul Oesterman, Chairman: When did aripiprazole go generic?

Carl Jeffery: In the summer time, but we still prefer the brand name over the generic.

Paul Oesterman, Chairman: For our reports, rebates are not reflected in what we see here.

Carl Jeffery: Right, with the proprietary nature of this.

Rob Earnest: We could report on a net basis

Carl Jeffery: What kind of information are you looking for? What are you going to do with this?

Paul Oesterman, Chairman: It goes with the brand vs. generic, and what costs more.

Carl Jeffery: The next is the pro-DUR report and it goes on for several pages.

Paul Oesterman, Chairman: End-stage renal drugs are not included in here.

Carl Jeffery: If they are being dispensed from an ESRD facility, then it is included in their per diem rate, but there are other drugs on the report that are used.

Paul Oesterman, Chairman: I see about 28% of the claims are rejected, is there a pattern to the rejection?

Carl Jeffery: You can see the types of rejection. Most are going to be ingredient duplication. These are edits that can be overridden at the pharmacy level if the pharmacist deems it is clinically ok.

David England: So there were several that were reversed.

Carl Jeffery: We can't tell why they were reversed, we don't know if the pharmacist reversed them because they were not clinically appropriate, or if the patient never picked them up.

Paul Oesterman, Chairman: The total plan paid, where does that number come from?

Carl Jeffery: The $96 million, that total doesn't mean anything because it accounts for paid, revered and rejected claims. We're not going to know what was resubmitted and then paid. If

you look at the specifics on the ingredient duplication, the number one drug is hydrocodone/APA P combos hitting with other hydrocodone/APAP.

Paul Oesterman, Chairman: on the ingredient duplication, there were no paid claims for Proair, but 376 rejected claims, I guess I'm not following report.

Carl Jeffery: I see what you are saying on the Proair, that doesn't make sense to me either, I'll have to dig in to that one.

David England: On page 9, the drug-age precautions, why would we pay for these if there is a black-box warning?

Carl Jeffery: I think that is part of the DUR Board purview, if you want to set up a hard stop, you can get that going. We use Medispan's rules.

Coleen Lawrence: The DUR Board changed the severity level about 4 years to include only the most severe level would be a hard stop. The rest are allowed to be bypassed at the pharmacy level.

6. Closing Discussion

Chris Shea: I have a question, we get bethanechol rejected all the time when we ask for a PA, even if I ask to speak to a pharmacist. Can we ask that the P&T take a look at that drug? It falls in the wrong category because it is a cholinergic and it is with all the anticholinergics.

Carl Jeffery: Sure, it falls in the same category. We can bring it up with the P&T.

Paul Oesterman, Chairman: Any other comments on the reports or anything?

James Marx: Are you seeing any claims for naloxone for opioid overdose?

Carl Jeffery: We just looked at that, and there wasn't much utilization.

James Marx: There are some nasal drops that are not FDA approved. I think you are going to see it pick up. It isn't being actively promoted right now. It is something that can be very effective.

Coleen Lawrence: There is going to be a lot of training for the family members on how to handle this.

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

Carl Jeffery: January 28th, same time same place.

Paul Oesterman, Chairman: The meeting is adjourned.

Meeting adjourned at 8:48PM