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Nevada Medicaid
Drug Use Review (DUR) Board

Meeting Minutes
July 25, 2013

BEST WESTERN AIRPORT PLAZA HOTEL
1981 TERMINAL WAY
RENO, NV 89502-3215

Committee Members Present:

Paul Oesterman, Pharm.D., Chairman; James Marx, M.D.; Dave England, Pharm.D.; Larry Nussbaum, M.D, Joram Seggev, MD

Others Present:

DHCFP:

Coleen Lawrence, Chief, Program Services; Darrell Faircloth, Senior Deputy Attorney General; Laurie Squartsoff, Administrator; Marta Stagliano

HPES:

Beth Slamowitz, Pharm.D.

Catamaran:

Carl Jeffery, Pharm.D. Account Manager; Daniel Medina

Others:

Charrissa Anne, J&J; Jeff Forny, Shire; Eric Bizjak, Shire; Marykay Queener, J&J; Phillip Kenner, Acorda; Juan Trippe, Reckitt; Sarica Cohen, Acorda; Brooks Hubbard, BIPI; Debbie Lin, BIPI; Jenny Blackham, Lilly; Didic Dilli, Pfizer; Sandy Sierkowsky, Pfizer; Scott Larson, BMS; Charlie Collins, Gilead; Jeanette Belz, NV Psychiatric Association; Karen Campbell, Allergan; Joanne Stoche, VinoPharms; Nancy Wilson, Aegerion; Patrick Jensen, Aegerion; Julie Bertuleit, GSK; Nidal Naser, GSK; Helen Liau, Lilly; Davey Desai, St. Mary's

1) Call to Order and Roll Call

Paul Oesterman, Pharm.D. Chairman: Good afternoon everyone thank you for coming today on this nice weather day in Reno. This is the meeting of the Nevada Medicaid Drug Use Review Board and we will start with the call of the meeting to order and take a roll call with the members present starting on my left.

Coleen Lawrence: Good evening Colleen Lawrence, DHCFP

Larry Nussbaum, MD: Larry Nussbaum, University of Nevada school of Medicine

Dave England, Pharm.D: David England, pharmacist, Las Vegas

Paul Oesterman, Pharm.D. Chairman: Paul Oesterman, Pharmacist, Reno

Darrell Faircloth: Darrell Faircloth, Senior Deputy Attorney General for the committee

James Marx, MD: Dr. Jim Marx, MD, Las Vegas

Carl Jeffery, Pharm.D.: Carl Jeffery with Catamaran

Beth Slamowitz: Beth Slamowitz with HP

Paul Oesterman, Pharm.D. Chairman: We do have a quorum present so we will go ahead and proceed as everyone is aware we have a very full agenda, so a couple of ground rules. If you are going to speak please limit your presentation to no more than 5 minutes, if you go beyond that we will ask you to stop. Do not read us the package insert, we can all read. We want to try to give everyone a time to address the Board this afternoon. As a reminder, if you have cell phones please make sure they are on vibrate. We have the minutes from the meeting on October 25th to review and I would ask the committee members to review and if they have any questions or changes or if not if someone would make a motion to approve them as submitted.

2) Public Comment

Paul Oesterman, Pharm.D. Chairman: Okay we're going to divert for a moment does anyone have any public comment prior to us going into the agenda?
None.

3) Administrative

a) For Possible Action: Review and approve October 22, 2012 Meeting Minutes.

Paul Oesterman, Pharm.D. Chairman: The one question I had on the minutes is on the agenda it says to approve the October 22nd minutes but the minutes themselves state October 25th. Personally I don't remember which day it was.

Carl Jeffery, Pharm.D.: I would have to check, whatever that Thursday was.

Paul Oesterman, Pharm.D. Chairman: And then if you could also make sure to include my name on the minutes.

James Marx, MD: I move we accept the minutes.

Dave England, Pharm.D.: Second.

Paul Oesterman, Pharm.D. Chairman: A second, any questions, hearing none I will call for a vote. In favor of passing approving minutes as submitted with the amendments please indicate by saying "Aye."

Board: "Aye."

Paul Oesterman, Pharm.D. Chairman: All opposed say, "Nay". Ok, the minutes pass. Our next item on the agenda is our status update from a Division of Health Care Financing and Policy, Coleen?

b) Status Update by DHCFP

Coleen Lawrence: Good evening for the record this is Coleen Lawrence with Nevada Medicaid first of all thank you very much for showing up at or new time. We thought it was a good time considering a lot of the public comment we have received, to try an evening meeting. Please let me know what you think about doing it at this time and moving the DUR Board to Reno. First of all I would like to welcome our Administrator, we have not had a DUR Board meeting since the appointment of our new Administrator, Laurie Squartsoff. I have a couple announcements that we talked about at the P&T, if you have not had a chance to attend the P&T the last couple of times. The Division is getting ready for the implementation of ICD-10 programming and just to let you know there will not be any transition time where we will be running double codes between ICD-9 and ICD-10, we will be running ICD-10 when this starts with CMS. This is a large impact for our pharmacy system as you know, if you're reading Chapter 1200, we have ICD 9 codes throughout the Chapter. We also do a lot of programming based on the feedback from the Drug Use Review Board and a lot of our policies are based on diagnosis codes. So our pharmacy specialist, Mary Griffith who is not here today, has painstakingly gone through the process of converting the ICD-9 to ICD-10 and that process will continue over the next year. How can we partner over the next year? We are going to ask for your partnership when you're out there and working with the physicians to educate them on the ICD-10 when you are looking at our policies and to get them prepared. We have done several studies with ICD-10 and it is a whole new world if you have not looked at it. ICD-10s are nothing like the old ICD-9. They are numerically different, they are alphabetically different, everything about them is different. Even the concept of how they are used is different. The Division will not be posting any training. We will be depending on the private sector and trainings so we will be definitely partnering with training for other entities for training the prescribers. That is our biggest project we have coming down the pike for the pharmacy world. Do you have any questions regarding ICD-10? Each quarter we will update you on where we are with ICD-10.

Dave England, Pharm.D.: The question I have is the PAs that have been sent out before with the ICD-9 codes, have they all been automatically updated with ICD-10?

Coleen Lawrence: We are going to be doing updates of the policy number one, and then we are looking at a database with Point Of Sale and we have a table that we've already crosswalked to ICD-10. Our team members have already done a lot of hard work on the ICD-10 project.

James Marx, MD: I don't understand how you can cross walk over from 9 to 10. The 10s are far more specific and there really is no crosswalk from 9 to 10.

Coleen Lawrence: There is no actual crosswalk, the team actually had to go in and look up every ICD-10 and look up what the meaning of it and create new tables. No, they were not very happy, it was not a good day for months in my office. But the best thing is education out to the prescriber community for ICD-10.

Paul Oesterman, Pharm.D. Chairman: Is there a formal switchover date?

Coleen Lawrence: There is, it keeps getting pushed back and moving around right now but we'll keep giving you updates on the actual dates itself. Oh I'm sorry, I have one more, the other issue is the

ACA implemented ordering, prescribing and referring physicians, we call it the OPR process, because we need another acronym. CMS has actually put a halt on the process. It was something that was easier to the pharmacy system because we already pulled those fields but what it requires is every Medicaid provider be enrolled in our system. So for pharmacy what we care about is if you wrote a prescription you must be enrolled in the program. That is not a requirement at this time. So as you can imagine that is a large education outreach for us also. That date has been on hold right now for CMS. We have done preliminary rounds based upon the pharmacy prescriptions and the good news was it was largely residents that were not enrolled into our system. However we did we receive word from CMS that that was okay and they were going to be exempt from this and some out of state providers that were related to facilities and those types of things, so for us with education and facilities and teaching hospitals and those types of things. Our plan overall was to implement the pharmacy edits first with some soft edits, notify them that way and then turn on the rest of the system. It affects other types of providers as well such as home health agencies, DME providers and those sorts. Again, that is on hold right now and it is exciting for you guys because we will get better reporting out of it. That is all I have, I promise.

c) For Possible Action: Approval of 2011 Annual DUR report.

Paul Oesterman, Pharm.D. Chairman: Thank you. So we have in front of us the 2011Annual DUR Report. This report has already been submitted and it's just for us to after- the-fact review.

Carl Jeffery, Pharm.D.: The 2011 is in here for more of a formality because reading through the past meeting minutes we neglected to actually vote and approve the report. I think you reviewed them, but never actually voted to approve, we just need the formal vote to approve.

Paul Oesterman, Pharm.D. Chairman: Out of curiosity what would happen if we didn't?

Carl Jeffery, Pharm.D.: I don't know.

Paul Oesterman, Pharm.D. Chairman: So I will go ahead and ask the Board for a motion to approve the 2011 annual DUR report that we have read and approved previously. We have a motion and a second. Any questions or discussion? Seeing none I will go ahead and call for vote. All in favor of approving the 2011 DUR Annual report indicated by saying Aye.

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: All those opposed, nay. Motion carries.

d) For Possible Action: Review and approval of the 2012 Annual DUR report

Paul Oesterman, Pharm.D. Chairman: We also have in front of us the 2012 Annual DUR Report to review and approve. So I will open it up for any discussion regarding this report. It is a report that is pretty much fill in the blanks.

Carl Jeffery, Pharm.D.: They are asking for standard reporting so all the states have to do the same reporting to CMS. This one has also been submitted so hopefully you guys will approve it because it's too late at this point. I think it has pretty standard information, the actual screen prints are difficult to read because they're all sorts of tables to scroll over to fill out, those don't contain the best information, but the tables will have the best information.

Coleen Lawrence: We were caught in another timing issue with this because we didn't have our DUR Board last time. We had a time issue. Whereas the last Board report, we hit the timing perfectly right before it was submitted. This one we just ran out of time because of the last meeting.

Paul Oesterman, Pharm.D. Chairman: The one thing that I did notice in comparison between the 2011 and 2012 was very good trend towards generic utilization 71 percent to 77 percent and I think the practitioners should be commended for that.

Coleen Lawrence: As you'll notice the trend with all the review criteria the Board adopts through the whole Federal Fiscal Year, is listed throughout the attachment.

Dave England, Pharm.D.: I'm just kind of curious because this is a standard report that all states submit and the criteria is the same, where does Nevada fit into the mix with all the other states as far as with the specific criteria, are we at the top or the bottom?

Carl Jeffery, Pharm.D.: That is a good question. I've never actually seen CMS produce a report. We submitted it and it goes into a big black hole and we never see again. We never see a report saying OK Nevada here's where you fall.

Coleen Lawrence: The idea is to reformat the report and put them on the website so we can compare. The last couple of years they have been tweaking the reports. So this is the second report and the second revision of this Annual Report. The whole idea is that they are supposed to take this report and they are supposed to start trending the States. This is the second year they have taken this report. This report this year came out, I want to say around two weeks before it was due and hit the cycle and it was very quick because we had to reformat the report. So I know that is the goal from CMS because all the states reports are available on their website once they are submitted, but it is a matter of how they're submitted and they have to go through all the states reports for the trending reports.

Dave England, Pharm.D.: Thank you. You think they would have a best practice posting from the CMS.

Paul Oesterman, Pharm.D. Chairman: Any further discussion on this 2012 report.

James Marx, MD: I move to approve.

Dave England, Pharm.D.: Second

Paul Oesterman, Pharm.D. Chairman: We have a motion to approve and a second. Any further discussion? Seeing none, call for a vote, all in favor of approving the 2012 reports indicate by saying "Aye."

Board votes unanimous: "Aye."

Paul Oesterman, Pharm.D. Chairman: All opposed say "Nay", motion carries.

4) Clinical Presentations

a) Presentation of Hereditary Angioedema Agents (HAE) use and clinical information.

Paul Oesterman, Pharm.D. Chairman: Moving forward on our agenda. We have a series of therapeutic categories that we are going to be reviewing for clinical presentation and Prior Authorization criteria. If

someone wants to address the Board please step forward identify yourself and which company you represent and you will be limited to no more than 5 minutes. Our first one is the presentation of hereditary angioedema (HAE) agents and clinical information. We will start off by asking for any public comment.

Eric Bizjak: I will be less than 2 minutes Eric Bizjac, Pharm.D., Medical Science Liaison for Shire, here to talk about Firazyr or icatibant for HAE. This is an ultra-orphan disorder with five to seven thousand patients in the United States with this disease. It is a disease of deficiency of a C1 protein or a defect in that protein that ultimately results in the creation of bradykinin and that's what leads to the localized swelling. This disease is not only disabling, but it is also can be life-threatening with untreated angioedema having a mortality rate of about 30 percent. These attacks can occur any time and without warning. Several drugs are now available which is very rare in the ultra-orphan disease. Recent guidelines and consensus papers suggest and outline the indications and they do recommend all patients have on demand therapy for home administration. Firazyr is a synthetic dipta-peptide that blocks the bradykinin receptor. It was approved in 2011 for the treatment of HAE attacks in adults 18 and older. Clinical trials have shown Firazyr to be safe and effective when compared with placebo with over 90 percent of the patients being treated with one syringe, but our label in our trial allowed patients to receive a second dose after 6 hours and up to three in 24 hours. The major side effect is redness at this injection site and over half the patients having some burning. Firazyr is a sub-q injection supplied in a prefilled syringe and can be kept at room temperature. This portability is one aspect that makes us different from the other agents out there. Kind of like an Epipen for people with peanut allergies or albuterol for asthma. These people can carry this drug around with them, keep it at room temperature and inject themselves whenever an attack occurs and this is the one thing that is important because a laryngeal attack can occur at any time any place. And that's it, thank you.

Paul Oesterman, Pharm.D. Chairman: Do we have a second person indicating they want to speak? Okay. Just as a reminder, please try to keep it to new information about the medication. Carl if you want to go ahead and address.

Carl Jeffery, Pharm.D.: I think he gave a very good thorough review of the disease state product available. There's one drug that is indicated for prophylaxis treatment and given every 2 to 3 days depending on what kind of reaction the patient has. I think the most common one is one where there is a known procedure that initiates this response so they can give it before a dental procedure or something. All the other ones are indicated for treatment. So with these, they are incredibly expensive. So I think what we want to do is, what our intent with this is to make sure use is appropriate. We don't want this drug thrown at every person who comes in with an ACE or ARB related angioedema. It really only works for the C1 protein deficiency. We have the criteria here, it identifies which patients should meet the criteria.

Paul Oesterman, Pharm.D. Chairman: So the criteria that is proposed, the recipient must have a diagnosis of hereditary angioedema and the product must be prescribed by or in consultation with an allergist or immunologist, and the medication is being used for prophylaxis for the treatment.

Carl Jeffery, Pharm.D.: And to point out that the prophylaxis is just for that one drug.

Paul Oesterman, Pharm.D. Chairman: And obviously this is not the first line therapy, they would have failed other treatments. I am very naïve, so I will ask those who know, who've had a patient experiencing more than one severe attack per month. How do we define severe?

Carl Jeffery, Pharm.D.: Oh, that's a good question. Is it a visit to the ER department? Or is it the need for a rescue agent?

Paul Oesterman, Pharm.D. Chairman: It is in there as part of the proposed criteria and I want to try to have it a little bit more quantified, if it requires a visit to the emergency department or intervention with the primary care provider.

Carl Jeffery, Pharm.D.: Or used as a rescue treatment.

Coleen Lawrence: Are you going to do it on the Prior Authorization form? So the doctor is attesting to it being severe?

Carl Jeffery, Pharm.D.: Right.

Coleen Lawrence: So then you don't have to define what severe is, the doctor then would identify what severe is.

Dave England, Pharm.D.: Is there a medical definition of being mild, moderate or severe? Is there specific parameters? If I was the patient going through this, then anything would be severe.

Carl Jeffery, Pharm.D.: I don't know enough about the disease to tell you that.

Paul Oesterman, Pharm.D. Chairman: I would propose that may be eliminating the severe wording and just have wording that the recipient routinely experiences 1 or more angioedema attacks per month. That way you don't have the gradation.

James Marx, MD: They have to experience one per month and then they don't meet the criteria, and they have recurrent episodes?

Carl Jeffery, Pharm.D.: Oh, so this is just for prophylactic therapy, they would not be using it for treatment they would carry the other products for emergency treatment.

Paul Oesterman, Pharm.D. Chairman: So we have the proposed criteria for the inclusion of the hereditary angioedema agents for both prophylaxis and treatment. Do we have a motion to approve the Prior Authorization criteria?

Larry Nussbaum, MD: Motion to approve as amended.

Paul Oesterman, Pharm.D. Chairman: So moved. Do we have a second?

Dave England, Pharm.D.: Second.

Paul Oesterman, Pharm.D. Chairman: So we have a second. Any further discussion on this? Seeing none then we will call for a vote. All those in favor of approval of the presented criteria please indicate by saying "Aye.".

Board votes unanimous: Aye

Paul Oesterman, Pharm.D. Chairman: Those opposed say "Nay". It passes unanimously.

b) Presentation of Colony Stimulating Factors use and clinical information

Paul Oesterman, Pharm.D. Chairman: Our next class is going to be Colony Stimulating Factors. We will ask for any public comment. This is your chance going once.

So we have the Colony Stimulating Factors that are a covered benefit if the recipient meets the criteria. We have their requests for several products including Leukine, Neulasta and Neupogen. Carl do you want to go ahead and differentiate them out for us?

Carl Jeffery, Pharm.D.: There is the Neupogen and the Neulasta, they really are similar agents. They're Colony-Stimulating Factors and are mostly used for patients receiving chemotherapy or other medications that cause decreased white blood cells. Probably 70 percent of these are given in a physician's office, so it creates some sensitivity because we have to understand how physician's bill. It's often given then billed after the fact. So if we decide to move forward with Prior authorizing these for physician administered drugs, we need to make sure we communicate to the physicians. Then there is Leukine which hasn't really shown as effective as some of the other ones, but it is a little bit different. It is called a granulocyte macrophage CFS. It really has the same result.

Paul Oesterman, Pharm.D. Chairman: Up to this point how many patients have we had? It has to be a relatively small number.

Carl Jeffery, Pharm.D.: Yeah they're in your binder there's a graph, this shows how many patients you have. As of June 2013, this is the number of claims so under 50 claims per month for the Neulasta for the last several months, for the Neupogen, 30 per month.

Paul Oesterman, Pharm.D. Chairman: I don't for see this as being something that everyone would run out and prescribe.

Carl Jeffery, Pharm.D.: Its certainly up to the Board to decide that they don't want to put any criteria on it as well. We bring these before the Board as just ideas for the agents that are expensive and have potential for misuse. Looking at the numbers here, I don't see a lot of misuse.

Paul Oesterman, Pharm.D. Chairman: Our concern is more the misuse, P&T can deal with the costs. Do you potentially foresee any concern for the Neulasta or Neupogen with the "and" or the "or" in the criteria? It looks pretty straightforward to me but I would like you to throw it out for discussion.

Carl Jeffery, Pharm.D.: Please let the record show that Doctor Seggev has joined the meeting.

Joram Seggev, MD: I understand it's already past ready hereditary angioedema, but I like to go back if possible.

Paul Oesterman, Pharm.D. Chairman: Perhaps we can finish this one and we'll go back to and angioedema. So Carl to "and/or" statements with the Neulasta, it looks pretty straightforward to me, I just want to make sure we are all in agreement.

Carl Jeffery, Pharm.D.: It looks fine to me, I've stared at these long enough, it makes sense to me.

Paul Oesterman, Pharm.D. Chairman: So I will go ahead and ask for a motion to approve the for the Prior Authorization criteria for these three products.

Carl Jeffery, Pharm.D.: I don't know if you want to make a distinction if this is going to be for physicians drug claims or just outpatient Point Of Sale claims?

Paul Oesterman, Pharm.D. Chairman: I think it should be just for the Point Of Sale. So we will request a motion to approve this criteria for point of sale recipients, not for physician administered.

Dave England, Pharm.D.: Moved as amended.

Paul Oesterman, Pharm.D. Chairman: So moved as indicated.

James Marx, MD: Second

Paul Oesterman, Pharm.D. Chairman: So we have a motion and a second to approve the Colony Stimulating Factor Prior Authorization, slightly modified. Any further discussion? All those in favor please indicate by saying "Aye."

Board: Unanimously, "Aye."

Paul Oesterman, Pharm.D. Chairman: All those oppose, say "Nay". Motion carries.

Dr. Seggev has a request to speak on the hereditary angioedema. Just to give you the background, we did approve the criteria.

Joram Seggev, MD: I understand, but there a couple things, the most important reference just came out less than a month ago and this is the focus and I have the article here. The most important thing is the medication is for any patient with a severe attack regardless of what's causing it. Either medication should be started right away and the most important thing is the need to add to the criteria is, A: outside the hospital and B: in case of failure in the area. And the most important thing to add to the criteria because it is not FDA approved, but there are good data for ACE inhibitor induced severe angioedema. Both medications have been shown in clinical studies to be effective for patients who have life-threatening angioedema. That is more in the larynx and the mouth than hereditary angioedema, and so it should be available for patients who face a life-threatening reaction.

Paul Oesterman, Pharm.D. Chairman: OK, Coleen, let me ask a question, can we approve anything that is not FDA approved like an off label indication?

Coleen Lawrence: No unfortunately, it must be an FDA approved indication, so what occurs if a drug is prior authorized is that that will require that the drug have an FDA indication for the utilization of the drug. So this class of drugs we're looking at, the indication must be for an approved indication. Does that answer your question?

Dave England, Pharm.D.: So if a physician called in and said he wanted one that wasn't successful but he had some literature or do they call that to the PA center to get that override?

Carl Jeffery, Pharm.D.: Our call center will take that into consideration, if there is peer reviewed literature available or if it is an accepted indication available in the community, they will approve it.

Joram Seggev, MD: The whole issue is that the study, it has not been peer reviewed. All that is available right now is case reports. The problem is, those patients that have absolutely no other medications available, Firazyr is not indicated for the end-point only, so physiologically, it is unlikely to have an effect for the patients because the problem they have is not with the C1 protein, it is a problem caused by the bradykinin. I personally treated a patient that required a tracheostomy. I realize we're talking about something from a medical aspect is very significant, so I want to separate the two issues. One is the patients who have severe HAE, classically speaking, and need to have an emergency injection and need to have these products available to them at home. The other is a patient with HAE induced, life-threatening angioedema that requires the patient to have a tracheostomy otherwise, the drug should be available for those cases.

Carl Jeffery, Pharm.D.: Help me understand, does the article state the treatment of choice is to stop the medication causing angioedema, do the effects last after that?

Joram Seggev, MD: The treatment of choice is to stop the medication. If a patient comes in with a drug induced case of life-threatening angioedema, the patient is going to die if we can't open the airway. We can't wait 3 days for the medication to wear off and the angioedema to resolve on its own. There are no other classes of medications that will be effective.

Carl Jeffery, Pharm.D.: If we make a distinction here, it sounds like if someone is having acute attack from an ACE inhibitor, they show up at the emergency department or urgent care, they administer one of these agents in the office, this isn't something we would give to the patient to have be filled at the pharmacy so the patient can have this at home with them. With that distinction the physician administered drug claims, they are exempt from this criteria.

Joram Seggev, MD: The practical problem is that most hospitals and urgent cares will not carry these medications because of the cost. We are having a problem in principal and practical.

Paul Oesterman, Pharm.D. Chairman: In the interest of time, in order for us to proceed forward on this we would have to receive a motion from somebody, other than yourself, to recall the prior approval of the criteria and then we can re-open it and discuss it. Do we have a motion to reopen it and discuss it and it's not to say we can't reopen it again at a future Board meeting but do we have a motion to recall the approval of the Prior Authorization criteria that has been approved?

James Marx, MD: I move to reconsider, I think the information is sufficiently novel for us to talk about.

Paul Oesterman, Pharm.D. Chairman: So we have a motion to recall do have a second?

Larry Nussbaum, MD: I second.

Paul Oesterman, Pharm.D. Chairman: So we have a motion and a second. For the committee, all those in favor of recalling the previous motion please indicate by saying "Aye."

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: All those opposed, say "Nay". So we will recall our prior approval so we want to add to the Prior Authorization criteria that for somebody in the event of…

Coleen Lawrence: Mr. Chairman let me give you some for information that may be helpful. So doctor, let me try to assist a little bit here. So, we have two separate issues so you might want to take the first issue first. The second issue is I heard you say is definitely on a compassionate needs basis. And so when you are looking at the overall development of the policy for Prior Authorization, first of all you were not able to hear the first part of the conversation, so this Prior Authorization criteria that you're voting on is only for claims that are going to be processed through the retail pharmacy. So they're not going to be processed through the outpatient hospital that is probably where it may be an incident or through the physician's office. So I want to make sure that you knew which environment we're talking about, because we talk about the physician claims and throw terms around. Secondly, if this is something more of an exception to the environment we're looking at I would encourage the Board to look at it like it might be an exception to the rule verses the rule itself of what occurs. So if its compassionate need then we might want to look at how it applies to the policy too because if we say it's a child who is under 21 then we have what's called EPSDT. That means we can look at children a different way and take a medical necessity, outside of the actual policy, and look at children and we will look at peer reviewed literature, we will look at everything else. It's almost like when clinical trials come in. We turn around and look at all peer reviewed literature in addition to what is written in the criteria. So I would consider if this is a compassionate need or more of an exception to the rule, if you're trying to write the policy around.

Joram Seggev, MD: For compassionate use, what I'm talking about so we're talking about ACE inhibitors. Most patients, when a patients comes in with life-threatening angioedema and can't breathe, there's no time to wait. On the other hand, this is definitely something that will be given in an urgent care or a hospital.

Coleen Lawrence: So we would never see them for this policy then. Because this policy is only going to be at Walgreens or Walmart or the other outpatient pharmacy at the retail corner pharmacy because you guys already exempted the physician's office and it will not apply at the emergency room.

James Marx, MD: I think we're trying to create a policy for a problem that doesn't exist. Has it been an issue where retail pharmacies have been dispensing this?

Coleen Lawrence: That is what I'm trying to hear from the Board and that is what I'm trying to make it clear for the doctor because he didn't hear the first part of the conversation where this policy takes place. I wanted to reiterate that conversation because he was saying when and how quick it happened, I want to get the setting straight.

Joram Seggev, MD: The other problem we have relates to is the patient with documented HAE, who has severe HAE and is required to have this at his disposal.

Paul Oesterman, Pharm.D. Chairman: That's covered.

Coleen Lawrence: I think we already have this covered with your intent.

Paul Oesterman, Pharm.D. Chairman: So my understanding is, right now the recall of what we passed, do we want to rescind our recall and go back? I think we have your concern addressed. Can we reverse our reverse?

Darrell Faircloth, DAG: Sure, your previous action is still in place, so if you want to call for a motion to leave in place.

Paul Oesterman, Pharm.D. Chairman: So I want to call for a motion to leave our motion that we passed and approved in place.

Dave England, Pharm.D.: Moved

Paul Oesterman, Pharm.D. Chairman: Second?

Larry Nussbaum, MD: Second

Paul Oesterman, Pharm.D. Chairman: All those in favor of approving what we already approved, say "Aye.".

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: Those opposed say, "Nay". Ok great, thank you.

c) Presentation of Ampyra use and clinical information

Paul Oesterman, Pharm.D. Chairman: Ok, moving to our next topic is the use and clinical information regarding Ampyra. Do we have anyone in the audience who wishes to address the Board, please come forward.

Phillip Kenner: My name is Philip Kenner, I'm a medical science liaison with Accorda Therapeutics. I just wanted to share some new safety information that we found post marketing. And I just want to report that the safety information that you have seen in the package insert is very consistent with what we saw post-marketing so there's nothing new to report there. As a result of the consistency, the FDA has allowed us to cancel our REMS program that we were approved with. Any questions?

Paul Oesterman, Pharm.D. Chairman: Thank you, so okay Carl equally quick review?

Carl Jeffery, Pharm.D.: In your packets, I printed off the current Chapter 1200 about Ampyra and it has been three years since this has been reviewed. So this is why we brought this before the Board because there has been some new information about the walk test and we were requested to review this. There hasn't been a whole lot of changes when we went back to review it. We bought this forward based on what the manufacturer provided. Comparing the old and the new criteria, section D, that is the one that has been removed, the patient has undergone the 25 foot walk test, steps based on walking speed and walking speed is documented to be between 8 and 25 seconds. So that's the biggest thing to change that has been stricken.

Dave England, Pharm.D.: I also see ICD-9 codes, you will changing to ICD-10?

Carl Jeffery, Pharm.D.: Right.

Paul Oesterman, Pharm.D. Chairman: The Prior Authorization criteria, A. had the prescriber being a neurologist, that has been removed.

Carl Jeffery, Pharm.D.: Well the second one in the new criteria is in consultation with a neurologist so we switched it.

Paul Oesterman, Pharm.D. Chairman: Okay

Carl Jeffery, Pharm.D.: So the new criteria is just clearer and follows the new step guidelines.

Larry Nussbaum, MD: I move to accept the great new criteria.

Dave England, Pharm.D.: Second

Paul Oesterman, Pharm.D. Chairman: We have a motion and a second. Do we have any further discussion? Seeing none, I will call for a vote. All those in favor say "Aye."

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: All those opposed say, "Nay". Okay the motion passes.

d) Presentation of Cymbalta use and clinical information

Paul Oesterman, Pharm.D. Chairman: Our next topic is presentation of Cymbalta. Do we have anyone in the audience who wishes to come forward and speak. Was it something I said? Okay, so duloxetine, Carl do you want to go ahead?

Carl Jeffery, Pharm.D.: A couple pages back in the packet is Chapter 1200 and the current Cymbalta criteria. But we have done is expand the coverage because the past criteria was really only limited to two diagnoses and more has been approved. You can see in Chapter 1200, the only listed diagnoses are Diabetic Peripheral Neuropathy and Fibromyalgia. It has indications for muscular pain, Generalized Anxiety and Major Depressive Disorder. So we would add those in the new criteria. Also in the handouts is a comparison of the other agents in this class. Cymbalta by far has the majority of the claims.

Paul Oesterman, Pharm.D. Chairman: I had one question for you in regards to number one, the product for musculoskeletal pain, it looks like there is a section A., part one and part two, part two reads, "the recipient has an allergy or contraindication to all NSAIDS". How do you define that, do they have to try every single NSAID?

Carl Jeffery, Pharm.D.: I guess we can modify that to say 2 NSAIDS, or if it is a severe enough reaction, you wouldn't want to retry a second.

Dave England, Pharm.D.: Would that be two different NSAIDS or two different classes?

Carl Jeffery, Pharm.D.: Personally I would just leave it as NSAID.

Dave England, Pharm.D.: I don't know that would make a difference, if you want to get that selective, but having two NSAIDs would be fine.

Joram Seggev, MD: Well, there is an option of Aspirin, with desensitizing the patient to be able to take aspirin.

Larry Nussbaum, MD: Carl, when I looked over the previous Prior Authorization, we use Cymbalta for psychiatric purposes, was there not a Prior Authorization needed for Cymbalta?

Carl Jeffery, Pharm.D.: There was, and that is why we are bringing it up today. We were getting a lot of requests for depression and generalized anxiety and our call center really had nothing consistent to hold the criteria to. Basically, everything was kind of a gray area for every request they received.

Larry Nussbaum, MD: So was it being approved for major depressive disorder?

Carl Jeffery, Pharm.D.: Yes it was.

Paul Oesterman, Pharm.D. Chairman: Anybody wish to make a motion to approve the proposed Prior Authorization criteria as amended?

Joram Seggev, MD: Moved.

Dave England, Pharm.D.: Second.

Paul Oesterman, Pharm.D. Chairman: Any further discussion from the Board on the proposed criteria for Cymbalta? Seeing none, all those in favor please indicate by saying, "Aye."

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: Those opposed say, say "Nay" motion carries.

e) Presentation of Celebrex use and clinical information

Paul Oesterman, Pharm.D. Chairman: Okay the next presentation is Celebrex use and clinical information. Anybody in the audience?

Sandy Sierawski: Hi, I'm Sandy Sierawski I'm a pharmacist, I work for Pfizer in the Medical Division. Celebrex has had CoxII Prior Authorization criteria and it has been in place for a number of years. Last year it was discussed at the July meeting with this Board of potentially removing the bone pain indication because that's not an FDA approved indication. That discussion occurred, but it never got to the public hearing approval process. So I'm hoping this is just a housekeeping formality and request that you remove the bone pain indication because it's not an FDA approved indication. Otherwise, we're good.

Carl Jeffery, Pharm.D.: Sandy's exactly right this is a housekeeping issue to remove the bone pain from the criteria.

Paul Oesterman, Pharm.D. Chairman: Do we have a motion from the Board to approve this minor change this bone pain indication.

Dave England, Pharm.D.: I make a motion.

James Marx, MD: Second.

Paul Oesterman, Pharm.D. Chairman: We have a motion and a second, any discussion? All those in favor indicate by saying, "Aye.".

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: All those opposed say, "Nay". The motion carries.

f) Presentation of Botulinum Toxin use and clinical information

Paul Oesterman, Pharm.D. Chairman: On to next Botulinum Toxin. Anybody?

Karen Campbell: Good evening my name is Karen Campbell. I am a Pharm.D and the Senior Scientific Manager with Allergan. I want to thank the Board for allowing me to make comments related to the Botulinum Toxin class. There are currently four toxins available in the US. Each has a unique list of FDA approved indications. Botox has 8 indications the others have one or two. Cervical dystonia is the only indication shared by all toxins. We support the proposed clinical Prior Authorization criteria and commend the Committee for differentiating coverage based on the evidence and labeled indications. However, we also want to encourage the DUR Committee to recommend that an update be made to the 2013 Medicaid Services Manual Chapter 600 attachment A, 6-11, Botulinum Policy. We request that the committee update this policy to reflect what is currently proposed in the Prior Authorization criteria. The policy does not include all the indications that are in the proposed Prior Authorization criteria nor does the Prior Authorization criteria include all the ICD-9 codes that are currently listed in the provider billing guidelines. The policy has not been updated since 2007.

Coleen Lawrence: On Botox?

Karen Campbell: On Botox.

Carl Jeffery, Pharm.D.: I'm not familiar enough with Chapter 600 to speak on it.

Coleen Lawrence: The DUR Board will have to have that document before we do.

Karen Campbell: So we're just asking the Committee to make that consistent with the proposed criteria presentation and that the billing guidelines, and the ICD 9 codes also be included in the Prior Authorization criteria. I have the ICD 9 codes that have been, for the conditions that have been added to the proposed criteria. Does the committee have any questions for me? We're just asking for the three documents to be consistent.

Paul Oesterman, Pharm.D. Chairman: That's beyond our realm, but we will ask Colleen, and to provide us with the ICD-10 codes.

Karen Campbell: Yes, we will be happy to help you, Medicaid with the conversion to ICD-10.

Coleen Lawrence: So Mr. Chairman, there is a Botox policy in Chapter 600 and what we will do at the next DUR Board, we can pull that and we can look at that based on the new recommendations for Point of Sale. Depending on how you apply it here, we will work on having Chapter 600 next time so we can make it consistent.

Paul Oesterman, Pharm.D. Chairman: So probably what we'll do is make a motion to ask you to do that.

Coleen Lawrence: Absolutely, and we can bring it back, because it is in the physician's offices.

Dave England, Pharm.D.: This is another question, a lot of stuff we are dealing with have an impact on that manual as well. Are these automatically being updated in that manual as well? Or is it completely separate?

Coleen Lawrence: We have our Medicaid Service Manual Chapter 1200, so when you make a change in the pharmacy system, then we have another string of updates in the Chapter 1200 for the pharmacy section, we just happen to have a policy for a procedure in the Physician's Chapter, and that is what the last speaker was asking to make similar. You can review this now or table it and we could bring Chapter 600 to the next meeting and do it together, or you could update this now. You do have the authority to look at Chapter 600,

just because it happens to be the physicians chapter is irrelevant. That is a regulatory process on how we placed it in a chapter.

Dave England, Pharm.D.: I think we would want to be consistent.

Larry Nussbaum, MD: I would like to make motion that we table this and bring them both back at the same time.

Dave England, Pharm.D.: Second

Paul Oesterman, Pharm.D. Chairman: Any further discussion? Ok, we'll call for a vote. All those in favor, say, "Aye."

Board: Unanimous, "Aye.".

Paul Oesterman, Pharm.D. Chairman: Those opposed, say, "Nay".

g) Presentation of buprenorphine and buprenorphine/naloxone use and clinical information

Paul Oesterman, Pharm.D. Chairman: Our next topic for discussion is the buprenorphine and the buprenorphine/naloxone. Anybody in the audience?

Juan Tripp: My name is Juan Tripp, clinical pharmacist with Beckett Pharmaceuticals, we are the manufacturers of Suboxone and Suboxone Film, here to speak on continued access to office based opioid treatment. And a key component is appropriate use and is outlined in the guidelines. A clear diagnosis of opioid dependence, which is consistent with the current criteria, DATA 2000 waiver prescribers, limiting those restrictions because of the chronic nature of this disease. Ensuring there is therapeutic dosing and the flexibility with 2, 4, 8 and 12mg doses currently available. The company also supports clinical monitoring of the patient with urine drug screens, where appropriate, to ensure taking the medication buprenorphine and also not taking other illicit substances. And of course psycho-social support, documented counseling that is critical for recovery for this patient population. Suboxone Film was designed to decrease the misuse, abuse and diversion in accordance with the recent research in the abuse and addiction related surveillance data showing significantly less pediatric exposure when compared to the tablet. I would request continued access with flexible dosing of Suboxone film with the appropriate use of guidelines for the class as currently in the criteria. Any questions?

Paul Oesterman, Pharm.D. Chairman: Thank you. Not sure I am up on this, but we are seeing an increase in the use of illicit products by younger and younger patients. We have the criteria here of 16 years of age, is that part of the packaging?

Juan Tripp: Yes, that is the package insert, the clinical studies were done only in a patient population above 16.

Paul Oesterman, Pharm.D. Chairman: Are there any on-going studies looking at the younger patients?

Juan Tripp: There are not.

James Marx, MD: I have a comment on the criteria. There was a recent study, done last December, that showed there was absolutely no difference whatsoever in patients who receive counseling and those not

receiving counseling in terms of success in treatment whether it be on treatment or off treatment. So I'm not sure making the criteria…I mean politically it is correct to say that these people should be counseled, but in fact a fairly large study shows that there was no difference. I'm sure you are aware of that study. So I'm not sure that should be part of our criteria. What will happen is, some patients may get denied because they did not receive counseling, in fact the upshot of the study, was that if the patient received it, they were more successful than not receiving it. While counseling, while we should encourage it, I don't think it should be mandatory.

Carl Jeffery, Pharm.D.: What if we rephrased that to say, "Counseling is offered."? Or available,

Coleen Lawrence: Encouraged? I think we have used that in other areas in the policy.

James Marx, MD: I don't think it should be a barrier to getting approval.

Coleen Lawrence: I think we have used is somewhere else, I think you decided on, "encouraged."

Carl Jeffery, Pharm.D.: I can give a quick overview of our intent with updating the criteria. We wanted to call out, if you look at the current Chapter 1200, it has both Suboxone and Subutex combined in the same criteria, we wanted to call them out because the Subutex should be limited either for the first couple days while being transitioned from methadone or if they are pregnant or breastfeeding. There is really no evidence to say that a narcotic addicted baby gets any naloxone through the breast milk, but we put it in there to be safe. That is why we have this here.

Paul Oesterman, Pharm.D. Chairman: So the fourth bullet point regarding counseling is going to be rewritten to read some to the effect that formal substance abuse counseling and treatment is encouraged and leave it at that.

Joram Seggev, MD: The other point, is perhaps we should try to specify the Subutex should be limited to a short time.

Carl Jeffery, Pharm.D.: You're right, we do not have any criteria that states that. I think it really is up to the practitioner. The guidelines state that the patient should be moved to the Suboxone as soon as possible, because the more Subutex you have on the street, the more potential it has for illicit use. So often times, the guidelines state to give two days at a time of the Subutex until they feel they can transition.

Paul Oesterman, Pharm.D. Chairman: Could we consider a quantity max on the Subutex?

Carl Jeffery, Pharm.D.: Given the nature of the disease, I would be hesitant to put a solid max on there.

James Marx, MD: I think it should be up to the prescriber.

Carl Jeffery, Pharm.D.: Maybe we could put that in the criteria, like we are encouraging counseling, we could say we encourage the prescriber to switch to Suboxone as soon as possible.

Paul Oesterman, Pharm.D. Chairman: That might be something on the next update for the newsletter.

Coleen Lawrence: One thing if you would like us to do, is look at the dispensing patterns of Subutex.

Carl Jeffery, Pharm.D.: They are in here.

Coleen Lawrence: The days supply? Until they move to the Suboxone?

Carl Jeffery, Pharm.D.: In the graph here, they are listed, but they are all together.

Coleen Lawrence: That's why I was thinking if we could get creative to see how long they are on the Subutex before they transition to Suboxone to see if it is an issue.

Joram Seggev, MD: Something that suggests a time, like 5 days or two days limit, this way having to get this re-authorized.

Carl Jeffery, Pharm.D.: Would it add an undue burden to give a week-long PA and have the prescriber renew the PA if they want more than a week?

Coleen Lawrence: Or instead of doing a PA up front, do a quantity limit and after 7 days, then flip it to a PA. Pick a reasonable time frame of quantity limit, and then after the quantity limit, then flip it over to a PA as necessary. And you could have that many however during a 90 day period. You might want to look at it that way.

Joram Seggev, MD: Seems like more and more of this drug hits the street, by limiting the initial number, or quantity limit, I think limiting the number of days is a better idea because that limits the number of pills, the pharmacy may not have the correct strength, so they could double up on a lower strength if necessary.

Larry Nussbaum, MD: It might be helpful for a provider who specializes in this type of treatment come talk to the Board about the treatment and what their suggestion is for the appropriate treatment.

Coleen Lawrence: I could do that, I will reach out to our sister agency and ask them if they can come give a presentation.

Larry Nussbaum, MD: That would make more sense rather than doing a PA from the front end or back end. I don't think we have a real clear sense on the treatment parameters.

Coleen Lawrence: OK.

James Marx, MD: I think the main thing that we have encountered with other pharmacy benefit managers, is a limitation on the period. I'm glad to see there is no limitation on the length of treatment. The other part of that study was that virtually all the patients reverted to their previous drug seeking behavior once treatment was stopped. So I think you want to make sure there are no criteria to limit the length of time.

Coleen Lawrence: I will take that away for the next Board meeting to get a presentation.

Paul Oesterman, Pharm.D. Chairman: In the meantime, we can always revamp or readdress the criteria. Do we want to move forward with the proposal that is in front of us now? Without putting any other limitations on this, so there is something you can work with.

Carl Jeffery, Pharm.D.: As a caveat, and something we can discuss at the next meeting, is there is supposed to be another buprenorphine product available in the next couple months. So maybe October would be a good time to discuss.

Paul Oesterman, Pharm.D. Chairman: Do we want to table this or pass what we have? Any strong feelings? Where does it stand right now?

Carl Jeffery, Pharm.D.: Right now, there is no distinction between the Suboxone and the Subutex, and I think that is what our concern is, that potentially we have a provider requesting just the Subutex and it ends up on the street for illicit use. The new criteria adds the different criteria to the Subutex, the breastfeeding or stepping down from another drug.

Paul Oesterman, Pharm.D. Chairman: We have the old criteria, and the proposed new one.

Coleen Lawrence: And it doesn't put a time limit on the use of the drug. So the differentiation is that the Subutex allows for if the recipient is pregnant or breastfeeding an infant.

Carl Jeffery, Pharm.D.: Right, it does add more restrictions on the Subutex from the old one. I would like to see the updated criteria pass, because I think it means there may be less Subutex on the street.

Paul Oesterman, Pharm.D. Chairman: Can we get a motion to approve these criteria, with the addition that we will re-review them at the next meeting with a presentation.

Coleen Lawrence: The one thing I want to point out, is that it doesn't address counseling is in place, not encouraged.

Paul Oesterman, Pharm.D. Chairman: So we want to change that part. "Formal substance abuse counseling treatment is encouraged." And leave it at that. Looking for a motion to approve.

James Marx, MD: I'll move to accept.

Larry Nussbaum, MD: Second

Paul Oesterman, Pharm.D. Chairman: Any discussion from the Board? All those in favor as amended, indicate by saying, "Aye."

Board: unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: Those opposed say "Nay". Motion carries.

h) Presentation of Fentanyl Immediate-Release products use and clinical information

Paul Oesterman, Pharm.D. Chairman: Our next topic, Fentanyl Immediate Release products. Anybody in the audience wish to speak? We have in front of us the proposed Prior Authorization criteria for immediate release Fentanyl products.

Carl Jeffery, Pharm.D.: Our intent with this was to expand to the new products that have been introduced. Right now, Chapter 1200 only identifies Fentora and Actiq, so we are missing a whole bunch of other ones. I have a lot of faith in our prescriber community, but things do slip through, there is always something. This would apply the same criteria that are on the others currently.

Paul Oesterman, Pharm.D. Chairman: I have two questions for you. Under the last bullet point of number 1, you have listed some immediate release products, what about the inclusion of Methadone in this list?

Carl Jeffery, Pharm.D.: I think we may have some differences of opinion, but I don't know that I would consider methadone as a medication for breakthrough pain. I think that was the intent with these others, were they are for breakthrough pain or acute pain.

Paul Oesterman, Pharm.D. Chairman: And my second comment, the first part is the authorization, and then the second part goes into, "Immediate release Fentanyl products will NOT be covered…" I would not necessary include things that are not covered in a Prior Authorization criteria. I would just say this is what it is covered for, it is a redundancy to me, to be consistent with the other policies.

James Marx, MD: I think the reason that is in there, is there was a retro-DUR a few years ago, we had about 42 patients receiving Actiq or Fentora and only 3 had a malignant diagnosis. I think that is probably what Carl is trying to get at and I think it really is critical because those 42 claims resulted in about $1.4 million in expense.

Paul Oesterman, Pharm.D. Chairman: The second part of A . says the patient has pain resulting from malignancy, so it is in there as a positive.

Coleen Lawrence: I have to ask on this one because when we are doing Prior Authorizations, if we can move it to the therapeutic class or to the higher level, your intent is to cover the entire class, we can write it, verses doing drug A., drug B., drug C. I would like to get that in policy rather than naming the drugs, if that is the intent of this policy.

James Marx, MD: Why don't we say it covers the transmucosal oral fentanyl?

Coleen Lawrence: I'm all for that, because we may be back here next meeting with a new product. So that is where we would like to take the policy.

Carl Jeffery, Pharm.D.: I think that works really well here in particular. Not every drug here has a different indication.

Paul Oesterman, Pharm.D. Chairman: So we will revamp this to Immediate Release Oral Fentanyl products.

Carl Jeffery, Pharm.D.: Do you want to say, "Oral"? Because there is a nasal spray too.

Paul Oesterman, Pharm.D. Chairman: Ok, Oral and Nasal.

Joram Seggev, MD: Or immediate release.

Carl Jeffery, Pharm.D.: And did you want to strike the bottom part of this?

Paul Oesterman, Pharm.D. Chairman: I would like to. One other thing we might want to address is the quantity restrictions. You have lozenges and tablets, what about nose spray.

Carl Jeffery, Pharm.D.: Oh yeah, missed that.

Paul Oesterman, Pharm.D. Chairman: I have never seen the nose spray.

Carl Jeffery, Pharm.D.: Do we want to limit that to 120 doses per rolling 30 days?

Paul Oesterman, Pharm.D. Chairman: I would say that is the same base supply, so yes. With the lozenges, they are the only ones available with a generic form right now, correct?

Carl Jeffery, Pharm.D.: Yes

Paul Oesterman, Pharm.D. Chairman: Can we get a report for next time giving us the breakdown of how many of these products are being used of all the IR Fentanyl products?

Carl Jeffery, Pharm.D.: Actually, you do have a report. The products that are not listed have no usage. There is really, we have 8 in January 2013 of the Fentora, so we're spending a lot of time on a few claims.

Darrell Faircloth, DAG: Sorry, Carl, what were you referring to when you said to strike the bottom part of this? I just want to make it clear for the record.

Carl Jeffery, Pharm.D.: Sure, Chairman Oesterman had suggested that we strike the bottom part that includes the exclusion criteria on the form that starts, "Immediate release fentanyl products will not be covered for the following…" and the it lists out A, B, C, D and E.

Darrell Faircloth, DAG: Thank you.

Paul Oesterman, Pharm.D. Chairman: Just to recap, we have a proposal for immediate release Fentanyl products, oral and nasal, having the inclusion criteria and the change of the quantity limitations to include 120 nasal sprays per rolling 30 days. We need a motion to approve.

Joram Seggev, MD: Move.

Dave England, Pharm.D.: Second.

Paul Oesterman, Pharm.D. Chairman: Any further discussion? All those in favor of the revised criteria, say, "Aye."

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: Those opposed, say, "Nay". Motion carries.

i) Presentation of Oral Anticoagulants use and clinical information

Paul Oesterman, Pharm.D. Chairman: Our next topic is the Oral Anticoagulants. Anybody in the audience?

Diana Dills: I am Diana Dills, I am an endorcrinolgist and an internist and I am a research medical specialist and I work with Pfizer Cardiovascular. Today I wanted to address apixiban, or Eliquis. I believe today we are trying to establish reasonable Prior Authorization criteria for apixiban. One of the criteria being considered is warfarin failure. First of all, apixiban is an anticoagulant, and like warfarin, a common side effect is bleeding. Also, as an anticoagulant, if you stop therapy you will increase your risk of having a stroke. But what does it mean to fail warfarin? Even the best Coumadin clinics obtain an INR in a goal range about 72% of the time. While the national average in the US is about 51% in the community. We know that with an INR outside the goal range the patient is more prone to bleeding if too high or stroke if too low. As it turns out, most patients who present with a bleed on warfarin are within the goal range. From the ARISTLE trial, apixiban will decrease the risk of stroke of 21% over warfarin and decrease the risk of major bleeding by 31% and will lower overall mortality by 11%. Two of the most dreaded complications of anticoagulants are intracranial hemorrhage and fatal bleeding. In spite of the fact that warfarin has an antidote and apixiban doesn't, intracranial hemorrhage was decreased by over 51% with apixiban when compared to warfarin. As far as fatal

bleeding, there were 36 fatal bleeds in the ARISTLE study on warfarin and only 10 on apixaban. This was a relative risk reduction of 73%, which was statistically significant. In AVEROSE, it is a study of stroke prevention and a-fib in patients who were deemed suitable for warfarin by the investigator. There, the fatal and intracranial bleeding rates for apixiban were identical to aspirin. The relative risk reduction for stroke however for apixiban was 55% over aspirin. In other words, by requiring that patient fail warfarin, we are subjecting patients to a substantial increase risk of stroke, intracranial hemorrhage, major bleeds and death. By requiring a prior auth on this class we may interrupt therapy, and if you interrupt therapy, you may increase the risk of stroke. The long term safety record of warfarin is well established. It is not a safe drug, it is an effective drug, but not safe, otherwise we wouldn't have put up with it for the last 50-60 years. So ARISTLE is the largest single study of a-fib, it demonstrated that apixiban is clearly the safer and more effective drug. AVEROSE established that apixiban was safe and effective for patients that were deemed unsuitable for warfarin for a variety of reasons. Costs are always a concern, but we really have to consider safety above cost. Any questions.

Joram Seggev, MD: In the data that we were provided, we have the cost provided of generic Coumadin. Can you give us an estimate of how much Coumadin therapy costs with labs compared to these others?

Carl Jeffery, Pharm.D.: I can't site any actual numbers, I have seen some at one point, but I think you still come out slightly ahead with warfarin.

Diana Dills: We do have some data on cost and therapy if you would like.

Sandy Sierawski: Sandy Sierawski with Pfizer. Pfizer works with IMS who has a lot of claims data, and we put together a data base. One of our tools we utilize is this claims database. They put together an a-fib cohort of patients. So we look back at two years worth of data, patients who had at least two diagnosis codes of a-fib, it could be outpatient or inpatient, identified them in the cohort. Once they were in the cohort, we were able to do some analysis of these patients, we have all their medical claims and pharmacy claims etc. So the new oral anticoagulants have only been out for a short period of time, the data we have in here is from the two year timeframe July 1, 2010 to June 30, 2012 and within that cohort there were only two products in there, so Eliquis is not in this data, it is only data on Pradaxa and Xarelto. But it was still striking. I can share this report and pass it around, but the basic demographics, looking at patients who were newly prescribed on warfarin or one of the newer agents and separated them out into two groups. And then looked at those patients, CHADS risk score, age, demographics very similar in the two groups, so we ended up with 2700 patients in the warfarin group and 2200 patients in the new oral anticoagulants. And we were able to look, and yes, when you look at the cost of the medications, compared the two classes, it was higher with the new agents, but when you looked at the total overall health care costs when you looked at outpatient facilities, ER visits, hospitalizations, other medication, etc. The total health care cost, mean cost per utilizing member was $35,000 in the warfarin patient and $28,500 in the new oral anticoagulants. And so I have other data to show how it pans out. But we do have data to show the utilization of data resources in this patient population is less than utilizing warfarin.

Paul Oesterman, Pharm.D. Chairman: I think what we are doing here today is to include apixiban with the others. What I would encourage Pfizer to do is to fund a study, head-to-head study of the three new products.

Sandy Sierawski: Now you're always asking for head-to-head data. We have head-to-head data with warfarin, which has been the traditional product out there.

Dave England, Pharm.D.: I have seen some presentations in some other places as well, along with the new anticoagulants with the old standby, warfarin. The question some of the physicians have been presenting is the problem they are having with the new anticoagulants is with warfarin, you kind of have an idea of when you are getting close to having problems. With the new agents, you don't know you have a problem until you have a problem, and then you have to fix it now, rather than with warfarin, its high or low, you have an idea of where you are going with it. The new medication, you have an NDR, you have an NDR going right now, there is no inkling it is going to happen, and then you have to treat it, emergently.

Paul Oesterman, Pharm.D. Chairman: How do you treat it?

Dave England, Pharm.D.: Is there any data from the studies that show for patient that do have bleeds on warfarin verses patients who have bleeds with the new anticoagulants, what the mortality rate is?

Diana Dills: The bleeds on warfarin, at least in ARISTLE were more severe and were left with more neurological impairment if they were on warfarin, than on apixiban. So they are more severe and more hemorrhagic bleeds. It seems to be a characteristic of warfarin, and all the studies show less intracranial hemorrhage. It is all less with all the products.

Dave England, Pharm.D.: How much sway is in the numbers, because there are so many more people on warfarin than the new anticoags? Even though, we have more issues with the warfarin, was it because we have more people on it? Is the mortality up? Is the bleed greater or worse with the new agents?

Diana Dills: That is what I was saying, in the fatal bleeding group, a lot of the fatal bleeds, there were 36 that happened with warfarin and 10 with apixiban, and this is with equal numbers in each group, 73% less fatal bleeding with apixiban than warfarin, and that is a huge trial, 1000's and 1000's of patients.

Dave England, Pharm.D.: That is good, I haven't seen any of that data.

Sandy Sierawski: That is what is exciting about looking at this data, because this is real world data, it isn't clinical trial data. This is just a sample of patients in a claims data base that we looked at and did some comparisons and identified that it is playing out in the real world.

Dave England, Pharm.D.: Thank you.

Mary Kay Queener: My name is Mary Kay Queener, I am a clinical liaison with the health outcomes group for Johnson and Johnson. I am here to talk about Xarelto or rivaroxiban. I was going to focus on the newest indication. This is a Xa inhibitor, it does have the widest breadth of indications. The first indication was prophylaxis of DVT following hip and knee replacement surgery. The second was reduction of stroke risk in non-valvular a-fib and the most recent indications we got at the end of 2012 was the treatment of DVT and PE and the secondary prevention of DVT and PE in recurrents. So that is really what I was going to speak to just for a few minutes. Because of the acute nature of DVT and PE, Xarelto really does provide an advantage over the standard of care of LMWH bridging over to Coumadin. In that they can be started on Xarelto either in the emergency room or wherever they are seen and then continued as an outpatient. It provides a good continuity of care and obviously that is extremely important in these patients. So there isn't a need for bridging, there isn't a need for INR monitoring, and following the first three weeks of twice a day dosing, it is a once-daily administration of the product, so very easy for the patient to maintain compliance. Also, Xarelto is on all the hospital formularies, so that continuity of care would be easy to maintain. So what I am asking is that you would extend the coverage without a prior auth for this indication. In addition, I think the proposed criteria

has a 30 tablet quantity limit, but with this indication, it is BID for 3 weeks, so the 30 tablet quantity limit would be problematic, so I would ask for the 15 mg dose have a quantity limit be adjusted for this indication. And finally, I just had a question, because the 10mg dose for the DVT prevention following hip and knee surgery is not addressed in the PA criteria, is that because it is new proposed language, is it because it doesn't require a PA? I only saw the stroke prevention and the DVT and PE treatment. I just want to make sure it will still be available.

Carl Jeffery, Pharm.D.: If it is an approved indication, it will be approved.

Mary Kay Queener: Thank you.

Debbie Lin: My name is Debbie Lin, Associate Director of Health Economics and Outcomes Research for BI. I am going to be providing testimony on Pradaxa, an oral anticoagulant. It was approved about three years ago in the fall of 2010 with over 4.3 years of safety trial data. It has been prescribed in over 750,000 patients in the US and over 5 million prescriptions to date. It is a direct thrombin inhibitor indicated to reduce the risk of stroke and system embolism in non-valvular a-fib patients. It is my understanding that in Nevada, there are restrictions for this class, one being the failure of warfarin. I would like to review some recent changes of the label, key defining features and answer any questions. Pradaxa 150mg twice daily is the first and the only approved oral anticoagulant shown to be superior in reducing the rate of ischemic and hemorrhagic strokes relative to warfarin. It is based on the pivotal RELY trial in 18,000 patients. Efficacy data demonstrates that this is the only oral anticoagulant that shows statistically significant reduction in both risk of stroke and systemic embolism and a statistically significant reduction in ischemic strokes and hemorrhagic strokes. We know that 9 out of 10 strokes is ischemic in nature. Further from the label in the RELY trial, the rate of all-c ause mortality was lower on Pradaxa 150mg than warfarin. That is 3.6% vs. 4.1% and to address the questions we just had about the fatal bleeds, it is 28 on Pradaxa vs. 39 on warfarin in the trial. Per the drug safety, November 2, 2012, the FDA conducted the mini sentinel assessment to evaluate risk of GI and major bleeding in the new users of Pradaxa vs. warfarin. Over one year time span what they found was that bleeding rates for both GI and intracranial hemorrhage associated with the new use of Pradaxa do not appear higher vs. new users of warfarin. And those results are consistent with observations from the pivotal RELY trial. As a result of this assessment, the FDA said that it hasn't changed any of its recommendations regarding Pradaxa and Pradaxa provides an important health benefit when used as indicted. It has been recommended as the anticoagulant over warfarin in the CHEST guidelines this year in February 2013, as an alternative to warfarin in the ACCHA and the AHRS guidelines published per its indications. In summary, Pradaxa is the first and only anticoagulant to show superiority in both reducing ischemic and hemorrhagic strokes relative to warfarin in patients with non-valvular a-fib. There are similar rates of major bleeding. Based on this information, we want to suggest that Pradaxa be retained on the PDL and there are no restrictions or PA requirements.

Carl Jeffery, Pharm.D.: The reason we are here is because Eliquis is the new agent to add criteria.

Paul Oesterman, Pharm.D. Chairman: Correct me if I'm wrong, but what I'm hearing is they are trying to compare these three relatively new products, that are good products, with the standard of many years that is also an effective product. We want to level the playing field, but we also want to make sure these products are not being used inappropriately. I think the PA criteria process has been made it such a manner that it is relatively easy for a practitioner to go through this process and I don't know that it is necessarily a bad thing to have in here that the patient had an adverse event with warfarin. I think what we are trying to do today is include a level playing field for the three new products.

Carl Jeffery, Pharm.D.: From my standpoint, what I would like the Board to do is have a discussion about this step through therapy through warfarin. The guidelines are evolving, and warfarin will not always be first line therapy.

Joram Seggev, MD: I think the one thing to take away from the presentation and my experience, is having patients on well-controlled warfarin. The patients we are talking about here are not always the most compliant, and the overall cost of the readjustments, are probably really costing more than any of these newer agents. More importantly, we are talking about patients who are in the hospital for an average of 4-5 days and are on a heparin drip plus warfarin for an average of 5 days, where patients on one of these agents can be out in 2. Observationally, the patient can go home early, we are saving three days of hospitalization. Another issue, is that the only medication that has all the indications is rivaroxiban, so any other medication is limited. Spending the money that can be used for other indications would be a plus.

Carl Jeffery, Pharm.D.: And to follow up on what Dr. Seggev was saying, if you look at the utilization in your binder, right now, the Eliquis has no clinical Prior Authorization criteria. The criteria for the Xarelto was added in May. Looking at the utilization of warfarin in May, there was a small dip and then went back up. Before then, the Xarelto is pretty consistent. I don't know that adding the PA criteria stopped any over-use. It has been flat the whole time.

Dave England, Pharm.D.: So with this, we are just adding Eliquis to the same scrutiny as the others.

Carl Jeffery, Pharm.D.: Right, that is why we are discussing it.

Coleen Lawrence: So let me ask the Board, what if a patient was discharged from the emergency room and they weren't by chance on warfarin, what if we did a continuity of care clause for one of these other drugs. Would that assist? Because that would mean the treatment was established if they were started in a clinic.

Dave England, Pharm.D.: I thought that was in there already, we wouldn't want a patient already established on this already somewhere else, and then we wouldn't make them switch to warfarin.

Carl Jeffery, Pharm.D.: Not specifically for this class. What probably happens, is a patient takes a prescription for Xarelto to the pharmacy, it stops for PA, the pharmacy can fill a 72 hours emergency supply while the PA is processed, but if they don't meet the criteria, that PA may get denied and then the patient may end back up in the hospital.

Coleen Lawrence: I think we could do something like what we do with the antidepressants, I don't know if that meets what you're looking at.

Dave England, Pharm.D.: I think that makes sense, I wouldn't want to take someone off this medication that is already working to make them try something else. If they are already established on this, I think we should continue on this.

Carl Jeffery, Pharm.D.: But how many people are started in the outpatient setting on one of these agents? They are probably all started in the hospital?

Joram Seggev, MD: Cardiac patients with a-fib would be started by an internist, but these really need to meet the criteria. In the hospital, quite a few will start in the hospital, but they are saving 3-5 hospital days. I guess the majority would be started by physicians in the offices.

Dave England, Pharm.D.: How would we want to word it if a patient is already established on this medication, to allow to continue? It would be added to a list of provided medications, it could be the first line check box.

Paul Oesterman, Pharm.D. Chairman: Continuation of therapy. I think we want to word this very carefully, I am thinking we might want a stop-gap measure to approve the addition of apixiban, and then put on the agenda for the next meeting some in-depth processing to assure patients that are started on this don't have an interruption in therapy.

Dave England, Pharm.D.: Right now, if someone had been established on any of these three, and a request comes in, the doctor explains the patient has been on this before, we would still have to go and make our modification to the PA next time.

Carl Jeffery, Pharm.D.: If you approve the criteria as stated now, a patient shows up to a Walgreens, the pharmacy could fill a 72 hours supply while the PA is processed, but the doctor would still have to complete the PA and justify why the patient either can't take warfarin or why they failed. So they would still have to have the step-through program or justify why they can't take warfarin.

Dave England, Pharm.D.: They may still have to go to warfarin after they get their three days?

Coleen Lawrence: They could show why warfarin was unsuccessful and get that.

Carl Jeffery, Pharm.D.: But if they don't have the documentation in the chart, or if the doctor isn't willing to complete the paperwork, there is a good chance the patient is going to go without therapy or they are going to be on a trial of warfarin.

Paul Oesterman, Pharm.D. Chairman: The other alternative would be to add another "or" is currently on the medication.

Carl Jeffery, Pharm.D.: I was trying to see if we could use the same wording as the antidepressants.

Coleen Lawrence: The antidepressants is continuation of therapy. It is in our PDL exception criteria. We can come back with it. All the other policy you have done is for existing Medicaid recipients. They have had the claim that has hit the system before, so if they have had the drug before, then it bypasses the requirement.

Carl Jeffery, Pharm.D.: The problem is with these patients being in a hospital, we may not see that claim for days or months.

Dave England, Pharm.D.: So at the retail level, the retail pharmacy could produce the medical reconciliation to show they were on it in the hospital.

Coleen Lawrence: On the antidepressants, one of our continuity of care is "was discharged on a hospital on this medication" and it is on the PA form that way as a check-box.

Paul Oesterman, Pharm.D. Chairman: Do we want to add that.

Carl Jeffery, Pharm.D.: I'm just thinking of the logistics of how it would work in a pharmacy. Right now we only accept PAs from the prescriber, not the pharmacy. So if we were going to go down that avenue, I would like some criteria either the pharmacist can call the call center, because if they have to call the doctor, it is going to delay the PA. Either that, or we have the ability in our system where a pharmacist can put in an override themselves.

Paul Oesterman, Pharm.D. Chairman: For today, what do we wish, to move forward? What is going to work best for you?

Carl Jeffery, Pharm.D.: I think to make it level for all the products, whatever we decide on, it needs to be equal for all agents. As it stands now, if we table, it is unfair to some of the manufacturers. How I would like to see, from what I have seen clinically, and what we have discussed at P&T is to remove the step through for warfarin. We could also put an edit in place where the pharmacy can transmit a diagnosis and get that approved immediately.

Coleen Lawrence: What you could do on the drug classes is, make it at the drug class level so if new products come out…

Carl Jeffery, Pharm.D.: Because they have different indications, that may not really work. I don't think there are any more in the pipeline.

James Marx, MD: I have an issue to that I think it is sort of punitive to require the patient to either not achieve an INR of 2-3 or have an adverse event before they meet the criteria. I think those two bullet points should be removed, I think it is totally inappropriate given the current knowledge, I have a problem with that.

Carl Jeffery, Pharm.D.: That is where I would like to see it go too.

Paul Oesterman, Pharm.D. Chairman: Has P&T addressed this yet?

Carl Jeffery, Pharm.D.: P&T just looked at the preferred agents, and they are all preferred right now.

Paul Oesterman, Pharm.D. Chairman: We could be very assertive and remove the warfarin criteria that is in there, and include the continuation of therapy.

Carl Jeffery, Pharm.D.: We don't have a system to look at continuation of therapy.

Coleen Lawrence: You wouldn't need to if you are going to remove the warfarin criteria.

Paul Oesterman, Pharm.D. Chairman: That's true.

Carl Jeffery, Pharm.D.: I think what the option is, if you remove the warfarin criteria, just make the edit so if the ICD-9 is transmitted on the pharmacy claim, the claims would pay. That way, at least we would check the diagnosis is matching up.

Dave England, Pharm.D.: I move to make that amendment.

Coleen Lawrence: So for warfarin, they're going to have a diagnosis?

Carl Jeffery, Pharm.D.: No, for the Eliquis, Pradaxa and Xarelto.

Dave England, Pharm.D.: We would have to have the ICD-9 diagnosis.

Carl Jeffery, Pharm.D.: Would be for a-fib for Eliquis and Pradaxa, and then Xarelto would have a-fib and the DVT and PE treatment and prophylaxis.

Dave England, Pharm.D.: I make that motion.

Joram Seggev, MD: I second.

Paul Oesterman, Pharm.D. Chairman: We have a motion and a second to approve the revised criteria for the newer anticoagulants that will have the pre-requirement for warfarin failure or adverse event and specific indications for the respective products.

Carl Jeffery, Pharm.D.: I would also strike, if we want this to go through at the pharmacy level, I would also strike the contraindication bullet point, that is not something the pharmacy can evaluate.

Paul Oesterman, Pharm.D. Chairman: Ok, then we would remove that.

Coleen Lawrence: But if they do not have the diagnosis, then they are subject to the Prior Authorization criteria.

Carl Jeffery, Pharm.D.: Right, the claim would deny, needing PA, but then it would it would go to the doctor and the criteria as stated would just be to check the diagnosis.

Paul Oesterman, Pharm.D. Chairman: Any further discussion? All those in favor of the amended criteria, indicate by saying, "Aye."

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: Those opposed, say, "Nay." The motion carries.

a) Presentation of Antiviral influenza products use and clinical information

Paul Oesterman, Pharm.D. Chairman: Good discussion. Our next topic is the antiviral, influenza products. Anybody to speak? So we have the criteria.

Carl Jeffery, Pharm.D.: The only reason we wanted to bring this up, and this was a suggestion from our clinical call center from what they have seen in other states is people who get a new Tamiflu every flu season. Based on their recommendation, we want to add some quantity limits for Tamiflu and Relenza.

Paul Oesterman, Pharm.D. Chairman: Based on this, how many courses of therapy per year are you seeing?

Carl Jeffery, Pharm.D.: So it would be two courses every 90 days.

Dave England, Pharm.D.: In the criteria, does it state they need the diagnosis of influenza. If it has been five days of therapy…

Carl Jeffery, Pharm.D.: We don't have any clinical criteria, we're only doing quantity limits right now. But we can certainly add some criteria.

Dave England, Pharm.D.: Especially with the shortage of Tamiflu we have seen in the past few years. Because of the prophylaxing rather than treatment.

Coleen Lawrence: And you guys have the utilization in the binder.

Paul Oesterman, Pharm.D. Chairman: At least the use is in flu season.

Joram Seggev, MD: The problem with pre-authorization for this medication is because you have 48 hours to start therapy. I think adding criteria would be detrimental. These are the clinical criteria, one of the things could be a post-treatment option for education. But for practical reasons, I think limiting quantity is the best practical option.

Carl Jeffery, Pharm.D.: We could also put criteria after the first course, so the first course is free, the next one you have to justify why you need additional doses. As it states now, it is just quantities.

Paul Oesterman, Pharm.D. Chairman: These quantities are consistent with what other states are doing?

Carl Jeffery, Pharm.D.: Yes.

Paul Oesterman, Pharm.D. Chairman: Requesting a motion?

Joram Seggev, MD: I'll move.

James Marx, MD: Second.

Paul Oesterman, Pharm.D. Chairman: Any discussion? All those in favor say, "Aye."

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: Those opposed say, "Nay." Motion carries.

b) Presentation of Antihyperlipidemic Agents for treating Homozygous Familial Hypercholesterolemia (HoFH) use and clinical information

Paul Oesterman, Pharm.D. Chairman: Our next criteria is for the Antihyperlipidemic Agents for treating Homozygous Familial Hypercholesterolemia use and clinical information.

Anyone wish to speak?

Patrick Jensen: Good evening, my name is Patrick Jensen, I am an MSL with Agerion. I am a Pharm.D. by training and prior to coming to Agerion, I managed a lipid clinic. Today we will be reviewing the limitations of therapy and then discussing some of the safety and efficacy of Juxtapid by reviewing some of the pivotal phase three studies. As many of you are aware, HoFH is a rare condition with a historically estimated prevalence of approximately of 1 in one million. HoFH is a serious life-threatening disease, characterized by elevated LDL-c levels despite lipid lowering therapies, resulting in premature arterial sclerosis. Diagnostic criteria for HoFH is variable and not universally defined. Genetic testing is rarely used in the diagnosis as there are over 1600 mutations, with others yet to be identified, which leads to a high false negative rate of about 20%. Due to the inaccuracies of genetic testing, a medical diagnosis is much more prevalent. The clinical diagnosis in the literature typically includes significantly elevated LDL levels in treatment naive patients. In patients on LDL lowering therapy, the LDL range can be wide due to the variability of the disease. In our phase three study, we had confirmed HoFH patients on LDL lowering therapy including apheresis ranging from 152 to 565. Other studying HoFH have documented LDL's in the 190's. Physical features may also be present and include corneolarkus, cutaneous or tendenous anthalmus. Parenteral history of significant hypercholesterolemia and or premature cardiovascular disease may also be present. So now a little on Juxtapid, which is an oral microsomal tryglyceride transfer protein inhibitor. Which prevents the assembly of Apo B containing lipoproteins. Which leads to the reduction in LDL-c, total cholesterol, ApoB

and non-HDL cholesterol. Juxtapid is contraindicated during pregnancy, with the concomitant use of strong or moderate 3A4 inhibitors and those who have moderate or severe hepatic impairment or active liver disease. Limitations include the safety and efficacy have not been established in patients who do not have HoFH. The effect on cardiovascular morbidity and mortality has not been determined. In addition, the safety and efficacy in the pediatric population has not been established. In addition, Juxtapid has a boxed warning regarding the risk of hepatotoxicity because of the potential for liver enzyme abnormalities as well as an increase in hepatic fat. Because of the potential for hepatotoxicity, Juxtapid is only available through a REMS program, which includes the mandatory certification of prescribers and an attestation form that is signed by the prescriber affirming the diagnosis of HoFH. I would also like to quickly review our pivotal phase three study, which was a multi-national, single arm, open label 78 week trial involving 29 HoFH patients. The primary endpoint of this study is the reduction of LDL-c at week 26. The study began with a 6 week run in period to stabilize other lipid lowering therapies including apheresis, and initiate a low-fat diet with less than 20% of calories from fat, which is important to assist in the GI tolerability. After the 6 week run in period, the patients entered the efficacy period from week zero to week 26 during which time they were started on 5mg for two weeks and then based on tolerability, the dose was increased every 4 weeks to the individualized dose which may have included a max of 60mg daily. After 26 weeks, the patients entered a one year safety phase, during which time, the max tolerable dose was continued and background lipid therapy could be altered. For example if a patient was on apheresis at week 26 through 78, the investigator could adjust the LDL apheresis regimen based on their thoughts. So almost 80% completed the primary endpoint at week 26 and the same approximately 80% completed the entire trial. At week 26, the mean percent reduction in LDL-c in the intent to treat population was a statistically significant 40%, and again that is on top of their existing therapy. The 23 patients that completed the 26 weeks, a statistically significant 50% reduction of LDL-c was observed. The most important and common side effects were GI in nature, reported by 93% of patients. And in closing, when used within the guidelines of the prescribing information as well as REMS program, the potential for the 40-50% LDL-c reduction on top of existing therapy provides the effective treatment option with patients with HoFH. Any questions?

Carl Jeffery, Pharm.D.: Do you have some cost data for apheresis?

Patrick Jensen: Heparin based or dextran sulfate columns?

Carl Jeffery, Pharm.D.: Either one, I just know that treatment is often an alternative to Juxtapid. Or can be adjunctive as well.

Patrick Jensen: Yeah, it can be adjunctive, in our study, we included LDL apheresis patients, and of the 13 patients who were on LDL apheresis at week 26 when lipid therapy can be changed, half of those patients were able to have their LDL apheresis adjusted. So of those 13, 6 had their LDL apheresis changed, three stopped LDL apheresis all together, the other three had theirs reduced. The costs is really treatment center dependent, it's going to be roughly anywhere between $50,000 to $100,000 per year, so it's not cheap.

Carl Jeffery, Pharm.D.: We're here for two new agents for a very rare disease, extremely expensive agents here. That is why we wanted to make sure they are being used appropriately. They are in limited distribution and in a REMS program. My fear is that a family practice doc may look in the book and see Juxtapid for high LDL's. I highly doubt that will ever happen, but one time it happens, is all it takes. So that is the reason for the criteria here.

Dave England, Pharm.D.: Basically we have nothing else other than the lipid lowering agents that we have right now.

Carl Jeffery, Pharm.D.: And the mechanical apheresis. Which is kind of a dialysis for your LDL's.

Paul Oesterman, Pharm.D. Chairman: Anybody have any insight? Have we had any patients with a diagnosis of HoFH?

Carl Jeffery, Pharm.D.: We have no use of either of these agents so far. There are two of them, there is an injectable one and an oral agent. The other one is Kynamro.

Joram Seggev, MD: So we are looking at an extremely small number of patients, and we should probably get some input here from an endocrinologist.

Carl Jeffery, Pharm.D.: Growth hormones are next, any endocrinologists around?

Scott Steppi: My name is Scott Steppi and I work for Novo-Nordisk, thank you for allowing me to speak. There are seven growth hormones…

Paul Oesterman, Pharm.D. Chairman: No, we don't want a growth hormone talk yet, this doesn't count toward your five minutes, we were looking for someone, endocrinology wise to speak on HoFH.

Scott Steppi: So I just embarrassed myself by coming up here. Should I go back and we can start over?

Paul Oesterman, Pharm.D. Chairman: You can just stay there.

Carl Jeffery, Pharm.D.: I think what the manufacturer didn't like about the criteria was using the genes for diagnosis. I think that was their heartburn when I spoke to them previously. It is really hard to diagnose based on this.

Dave England, Pharm.D.: Do we want to table this until next time? We might not see it between now and next time, so do we want to come back with an endocrinologist?

Paul Oesterman, Pharm.D. Chairman: Or do we want to include criteria that it must be prescribed by or in consultation by an endocrinologist?

??: These are lipid specialists, they are not always endocrinologists, it could be a cardiologist. There are a couple identified in Nevada, a couple lipidology specialists, but so far no patients as you mentioned.

Patrick Jensen: The majority of patients that see these HoFH patients are cardiologists and lipidologists. There are a couple endocrinologists, but the vast majority are cardiologists and lipidologists.

James Marx, MD: Does that REMS program limit the prescriber, so isn't there already a process in place to limit the prescribing of this already, so only REMS certified pharmacies too. So there is already a two level means of preventing inappropriate use already.

Patrick Jensen: We did self-impose a more stringent REMS program, actually we went to the FDA prior to them telling us what they would like our REMS program to be and asked them to include an attestation form that the prescriber has to sign affirming the diagnosis of HoFH. So to Carl's point, if you're worried about a family practice doc who maybe a lipidologist or a specialist in the field, whoever prescribes this is going to

have to sign that attestation form affirming the diagnosis. So that will definitely put the brakes on anybody whimsically prescribing Juxtapid.

Coleen Lawrence: But that is one drug right? So is that for Kynamro too?

Inaudible: They also have a REMS program.

Coleen Lawrence: So maybe the policy is to say participation in the REMS program.

Paul Oesterman, Pharm.D. Chairman: But they have no choice on that. Do we want to add, even though it is redundant, participation in the REMS program?

Coleen Lawrence: I don't know, that is something we can look at and discuss a little bit more.

Carl Jeffery, Pharm.D.: And if that is our criteria, why add that extra burden to the prescriber.

Dave England, Pharm.D.: They would have to be on the REMS program anyway.

Coleen Lawrence: But we could check out the other drug.

Dave England, Pharm.D.: I move we table this discussion.

James Marx, MD: Second

Paul Oesterman, Pharm.D. Chairman: So we have a motion and a second to table this until we have additional discussion information. All those in favor say, "Aye.'

Board: Unanimous, "Aye.".

Paul Oesterman, Pharm.D. Chairman: Those opposed say, "Nay".

c) Presentation of Growth Hormone agents use and clinical information

Paul Oesterman, Pharm.D. Chairman: Now, Growth Hormone.

Scott Steppi: Hi, my name is Scott Steppi and I work for NovoNordisk. There are seven growth hormone products on the market, there are no head-to-head trials. Norditropin Flex Pro is one of the products that is available for Nevada Medicaid. What I wanted to do is just show the Board how we are different because they are all somotropin products, but the pen devices are very different. Our pen, when the doctor prescribes it, the patient gets it just like this, so it is already prefilled, premixed, preloaded, refrigerated when it comes, the patient just puts the needle on the pen, and after the first dose, they are able to keep this next to their bedside at room temperature for three weeks. It is the only delivery device that does not have to be refrigerated after the first dose. So that makes it very convenient for patients when they are traveling to their grandparents or camp and they keep it in their backpack. Because it is small, they can administer it themselves after they get started on it. So I wanted to show you the device, it is available.

Carl Jeffery, Pharm.D.: This hasn't been reviewed since 2008. Had a lot of feedback from the endocrinologists about the criteria and how it doesn't meet the current guidelines. So we have updated it. One of the biggest changes we have made, and I think it may cause some problems, is we have taken out the idiopathic short stature indication as an approval. Take it for what you want, if it is cosmetic or how you

interpret that, but it is no longer an approved indication in our criteria. I'm warning the Board that you may get some pushback from the community.

Dave England, Pharm.D.: Does that reference this letter from this doctor in Vegas?

Carl Jeffery, Pharm.D.: Right, I'll highlight that letter from Dr. Saad here. She is a pediatric endocrinologist and we see a lot of requests from her and her office. Some of the bigger changes is for the recertification, right now we have a hard time recertifying these kids. The way it reads now is the kids have to have a bone age of less than 2 standard deviations below the mean. So the way we have it established now, we give them growth hormone until they catch up with their peers, and then we stop it and they fall back until they need it again and catch up. So the recertification criteria has been made a little easier. So once the kids qualify, it is easier to re-qualify, it is not a constant up and back.

Dave England, Pharm.D.: So basically, her comment here in paragraph four in here, once they reach the percentile, they are not cut off, so they can still continue therapy. But they are going to be out of luck if it is for idiopathic short stature.

Carl Jeffery, Pharm.D.: Right.

Dave England, Pharm.D.: She comments in here, in order to get around that idiopathic short stature, all they have to do is recode it as a growth hormone deficiency.

Carl Jeffery, Pharm.D.: Not all idiopathic short stature have a low growth hormone levels. This is one of our most challenging things is that we see that they have normal growth hormone, they are just small kids, so it is a tough decision.

Coleen Lawrence: That is one of the main reasons we go to hearing on growth hormone.

Carl Jeffery, Pharm.D.: Since I have been here, we have gone twice to hearing for growth hormone and it has been for idiopathic short stature. Right now they don't meet the recertification criteria because their bone age is caught up. But making the criteria more solid here, because I'm sure it will come up again.

Coleen Lawrence: So if this is removed completely, there would not be any coverage criteria, but it isn't a non-coverage.

Carl Jeffery, Pharm.D.: That's a good point, we may be setting ourselves up for a problem, because it is an approved indication and there is peer reviewed literature, and so potentially, they could get around it that way.

Coleen Lawrence: Because if you don't have it addressed in the policy as a non-covered indication, and you have peer reviewed literature and it is an actual approved indication for that drug, then the call center still has to address it. You are just in limbo of what is defined as short stature. And that has been the limbo, is the child just small or is it another diagnosis. I don't know by eliminating that written policy if it addresses the situation. I do know for the Board that this is an issue and I think we have seen some issues around inappropriate use for children trying to excel in athletics, unfortunately it is a sad thing, but you do see it. It is the next wave of trying to do things.

Dave England, Pharm.D.: By putting this idiopathic short stature as a cutoff, does it decrease that?

Coleen Lawrence: I don't know because one of her things says, no means can be identified for short stature. That means it is not diagnosable. Well then you would hope that you would throw a diagnosis on there. That goes back to another subject that every other drug we cover comes with a diagnosis. If you exclude it and you silence it, then you pretty much ok'd it. Does that make sense?

Paul Oesterman, Pharm.D. Chairman: So do we want to approve the criteria as it has been presented? A motion to approve?

Dave England, Pharm.D.: I move to approve.

Larry Nussbaum, MD: Second

Paul Oesterman, Pharm.D. Chairman: I have a motion to approve and a second. Just for documentation purposes for the record, Dr. Seggev had to leave, but we do still have a quorum.

Any further discussion? I will call for a vote, all those in favor please indicate by saying, "Aye.".

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: Those opposed say, "Nay". The motion carries.

d) Presentation of PA criteria for psychoactive medications for children – child psychiatrist updated rules

Paul Oesterman, Pharm.D. Chairman: Ok, we have the presentation of Prior Authorization criteria for psychoactive medications for children, child psychiatrist updated rules.

Anybody in the audience wish to speak regarding psych meds in children? Carl.

Carl Jeffery, Pharm.D.: There isn't any clinical information in your binder, just some utilization report, but what brought this up is a few pediatric psychiatrists in Las Vegas that would like a little bit easier access for their clientele to get these medications without having the burden of a PA. I think what they would love is to not have any criteria at all, but that isn't going to happen. So the options are that we have, we have some exceptions for the ADHD medications, if the prescriber is a child psychiatrist and the pharmacy transmits a diagnosis of ADHD. And for the anti-seizure medications, there is a bypass if the prescriber is a neurologist and the pharmacy transmits a diagnosis of a kind of seizure related code, the claim passes any kind of clinical edit. Outside of that, all claims need to meet the criteria that is outlined in the Chapter 1200. I think where they want to go is expand that to these other classes and the antipsychotics is the biggest class.

Coleen Lawrence: For the Board members, there are two reports that were handed out which is a prescribing pattern handout and a second from 2008 to 2012 and it breaks down all the psychotropic meds by class. And then we asked Catamaran to break down the prescribing pattern on the top 25 prescribers. We redacted the information because we are in an open meeting. How you read that report, because it is important to look at because everyone has their own information that when you're looking at these psychotropic medications that it might be your general practitioners who are your top prescribers, and this has always been the trend honestly in our area. So when you look at this report, if it says psychiatrist and 500 claims, that is one psychiatrist, psychiatrist A, we just wrote the specialty, just redacted the names. So we went to the next one is a pediatrician and then the next one. So you can see all the different groups of medications by class and then the

subspecialty underneath, by claim count and then the number of recipients next to that. I think that is your best information.

Larry Nussbaum, MD: This is a year?

Carl Jeffery, Pharm.D.: This is October 2012 through June 2013, 9 months.

Dave England, Pharm.D.: A lot of meds for kids.

Coleen Lawrence: And you have to remember that is with the Prior Authorization criteria for kids. The anticonvulsants, we are doing the bypass now, so if you're a neurologist if it is for seizure diagnosis.

Dave England, Pharm.D.: So the antipsychotics, the majority are written almost two to one by a pediatrician?

Coleen Lawrence: That is just one pediatrician, but the next one is a psychiatrist and the third one down is a child psychiatrist.

Larry Nussbaum, MD: There are multiple issues here. There are very few FDA approved rationales for giving antipsychotics to kids under 18. There are several, but certainly not to the extent of the adult doses. That in itself is a concern, just the number of medications, not necessarily the prescribers.

Coleen Lawrence: You can see that in the larger report that talks about the pattern and trend of number of prescriptions. Look at the zero to four, we have 2 point something prescriptions per month for 4 year olds on antipsychotics. And they took a blip back up. Remember, we're on Prior Authorization criteria right now, the way the criteria reads is that we are just asking for them to disclose a diagnosis or indication for each prescription that they are getting authorized. It really isn't that we have education or consultation with a psychiatrist, when possible, be prescribed or in consultation with a child psychiatrist, and should be part of a comprehensive treatment plan.

James Marx, MD: I'm trying to figure out 2011 to 2012, zero to four year olds.

Coleen Lawrence: I know, we have seen that before too, and then it spikes back up again. I know that there was a request to bring it back to the Board and asked what our proposal was and I have no proposal. I want to stay neutral and stay as-is. Dr. Nussbaum, he goes through the process on a Prior Authorization, and we made this in 2009, the criteria was made with five psychiatrists when developed initially. We extended it to over 18 policy in 2010 because we weren't seeing the change in the over 18 policy, and that is where it changes. And you can see where we implemented it in 2009 because there was a delay in our system, it made a difference in the zero to four and then it creeped back up again. So I don't…

Dave England, Pharm.D.: So even with that criteria we had five psychiatrists help us develop it and we're still getting this.

Coleen Lawrence: I think that…well the zero to four did take a drop and then has come back up and is leveling, I think that I would be cautious if I removed anything because even if you removed a child psychiatrist or psychiatrist in that arena, you could see some of your top prescribers are still, are bypassing that arena. And I always say that it is not the good ones that I am worried about, but there are some in that arena. And all we're asking for is that disclosure for indication or diagnosis. And if it is that we need to start looking at what we're collecting and do something different with and see how we can collect information on the system and start doing something with it.

James Marx, MD: Are there any cross steps that we have concern with, I mean for the zero to four groups where there are 250 kids with an anxiety diagnosis, to me that seems pretty incredible. I would like to see who is making that diagnosis, and the same is true for anticonvulsants, I don't have a problem with, but antidepressants and antianxiety agents, I think there can be severe consequences in using these drugs in patients in such an immature group. Plus the additional potential and the cost later on, this is just an incredible number, I'm shocked.

Coleen Lawrence: Honestly, every time we start looking at these numbers, that is usually the reaction we get. I don't mean that sarcastically by any means, every time we want to present something for relaxing our Prior Authorization criteria, we start showing these numbers and that is exactly it. Whatever data you would like us to try to get off the Prior Authorization, it is a manual process, but we will go through it.

Carl Jeffery, Pharm.D.: Especially diagnosis codes, those are more difficult to match up.

Coleen Lawrence: But they are collected on the Prior Authorization criteria though, that is why we have done this exercise before.

Carl Jeffery, Pharm.D.: But still they only have to put one in there, if a patient has multiple diagnosis, then it will just list the first one.

James Marx, MD: If you look at the atypical for the zero to four year old, you can make the diagnosis of anxiety or depression of any kind.

Larry Nussbaum, MD: I guess the question is, I'm not so sure the Drug Use Review Board is the arena to deal with this. I wonder from my point of view it seems like it is such an issue and these numbers are so compelling, that I guess I wonder if we want to put some kind of group together of both public and private sector people to address this issue. I don't think you're going to have strength coming from just a Prior Authorization standpoint. These numbers are crazy, and part of that is, I don't prescribe a lot of medication, but these numbers are ridiculous. These are only Medicaid sector, and this is probably nothing compared to the private sector. I guess I wonder if we can use this for a spring board for making some kind of cohesive group to address this important issue right now.

Coleen Lawrence: Absolutely, and there is a larger format with our counties and our partnership with DCFS, and I will tell you that they rely on our Drug Use Review criteria to manage those children right now, and so, we can definitely do that, and we can look at some data to pull together for that. I think with that, off line. My first question to you, is do you want to do anything with this Prior Authorization criteria then?

Paul Oesterman, Pharm.D. Chairman: I would propose at this time that we ask you to go ahead and leave that until we get more guidance and direction from what Dr. Nussbaum has proposed or another group.

Dave England, Pharm.D.: Do we want to initiate these now or come back to these too?

Larry Nussbaum, MD: I think there needs to be some pressure on the system to change. I think if you attempt to change things by changing the Prior Authorization criteria, you're always going to have that pressure.

Coleen Lawrence: And I will work with you on another group.

Paul Oesterman, Pharm.D. Chairman: So we're going to table any action on this.

Dave England, Pharm.D.: So moved

James Marx, MD: Second.

Paul Oesterman, Pharm.D. Chairman: All in favor, say, "Aye."

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: Those opposed say, "Nay".

5) DUR Board Requested Reports

a) Report on Promethazine with Codeine syrup use

Paul Oesterman, Pharm.D. Chairman: Now on to our requested reports. Promethazine with codeine use. I know we requested a report on this and the background on this is promethazine with codeine is one of the more widely misused products, abused products. We have this report showing the usage from October 2012 to June of 2013.

James Marx, MD: Are these individual patients?

Carl Jeffery, Pharm.D.: Yes, this one number…

James Marx, MD: This is incredible, this is what we expected.

Paul Oesterman, Pharm.D. Chairman: I'm just mind boggled, first of all that someone would have 18 different submission in less than a year for a quantity of almost 8 liters, there is a problem with our system. I don't want to sit here and put a Prior Authorization on this, but a quantity limit or something.

Coleen Lawrence: Well, it is one pharmacy and two prescribers.

Paul Oesterman, Pharm.D. Chairman: The next question I have, you mention two prescribers, these patients that have an excess of 10 claims, is it the same prescriber.

Carl Jeffery, Pharm.D.: We have the number of unique prescribers over here, so there are two different prescribers.

Paul Oesterman, Pharm.D. Chairman: No, I understand that, but is patient A. and patient C. seeing the same prescriber. We need to do something.

Coleen Lawrence: I can work with Dr. Marx off line, to come up with a number one, a web announcement for…

James Marx, MD: This is just incredible, in the good old days, about 20 years ago, I got a pint bottle of promethazine with codeine and it lasted me 15 years, I know it is outdated, but it still worked.

Coleen Lawrence: We will work with you for a web announcement, because that is our first level of education on this. Obviously our pharmacies are, not that many.

Carl Jeffery, Pharm.D.: Well if you look at the third one down, they have 5 pharmacies, that person is shopping around, but most are ones and twos, so they are…

Coleen Lawrence: We'll see if we can find a pattern.

Paul Oesterman, Pharm.D. Chairman: Thank you for providing this report, it did provide some eye-opening information and if you can dig a little deeper, there might be something to address with action items next time. Any other discussion?

b) Report on Top 10 Black Box warning medications:

Paul Oesterman, Pharm.D. Chairman: Ok, the report on the top 10 black box warning drugs.

Carl Jeffery, Pharm.D.: I don't have that one, I didn't have time.

Paul Oesterman, Pharm.D. Chairman: Ok, so we will defer that to the next meeting. Ok, the DUR reports.

6) Standard DUR Reports

Paul Oesterman, Pharm.D. Chairman: Ok, so we will defer that to the next meeting. Ok, the DUR reports.

Carl Jeffery, Pharm.D.: We have the top 10 therapeutic classes by amount paid separated by quarter, pretty much what you would expect, hemophilia products, we had a guy that gets a lot of factor product that was hospitalized, so that is why it took a little dip. That's why it went down and then back up.

Coleen Lawrence: I want to point something out with hemophilia, our patients, we know them so well, Carl actually looks at the processing of those factor drugs to make sure they are billed correctly down to the decimal point, calls the pharmacy to make sure they go through the system correctly because obviously they are a very high dollar in our system. But I just wanted to point that out.

Carl Jeffery, Pharm.D.: I don't do anything clinically, but check for keying errors, but when they are putting in 100's of 1000's of units, it is pretty easy to miss a decimal point. Then the next page the top 10 classes by number of claims, just what we expect, the hydrocodone products.

Paul Oesterman, Pharm.D. Chairman: It looks like the number of claims is consistent. A little off topic, the number of recipients in Nevada Medicaid, is that increased, decreased?

Coleen Lawrence: Laurie would have the best numbers, our eligibility count?

Laurie Squartsoff: It is about 321,000 covered under the whole program and about 60% are managed care, so those numbers won't show up in this report.

Coleen Lawrence: But we have been pretty consistent on the increase lately, we haven't had a spike, last year we had a spike.

Laurie Squartsoff: No, it's been pretty steady.

Carl Jeffery, Pharm.D.: It usually bumps right around 124-125,000 in the fee for service.

Coleen Lawrence: Last year we had a spike, but we haven't had any spikes that I know of lately. We'll have a large spike January 1, 2014, but honestly most are going to managed care.

Carl Jeffery, Pharm.D.: So then the top 50 drugs by claim count is a little skewed due to a rebill in our system, that isn't a real number.

Paul Oesterman, Pharm.D. Chairman: We had implemented the acetaminophen dose limit of 3 grams per day, how is that going?

Carl Jeffery, Pharm.D.: Yes, that occurred in May, and I haven't heard any pushback or complaints.

Coleen Lawrence: I haven't received any calls on that actually.

Carl Jeffery, Pharm.D.: The numbers are all consistent.

Paul Oesterman, Pharm.D. Chairman: I know in the past, we have had some issues with these reports, so accommodations to consistency with these reports, I appreciate it.

Carl Jeffery, Pharm.D.: And then by payment, Abilify is still our favorite drug, the Synagis pops in there when looking by payment during the season.

Paul Oesterman, Pharm.D. Chairman: Do we have anything coming off patent soon?

Carl Jeffery, Pharm.D.: I should have printed up something for you guys. Nothing really for this year. Starting in 2014 there are a few big ones coming off. And we have the proDUR edits, I believe this is the report you requested. You have the proDUR and clinical response from the pharmacy and if it was filled or not.

Paul Oesterman, Pharm.D. Chairman: Again, useful reports. Does the Board have anything in particular they would like to see for next time?

Carl Jeffery, Pharm.D.: One thing that didn't make it due to the full agenda is last time we tabled the discussion of the long-acting and short-acting narcotics. So we will bring that to the next agenda. And if there are any other topics that you can think of that you are seeing in your practice that you think we should review.

Coleen Lawrence: And as a reminder, any time any of the members of the Board can email us or send us ideas or thoughts for any information you may want in between because it is a quarter in between, so you may send us your ideas at any time.

7) Closing Discussion

Paul Oesterman, Pharm.D. Chairman: Alright, any comments from the audience before closing. Thank you for sticking around and enjoying this TV show. With that, our next meeting is scheduled for…

Carl Jeffery, Pharm.D.: October 24, 2013.

Paul Oesterman, Pharm.D. Chairman: The timing, any input on timing?

Carl Jeffery, Pharm.D.: And location, I would like some input. I know Dr. Marx had to take a few days off his practice to come up here and I will have to reach out to Dr. Seggev separately. Give us some feedback on time and location.

Coleen Lawrence: We can move it off a Thursday too if necessary. We were thinking about moving next to the Board of Pharmacy meeting because I know some of you were working along with that Board, so that was one idea, but they have a two day, but when they're in the North, the same day, the second half of their half a day, but we're better at catching the quorum if we do it in the evening with this Board. You email me with your thoughts of what works best. You want to move it a little earlier to like four?

James Marx, MD: Have you precluded the video conferencing? That seemed to work really well.

Coleen Lawrence: We can do video conferencing, we are just in more than one location.

Larry Nussbaum, MD: It is hard to find a place in the evening where we can video conference here.

Coleen Lawrence: In the evening, the video conferencing was getting difficult. So that does not rule us out, but just with the timing.

Carl Jeffery, Pharm.D.: With our experience with P&T, having all the members in one location, it really opens it up and there is much more dialog. When you have the video, they have to push the button to talk and there is always a delay.

Paul Oesterman, Pharm.D. Chairman: This night is getting late, so we will formally adjourn at 8:41PM. Thank you everyone, we got a lot done.

Meeting adjourned – 8:41PM