BRIAN SANDOVAL
Governor

STATE OF NEVADA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH CARE FINANCING AND POLICY
1100 E. William Street, Suite 101
Carson City, Nevada 89701
www.dhcfp.nv.gov

MICHAEL J. WILLDEN
Director

LAURIE SQUARTSOFF
Administrator

Nevada Medicaid
Drug Use Review (DUR) Board

Meeting Minutes
January 23, 2014

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.; Chris Shea, Pharm.D.; Jeff Zollinger, D.O.

Others Present:
DHCFP:
Coleen Lawrence, Chief, Program Services; Mary Griffith, RN, Pharmacy Services Specialist; Darrell Faircloth, Senior Deputy Attorney General; Laurie Squartsoff, Administrator;

HPES:
Beth Slamowitz, Pharm.D.

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

Others:
Camille Kerr, Allergan; Brandon Shaffs, Celgene; Deirdre Monroe, Allergan; Scott Larson, BMS; Raj Patel, BMS; Chris DeSimone, Aegerion; Lisa Jalaik, Genzym; Charissa Anne, J&J; Mike Stauffer, J&J; Gil Astruc, Takeda; Brian Hueston, Takeda; Fred Sego, Aegerion; Nancy Martin, Genzyme; Janie Tobilt, Vertex; Cathy Gross, Vertex; Lovel Robinson, Abbvie; Laura Hill, Abvie; Lori Hawarth, Bayer; Ken Laubmerc, Otsuka; Jeanette Belz, NV Psychiatric Association; Melissa Walsh, Novartis

Meeting called to order at 5:31 PM

Paul Oesterman, Pharm.D., Chairman: Ok, I would like to call the meeting to order for the Nevada Medicaid Drug Utilization Board. Thank you all for coming this evening. We brought nice weather for you, no snow on the ground and no ice, so that is a good thing. We will start off by doing a roll call by those in attendance, starting on the left, Coleen?

Coleen Lawrence: Good evening, Coleen Lawrence, Chief of Program Services for Nevada Medicaid

Mary Griffith: Mary Griffith, Pharmacy Specialist for Nevada Medicaid

Chris Shea, Pharm.D.: Chris Shea, Pharmacist in Reno

Dave England, Pharm.D.: Dave England, Pharmacist from Las Vegas

Darrell Faircloth: Darryl Faircloth with the Attorney General's Office on behalf of the Committee

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

Larry Nussbaum, MD: Larry Nussbaum, Physician, University of Nevada School of Medicine

Jeff Zollinger, DO: Jeff Zollinger, Pain Medicine Specialist here in Reno

James Marx, MD: Jim Marx, Pain Medicine in Las Vegas, Physician also

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

Paul Oesterman, Pharm.D., Chairman: What we are going to do is ask if there are any generic public comment by anybody in the audience before we get started on our agenda today? There is one item that has changed on the agenda and that is a sequence, under section 4, topic A, the antihyperlipidemics agents for homozygous familial hypercholesterolemia, that is going to be moved to after item J to enable to a guest who is coming from Carson City to speak on that. With that being said, we will go ahead and look at the minutes from our last meeting on July 25th, 2013, on the agenda it says 2012, so if the Committee could review those and make a motion to approve them.

James Marx, MD: I have some corrections. On Page 16, in the Juan Tripp paragraph, about the fourth sentence down, it is "DABA" but it should be "DATA", Tango instead of Bravo. Page 18, regarding what I said near the bottom of the page, "So you think you want to make sure there are no criteria to limit the time." The "no" is omitted there. Page 20, again me in the third paragraph, "42 claims resulted in about 1.4 million" not "4 million". On page 29, last paragraph, about seven lines down it has "Generic testing", it should be "Genetic testing." Page 37, again it is me, I guess I have to make sure I go on the record correctly, bottom of the page, "in the good old days about 20 years ago" it makes it sound like I got a pint of promethazine with codeine every year. That's all I have.

Paul Oesterman, Pharm.D., Chairman: Any other additions, deletions or corrections?

Larry Nussbaum, MD: I move we accept the meetings minutes as amended.

James Marx, MD: Second

Paul Oesterman, Pharm.D., Chairman: We have a motion and a second to approve the meeting minutes as amended. Any discussion? Seeing none, we will call for a vote. All those in favor of approving the minutes indicate so by saying, "Aye."

Board votes unanimous, "Aye."

Paul Oesterman, Pharm.D., Chairman: All those opposed say, "Nay". The minutes have been approved with the amendments. It is now time for our administrative update from the Department of Healthcare Financing and Policy. Coleen?

Coleen Lawrence: Good evening everybody, thank you very much Mr. Chairman. For the record my name is Coleen Lawrence, Chief of Program Services for Nevada Medicaid and Nevada Checkup. We have several updates that we want to give you. We are talking about Health Care Reform, members solicitation for the Board. Let me start off first of all to welcome Dr. Zollinger, thank you very much for accepting the appointment request for the Board. I'm going to turn it over to you first for an introduction vs. me trying to give everyone your background, I would just ask you. I will give you a few minutes to talk about yourself, this is your glory for a few minutes, you have a full captive audience.

Jeff Zollinger, DO: Ok, I'll keep it short. I am happy to be here, thank you for having me. I am pain management specialist, I work here in Reno. I finished my training about three years ago, so I am a newer physician on the block. I did my medical school training in Missouri, and then went up to the Mayo Clinic in Rochester in physical medicine and rehabilitation, and then my pain medicine fellowship in Jacksonville, FL at the Mayo Clinic in Florida. That's my training in a nutshell. I'm happy to be here and I know were in a kind of environment that there is a lot of discussion about opiates and things like that right now, all across the country, so hopefully I can provide the committee some advice and support in that regard.

Coleen Lawrence: You and Dr. Marx are going to have some very interesting discussions.

James Marx, MD: Yes, I think we are, it will be very interesting.

Coleen Lawrence: So welcome, we really do appreciate that you accepted our request for your appointment. For everybody else, we would like you to know that we are continuing to solicit more appointments onto the Board, we absolutely appreciate all your volunteer time on this Board, and what we would like to do is grow the membership on the Board to have additional education and different disciplines to have more lively discussion. Just because it is so entertaining at times. So if you have other colleagues that would be interested, please let me know, send them into my office and we will look for additional candidates. That also goes for you out in the audience. We have sent out solicitation letters to some of your colleagues to put that out there. It is also out on our website right now, there are some letters that you can take down off our website. According to the NRS and according to our own requirements, our members may not be a paid sponsor or accepting any funds at the time they are serving on any of our drug use review Boards or pharmacy and therapeutic committee from the manufacture at the time they are serving. So, that is our membership update right now. So at this time, I just want to say how much we appreciate all your time you serve on the Board because as you know you help us so much behind the scenes and you are a great asset for us in the Pharmacy Department, and we would not be where we are today. Nevada has had a great standing record of policy development over the years. So Health Care Reform. Health Care Reform is very exciting for us right now in Medicaid and Checkup. If you have not been following behind the scenes, we have given you guys an update each time. Nevada Medicaid and Nevada Checkup is proud to be one of the few states that has created what we call a seamless benefit plan for our newly eligible. The newly eligible population again as a reminder is the population between 19 and 64 of childless adults that have come in with the expansion of Medicaid. Expansion of Medicaid and the newly eligibles is kind of synonymous, you will hear the language intertwined with each other. We have been working diligently, our unit especially, we are writing the benefit policy plan for the newly eligible, and CMS, Centers for Medicare and Medicaid Services, has required that we submit a new State Plan Amendment just for this population. We have been diligently working every week with CMS since August to submit this State Plan. They wouldn't just let us use the

old one. And hopefully within days we will receive our approval from CMS. I say that as my fingers and toes are crossed right now, but that was the email I received today. We will be one of the first states in the nation to have received an approval on this plan, so we are pretty excited about that. What that means to you and how that translates is our pharmacy benefit is exactly the same as our fee-for-service pharmacy benefit. There is no difference, there are no new policies, there is nothing at all. It is what you see, so the preferred drug list is the same, Chapter 1200 is the same, there is nothing that you can go see that is going to say newly eligible policy is this. We might put one sentence in we decided in Chapter 100 that says the newly eligible get the same benefit as all the other eligibles. We thought we might do that. We haven't even decided. Other than that, it is a seamless benefit, so we are pretty excited about that part of it. The other pretty big piece about Health Care Reform is our provider recruitment. As you know if you are out there working in the field and you are a provider, if you are out there talking in the field and working with our providers, you know that providers within the State of Nevada are in a shortage in certain areas. So Medicaid is out there trying to find out the different reasons why. It is not just related to Nevada Medicaid and Nevada Checkup, it is across our whole health care system. This is a large issue and a discussion point in our last legislative session and it is from a public policy perspective. So they are looking from the department level, DHHS is, from licensure. We are looking at things like HRSA, as far as reciprocity issues from licensure from state to state. We are looking at things like APRN's had their scope changed this last year. So we are also looking at things we can do in the next legislative session to assist in that because with so many more people having health insurance, we are trying to figure out how we, as Medicaid and Checkup, can assure we have providers also because we are now competing even more with private insurance. So if you hear things out in the private market that are out in the market with private providers that you don't know if are true, or as I call them, Urban Myths, and you need clarification, especially in the pharmacy world, please refer them back over to our offices at Medicaid and we will clarify them. We are finding a lot of untruths out there regarding Medicaid and Checkup and we would like to help clarify them, because we don't want any barriers for us and for our recipients out there, and we definitely don't want to be barriers for our providers of health care. And if we find any opportunities to make things easier, we want to know that they are out there, that we can help clear things up for everybody. So that is pretty much our Health Care Reform update. OPR is coming, that is ordering and prescribing and referring provider initiative that is coming up. Medicare had implemented already. It is a mandate of Health Care Reform. What this requires is if you are an ordering, prescribing or referring provider, for Medicaid or Medicare, you must be enrolled with Medicaid or Medicare. We have not yet implemented it in Medicaid. We are staging this summer, we are looking at implementing it. We waited until after our January 1st, our big initiative first to see where we were going to implement this. What this means from a pharmacy perspective so everyone can appreciate this a little better than the rest of our system couldn't quite appreciate what was happening. But I'm sure you guys are going to be surprised. We have some practitioners out there that are not Medicaid enrolled and patients are going and paying cash for their prescription. I know, everyone is surprised. Nobody in our system actually believed me. So you will be required to be a Medicaid enrolled provider and so there is no shock on our system, they have come up with a streamlined app for those prescribers so they will just be known to Medicaid now. So we are looking at how we can assist this in the summer time. It is already required for Medicare now, but this affects more than just pharmacy, it is anywhere there is the triangle, where you have DME…

James Marx, MD: Coleen, is this the provider enrollment chain issue. Where people have to be in provider enrollment chain, is this what you are referring to? Is this the same issue?

Coleen Lawrence: So if you are…

James Marx, MD: So if you're not in PECOS, then you're not…

Mary Griffith: PECOS is the Medicare side

Coleen Lawrence: That's the Medicare side, so this would be for us. Right now Medicare is requiring it, we have not yet implemented it. I will tell you though if you are Medicare and you are denied for Medicare, we will deny you also right now.

James Marx, MD: So what is the impact of this, if a patient goes to a non-enrolled provider, they have no coverage for prescriptions, is that what you are saying? Or do you go shoot the provider? What happens?

Coleen Lawrence: Well, I'm not going to… the impact will be that they wouldn't get their prescription at the counter if the physician was not enrolled. What we are doing right now so you know, there is a lot of work happening behind the scenes. Looking at data to see which physicians and prescribers are not enrolled right now to see how big of an impact it is and honestly it is coming down to the residents, residents are exempt from this program, a lot of out of state providers, that is going to come down to a big PR program with our out of state hospitals, we will be working with them. And we are looking at how we can streamline that process. We are working with Sutter Health Care on out of state, we are going to work with Stanford, we are going to try to work with them before hand. We don't, so far, it doesn't look to be as big of a problem with us because we did an analysis and it was about 90% of the providers are enrolled already so far in our data that we are pulling, so we are looking pretty good. As it gets closer, they are going to start working with providers and start working through the associations and going there. But if they are not enrolled with us, it is going to be a little harder to outreach. Ok, that's all.

Paul Oesterman, Pharm.D., Chairman: Thank you Coleen. Let's go ahead and start with our clinical presentations. With each of the topics, we will ask for public comment first, as a reminder for those of you who have been here before and for those of you that are new to us tonight, we ask that you limit your talk to no more than five minutes because we have quite a bit to get through and it looks like we have quite a few people in the audience that have something valuable to add. As I said earlier, we are going to delay topic A, the HoFH products until the end. So we will start off with a discussion regarding the Ibuprofen and famotidine in combination utilization and clinical information. I will ask for any public comment regarding this product also known as Duexis. So we have no public comment, so we are now open to discussion by the Board in reviewing this. Just for background, Duexis is a combination product that contains two over the counter products, ibuprofen and famotidine, used for inflammation in those patients who have sensitive GI tracts. With that being said, there is a proposed criteria in the back, and Carl, I will let you take it from here.

Carl Jeffery, Pharm.D.: As Chairman Oesterman said, this is a combination of the over the counter products ibuprofen and famotidine. This product costs about $580 per month, so kind of excessive since both of these products are available over the counter for pennies and that is why we wanted to look at this one. You can see the utilization trends in the back here, and right now it is anywhere between $30,000 to $40,000 per month, in October around $50,000. I think it is worthwhile addressing by the Board. So the criteria that I proposed here, and I'm open to other input, it is the last page in the section. It can be approved for patients who have an allergy to the separate ingredients.

James Marx, MD: I don't understand that, how could they have an allergy to the separate ingredients and be ok with this? It doesn't make any sense at all. This is a solution in search of a problem.

Carl Jeffery, Pharm.D.: I'm perfectly happy to strike that first one and just have that they failed the separate ingredients.

James Marx, MD: What I would suggest is that they have failed an endogenous prostaglandin and or also a proton pump inhibitor, so that would be the only possible case I see for this. Absent that, I don't see any approval possible for this wonderful combination.

Chris Shea, Pharm.D.: Do we have to approve that? Is there a way, or has the P&T Committee already…

Carl Jeffery, Pharm.D.: We don't have a class like this on the PDL, but it is something we could bring to the P&T Committee, but it is this weird combination. We don't have an established class, it would be hard for them to address. With our open formulary we have for Medicaid there is really nothing we can do without the Boards okay to put any kind of restriction on it.

Chris Shea, Pharm.D.: So there is no way this Board or the P&T can actually just say you must use both drugs separately?

James Marx, MD: Yeah, what would be the advantage of taking this over, the over-the-counter products separately?

Carl Jeffery, Pharm.D.: I can't see an advantage, it is not extended release, or anything. If it was extended release, I could understand it a little bit, but it's not.

Paul Oesterman, Pharm.D., Chairman: But because of the open formulary, we have to cover it, we can't just say, no, it's not allowed. We have to put criteria in place.

Coleen Lawrence: You can put clinical criteria onto it.

Carl Jeffery, Pharm.D.: So I agree with Dr. Marx in that maybe we set some established drug classes that must be tried first before they have this.

James Marx, MD: Do we want to make a motion? Ok, I move that the proposed criteria for the coverage and limitation be such that first, a patient have failed either a misoprostal or an endogenous prostaglandin combination or individually administered prostaglandin or have an intolerance to proton pump inhibitors or an allergy to proton pump inhibitors and only then, failing those two criteria would it then be appropriate to authorize that.

Carl Jeffery, Pharm.D.: What would you think about including a Celebrex or

James Marx, MD: Or a COX-2 specific, be intolerant to a COX-2 specific non-steroidal. So I think that would be the criteria.

Dave England, Pharm.D.: I'll second that.

Paul Oesterman, Pharm.D., Chairman: So just for clarification, we have the three criteria will be, must have tried and failed a proton pump inhibitor, and/or failed a prostaglandin agent…

James Marx, MD: A proton pump inhibitor in combination with a conventional non-steroidal

Paul Oesterman, Pharm.D., Chairman: And then the third one would be an intolerance to a COX-2

James Marx, MD: Right.

Jeff Zollinger, DO: And I think to keep number two in there, they have to try and fail the separate ingredients too.

Carl Jeffery, Pharm.D.: So the other question I have for the Board, I need to clarify. Is this something that the Board wants to grandfather the people who are on this now, is this something we want to grandfather for the people who are currently on it or do we just want to cut them off and say get them over.

Paul Oesterman, Pharm.D., Chairman: I say we would cut them off or if we have to grandfather, give them one month to transition.

Darrell Faircloth: Just for clarity, do you intend that this, any one of these conditions be met, that would allow for utilization of this drug or some combination of those conditions you describe? Would they have to meet any one of those three?

James Marx, MD: They would have to be all three of those would have to have failed before it was approved. So it would be fail this AND this AND this. So it wouldn't it wouldn't be an "or", it would be "And" between these.

Darrell Faircloth: Thank you.

Dave England, Pharm.D.: I'll still approve that amendment.

Paul Oesterman, Pharm.D., Chairman: So we have a motion and a second for the modified proposed prior authorization criteria, including the fact that there would be a 30 day transition period for those members who are currently utilizing this combination Duexis Product. All those in favor of the motion as presented indicate so by saying, "Aye."

Board votes unanimous: "Aye."

Paul Oesterman, Pharm.D., Chairman: All opposed? Motion carries. Our next is the immunomodulators. Anybody in the audience want to present before the Board? For the record, please say who you are and what company you are with and remember you have a five minute time limit, otherwise the chair drops out.

Raj Patel: Hi, my name is Raj Patel, I'm a pharmacist by training. I am with Bristol Meyers Squib on the medical team. I work with rheumatologists and work with rheumatologists in this region. So I first thank you for the opportunity to provide public testimony on behalf of Orencia (abatacept) for rheumatoid arthritis. Currently, Orencia is not on the preferred drug list for this state. I would like to present some evidence and supporting data on why it should be considered.

Carl Jeffery, Pharm.D.: Let me clarify something real quick. This committee doesn't decide what is on the preferred drug list. All they are looking at is the criteria that is already established in Chapter 1200 and we are going to be updating that in case that changes your comments at all.

Raj Patel: My comments will just give an outline of Orencia in general and it will provide an overview as well an update on some of the clinical data. The indication for Orencia is intravenous and subcutaneous treatment for moderate to severe RA, as a first line agent. Meaning it does not require use of a DMARD or anti-TNF. It has a unique mechanism of action which is different than other agents in this class such as TNF inhibitors. With that unique mechanism of action it is a T-cell costimulation modulator and has been shown to decrease levels of multiple inflammatory mediators including TNF-alpha, IL-6, C-Reactive Protein, etc. So in addition to the T-cell activation, it doesn't work against just one cytokine, but several cytokines downstream from T-Cell activation. There are two formulations as I mentioned, intravenous and subcutaneous, where both have a fixed dose with no dose escalation allowed. As far as clinical information, we do have a comparative effectiveness study, a head-to-head study of Orencia subcutaneous vs. Humira subcutaneous in approximately 650 patients. In that study, efficacy was observed with Orencia plus methotrexate and Humira plus methotrexate and to be consistent at the one year time point as well as the two year time point. So 20% improvement 50%, 70%, 90% improvement. Radiographic non-progression was achieved at 85% for the Orencia plus methotrexate and 84% for the Humira plus methotrexate arm. As far as frequency of adverse events, they were similar in both groups numerically, but there were fewer discontinuations due to adverse events, serious adverse events, serious infections and fewer local injection site reactions on the Orencia plus methotrexate arm. As far as when we are looking at guidelines, the American College of Rheumatology as well as the European League of Rheumatism do suggest that after anti-TNF to move to another mechanism of action, such as Orencia. The European League does recommend Orencia as the first Biologic option. And in terms of a summary, so I have mentioned the comparative data where Orencia is shown efficacious and safety profile over a decent amount of years being on the market. So with the unique mechanism of action, and based on that information, it is the hope and with the utility out there with some of the rheumatologists I speak with, where Orencia is utilized after anti-TNF. So with that, that is the summary I have for you today.

Paul Oesterman, Pharm.D., Chairman: Before you leave, does the Board have any questions?

Carl Jeffery, Pharm.D.: I have a quick question. Have you had a chance to review the proposed criteria.

Raj Patel: I did notice that there were head to head studies as mentioned in the drug utilization review. And so, I did notice that there was a review that was published last year and then there was also a review that was kind of an older study with infliximab. I did review that.

Carl Jeffery, Pharm.D.: How about the proposed criteria, did you get a chance to review that? There is a copy on the back table, but I just wondered if you had a chance to review those.

Raj Patel: I haven't, no.

Carl Jeffery, Pharm.D.: Ok, I just wondered.

Raj Patel: Thank you.

Paul Oesterman, Pharm.D., Chairman: So we have in front of us the proposed prior authorization criteria. It appears that all of the immunomodulators are in here. Will this be coming back to us next time with the addition of Zelganz.

Carl Jeffery, Pharm.D.: Probably, it will probably be on the next agenda as well because the Xeljanz didn't make the time. I would also like to point out to the Board that I did print off a copy of current criteria from Chapter 1200 so you can compare the differences. The only difference in the criteria is the addition and subtraction and moving around of what products are included in what drug classes because some of the indications have changed. Other than that, the criteria is all the same.

Paul Oesterman, Pharm.D., Chairman: So these are all the FDA approved indications.

Carl Jeffery, Pharm.D.: Exactly

Coleen Lawrence: So I have a question on this one. Is this one of the ones we can move toward a more class level, or do we still have to continue bringing it back every time because we add a drug. We have been trying to get away from this going back and forth at the drug level.

Carl Jeffery, Pharm.D.: I struggled to see if I could get it that way, but because each one has kind of a different indication, it is difficult to do.

Coleen Lawrence: Just because the time it takes us to update it in the policy, we're 90 days out every time, we can't keep up. So then the other question, are we doing it 100% based on the FDA indication?

Carl Jeffery, Pharm.D.: Yes, that is how the criteria are proposed now.

Dave England, Pharm.D.: One question, I think we have discussed this in the past, but in the event a physician and the patient are going through the criteria, and a patient may or may not follow the criteria, but there is peer reviewed literature out there that suggests under these circumstances this may be utilized even though it is not an FDA indicated use. Is that the sort of question that goes to the system so that it can be revaluated to be used for that off-label use, even though there is literature out there to support the use? If it fails the criteria they haven't tried yet?

Carl Jeffery, Pharm.D.: Right, if there is good peer reviewed literature available, the clinical pharmacist at the call center can review those and make that judgment.

Dave England, Pharm.D.: For the most part, I can see you would want to follow the FDA guidelines, but there are those things that fall outside the FDA guidelines as long as there is some rationale for going off the guidelines.

Coleen Lawrence: I'm trying to play Devil's Advocate here. If it is the wish of the Board to follow specifically to the FDA indications, one possibility is to do like we do our antiretrovirals which we just put a statement in there that we follow FDA indications. If you're going to be more restrictive or if we are going to have other guidelines, then we just don't put that statement in there, but if you look in our policy for antiretrovirals, we say we are following the guidelines, and then you don't have to get that specific because we don't have to use it as an educational tool. We do somethings in other areas where we are using this as an educational tool. But it is an option, especially if things are coming out down the pipeline, it is just an option that we have.

Paul Oesterman, Pharm.D., Chairman: I think, going back to Dave's comment, that the approval does exist for off-label indications with this class of drugs, I think it will be very difficult to be able to say that we would adhere strictly to the FDA indications.

Coleen Lawrence: So it's not for off-label. What happens for under 21, you have Early Periodic Screening and Diagnostic Testing, so EPSDT, will come into play, so that will come into under 21 and so medical necessity would play out and if there is other peer reviewed literature that comes into play with the physician and then they could have a peer to peer discussion with the literature. That would come into discussion with that.

Dave England, Pharm.D.: But do we have to make some kind of comment to that, because in general we are going by FDA guidelines. But in the event that the patient falls outside that criteria, they fail or have an allergy or new trend we haven't caught up with, they still have that option to go with peer reviewed literature and have that discussion to say that even though this doesn't meet the criteria here, my patient meets this criteria.

Coleen Lawrence: That applies to under 21, EPSDT. EPSDT is an over-arching policy for all services and that is not a caveat you see on any of our services because it falls under Chapter 1500 of our Medicaid Services Manual, and that applies to any service that we provide for children under the age of 21. So you won't see that on any specific drug.

Dave England, Pharm.D.: But for some of these medications on here, granted you might see children using these under 21, but you will see the majority of these patients considerably over the age of 21 using these. I think there needs to be an option there if they don't meet the FDA criteria that there can still be some rationale so they can try it, of why we would approve it rather than, it sounds good, we want to try something else. See where I'm coming from?

Coleen Lawrence: If you want an indication that is for other than the coverage criteria listed in the policy then you would need to write why it would be an acceptable coverage criteria for that drug. Now if you want to have the peer reviewed, how are you guys handling that right now, other than EPSDT?

Carl Jeffery, Pharm.D.: A pharmacist reviews it at the clinical call center and uses their judgment if it is appropriate.

Dave England, Pharm.D.: OK, that is acceptable, I don't know if we need to include that in here, because I thought we had this discussion before, but it is kind of an over-arching concept anyway. I just want to make sure it is still in effect, we haven't made any changes to that.

James Marx, MD: Are we accepting the criteria as it is written here? I move that we accept the criteria as written here.

Chris Shea, Pharm.D.: I second.

Paul Oesterman, Pharm.D., Chairman: We have a motion and a second to approve the proposed prior authorization criteria for the immunomodulators. Any further discussion? All those in favor for approving as presented, please indicate so by saying, "Aye."

Board votes unanimous: "Aye."

Paul Oesterman, Pharm.D., Chairman: All opposed say, "Nay". The immunomodulators have been approved.

Carl Jeffery, Pharm.D.: Chairman, if you want to, the physician for the hypercholesterolemia is here.

Paul Oesterman, Pharm.D., Chairman: OK, I'll go back to that after J, don't mix me up here. Next topic is a presentation of long and short acting opioid use and clinical information. Any public comment on that? Seeing none, then the Board will go ahead and discuss our opiate use. What we have is an ongoing discussion regarding the use of long acting and short acting opiates. It may come as a surprise to no one that we have a lot of opiate abuse and we are trying to assure these are used most appropriately. I think that is one of the obligations that we as the Board have to make sure that patients are not using to excess the short acting in the absence of a long acting opiate. So I will go ahead and open it up for discussion with our Board. We have some pain specialists, so hopefully this will be a lively discussion and interaction.

James Marx, MD: Well, this is an obviously a very complicated issue and it's somewhat affected by the retail availability of these agents, of the willingness of retail pharmacies to stock the agents that might be more preferential. It appears to me that what has happened that there has been an escalation in price and some of the pharmacies are being under paid for the wholesale pricing and are refusing to stock some of these long acting. I don't know if some of you guys in retail can tell, but what we are seeing in Las Vegas, is it is very difficult to get most of the long actings on a predicable and continued basis and consequently, we end up relying more on the short actings. I think there is no question that the long acting formulations are preferable, but the reality of the situation is that they tend to be not available in the market place. Patients do use a lot of opioids, and part of the reason we do use a lot of opioids is, they are a very effective drug class, probably one of the most effective drug classes out there that comparative to most of the other drug classes, opioids tend to be very effective at reducing pain, whereas most of the other drug classes are only marginally effective at what they are purported to do. And patients do become dependent on them, not necessarily in a bad way, and what has happened is that there has been a pendulum swing from the maybe the more freely prescribing and dispensing to one now where we see some of the retail pharmacist, and Walgreen's in particular, In don't have any problem, make them call now on every prescription and ask for the physician, they want to know the ICD-9 codes, they want to know what the plan is to get the patient off the medication. They want to know what alternative therapies have been used. It is has really become onerous, and it is even escalated, or deteriorated to the point where patients are being pigeon holed, particularly if they are young and don't look like they have any sort of underlying medical issue that would require an opiate, they are made to feel very offended, I guess is a polite way to put it. It is a very complicated issue. I think it is going to be more determined by the stocking patterns of the retail pharmacies than it is about prior authorizations. We know that we have made it fairly easy to get authorization of long acting, but we are just seeing it difficult to actually get them.

Paul Oesterman, Pharm.D., Chairman: I think, what you are saying is that the drug wholesalers are limiting the amounts they are supplying to pharmacies. There is a set amount and once you hit that, toward the end of the month, if you want a particular product…

James Marx, MD: Sometimes not even at the end of the month. For example, Wal-Mart, like a lot of other pharmacies that have just in time mechanism, actually, most of the Wal-Marts in Las Vegas only order

opiates twice a week and they sort of bunch their orders together. So if you happen to hit at the wrong place, you may be waiting for 10 or 11 days for your prescription to be filled. That begs the question if the patient, if they are really opiate dependent and they really need their medication, what do you want them to do. Well what they are doing is they are going to seek alternative sources for that medication which is exactly the opposite of the intent of the regulatory effect has been.

Jeff Zollinger, DO: So from my perspective, I have a lot of Medicaid patients in my practice, a fair amount of experience with the patients. Obviously with opiates, there is inherent risk that we are all concerned about, addiction, tolerance, those are very common issues that we have to deal with as pain specialists. In my practice, what I try to do is limit the amount of short acting as much as possible and convert to long acting. And like what Dr. Marx was saying sometimes we get access problems, getting patients on the long acting agents. One of the theories I hold to is that you take a short acting and taking two oxycodone 30's every 4 hours and is like you get that immediate release and it is kind of an up and down effect all day long. You get his huge dose and then after 4-6 hours it is leaving your system and you have to take it again. I tell my patient it is the roller coaster effect that we want to get away from. Not only that, but a lot of patients will mistake pain relief for the euphoric effect they get from the immediate release. So in my opinion, I try to convert as many patients as I can to a long acting agents and try to reduce the amount of short acting. And we are talking, Dr. Marx mentioned that it is an effective class of medication in relieving pain, and I think when we talk about acute pain, it can be a very effective treatment. When we are talking about chronic pain conditions, there is limited evidence to support narcotics on a long term basis. We don't have a lot of evidence to support opiates to begin with on a long term basis, for chronic basis. But we do, because there are limited options for our patients. But I agree, if we have more options and more availability to long acting, I think that would be helpful to us. One of the medications, I have very little problem getting is fentanyl. I don't have a lot of problems getting, but when you look at the use deterrent medications like Opana, OxyContin has a new formulation, those are difficult to get for our Medicaid patients.

Carl Jeffery, Pharm.D.: Looking at trends in the back here, does this surprise you or is this what you would expect?

Jeff Zollinger, DO: I would expect that the morphine would be up there, the long acting morphine, it is the most accessible for our patients. That is kind of what I would expect.

Dave England, Pharm.D.: This is, from the discussion, that this appears to be a discussion you might need to have with the Board of Pharmacy or the local Narcotic Task Force. The only reason I can see from my community practice days, that the pharmacy would be hesitant to keep these medications in stock is because either one, the Board or the DEA is coming down on them, or for some reason their corporate headquarters is saying, we have issues nationally, so therefore we are going to put the kibosh on this and maybe we need to have that discussion with some of the regulatory agencies, not just us, but some regulatory agencies as what other problems are going on out there that is causing this to take place. I know from when I was in community practice I didn't have any restriction put on me saying you can only buy so many of this per month, but I have had this happen to me in California where they have restrictions on so many, like the patients couldn't have so many prescriptions per month and that restriction on them. So it is kind of strange that that is coming from a regulatory point and not from a treatment point of view.

Coleen Lawrence: So we actually have had this conversation with Walgreens because, and what I would suggest is that we could get the Board of Pharmacy and the Retails Association of Nevada and have the discussion overall to see what we can do, like a little mini task force, to continue our force in what we are trying to do in general with Nevada Medicaid and Nevada Checkup and bring them in as partners to the table. We were looking at our lock-in program and starting to see trends in the lock-in program and we were wondering if there was some patterns happening on how they were stocking. And if they had an internal procedure that was occurring. So they had volunteered to come help us and looking at some of their internal procedures also. What we can do is take it back and talk to the Retail Association of Nevada also the Board of Pharmacy and Dr. Marx and Dr. Zollinger and anyone else that would like to work with us, we can form a little subcommittee from here to look at these procedures.

James Marx, MD: I know the task force is scheduled to meet fairly soon. I haven't talked to Larry recently, but I know it is coming very soon. The real issue I see is that, what we see in Las Vegas and Southern Nevada is there is virtually no class that is readily available. So even the extended release morphine is dependent on the day of the week, the phase of the moon. It is frequently not available, and patients are going to 10-30 pharmacies to find it, and it is creating a hazard because the pharmacist won't call, or won't disclose how much they have and if they did there would be a rush of people or be held up, so they don't want to disclose what their stock situation is. It has really become a mess. I think the long-term or even the short-term effect is going to be detrimental. We are going to see, and we already see it, a lot more heroion overdose because people are resorting to heroin over the pharmaceutical available. It is becoming a serious problem and I think the real issue, I think the pharmacies are under tremendous pressure, the distributors are under tremendous pressure, they put pressure on the chain and retailers and the result is there is a real shortage in the market place.

Coleen Lawrence: We discovered it based on our lock-in program and it wasn't because of Walgreens itself, it was the location of the Walgreens, I just want to be very clear about that. Walgreens has actually been a great partner with us with helping us to identify and we have got that Walgreens was turning people away, but what it was it was that they didn't have it on their shelves. So it was the same issue that you are identifying. We thought someone was jumping from pharmacy to pharmacy, and they were getting locked in.

James Marx, MD: The one pharmacy requirement went away about 18 months ago, we want the patient to tell us, but it is virtually impossible for a patient to use one pharmacy in a given a month, not even month to month, but if they have a long-acting and short-acting, they may have to go one place for the short-acting and another for the long-acting. It is impossible to monitor the situation.

Jeff Zollinger, DO: I think now, it is obviously an issue now with patients going to different pharmacies, if physicians are using the prescription monitoring program that Nevada has, it is less of an issue because now, when I walk in to see a patient, I know if they have gone to another pharmacy. To me it isn't that big of an issue to go to another pharmacy because I can see where they filled, how much, what was dispensed. I haven't had any issues with getting morphine, that must be different here in Reno. Long acting morphine, I haven't had any issues getting. I have a lot of Medicaid patients on morphine and I can't think of a single patient who has called me back and said they couldn't get it or they didn't have access to it. If they did, I wouldn't have a problem with them going to a different pharmacy to get it.

Paul Oesterman, Pharm.D., Chairman: You brought up the task force reports, and those are very valuable to use. I would like to see them used more appropriately. There are some of the chain pharmacies that will not allow their pharmacists to have internet access to access this. They have no way of looking at that.

James Marx, MD: Currently some of them are actually doing the inquiries through some sort of intermediary, so they don't get them right away, they have to wait, they have to queue them up somewhere, and then they have to wait for them to come back. We went through a lot of effort to make it an almost real-time system for them, it is thwarted in that situation.

Jeff Zollinger, DO: I think, the last time I checked, it has been a year now, I know it was less than 50% of Nevada physicians are actually registered on the Nevada Prescription monitoring program, which is terrible. The last I heard was that it was going to become more mandated by the State Medical Boards that physicians become registered. So hopefully, that will lend to help diversion and problems with medications if more physicians are looking at the monitoring program.

Chris Shea, Pharm.D.: Something I have talked to Carl about before and I don't have any experience in the clinical setting at all. In rehab and nursing side, what we have seen and what we will often run into with the other pharmacies is what Dr. Marx is saying is that they one, won't stock some of these drugs because the reimbursement on their side isn't worth the time of day, if you're going to put out $1000 for a bottle of OxyContin and get $1010 back, they would just as soon not do it and then have all the paperwork that goes with it, to track it. Schedule 2 is not like any other legend drug, so it becomes a real issue, and one of the issues I was talking to Carl about, and it's not the case now, but as an example, the pharmacies were supposed to be using brand name Duragesic because that is what were told you had to use, but that is in conflict with our laws that state a generic must be used if available. So then you have a pharmacy that is buying a box of branded generics for $400 when the generic equivalent is $25 and they are not even recouping what they paid, they might get $375 for it. I think it is a crazy dynamic, like you said, I don't know what the issue is, but I can tell you that a lot of times the outcry is the reimbursement. And then the handling of these drugs, like you mentioned Paul, is the wholesaler, if you go above a certain percentage of your dollars, or pill per day, they will cut you off, because they have gotten in trouble with the FDA, so you can go up, I've already met my narcotic limit for the week. I have to buy more omeprazole just so I can get a stupid bottle of Percocet. That is how crazy it is. I think there is just so many dynamics that could be affected here. I think in Las Vegas you have a lot more small independent pharmacies around

James Marx, MD: Not any more really.

Chris Shea, Pharm.D.: Well, they are going away, but in Reno, you have a couple comparatively speaking, where in Vegas there are more independent folks than there would be that could be impacted by some of those things.

Paul Oesterman, Pharm.D., Chairman: I think this this is a really good discussion, and I really don't want to put an end to it, but in the interest of time, I think Coleen, you have come up with an idea of a task force subcommittee and the members of this Committee, maybe we can sit down with the Board of Pharmacy and the DEA and maybe some of the leadership from the chains to see what we can do to try to make sure the Medicaid and other patients in general, don't run into this brick wall that they are running into.

Dave England, Pharm.D.: And if that is the issue, can we put the wholesaler on the Board too, someone from Bergen and Cardinal and all the other places. If we can have one of their representatives too so they can see what is going on. The pressure is being put on by someone somewhere else, and that is where we have to find where that pressure is coming from, and we have to see what we can do to alleviate that. Therapeutics should be the bottom line, not necessarily do we want to limit our economics.

Paul Oesterman, Pharm.D., Chairman: And this is not a unique situation to Nevada, so maybe we should reach out to other contacts to find out how they are handling some of these issues. So we won't take any formal action on this. So we will move it to the agenda for next time.

Our next topic is the presentation for the platelet inhibitor use. I will ask for any public comment. Seeing none, the primary focus of this is we have platelet inhibitors as a therapeutic class and there are a couple of new products, so we are updating the criteria to include the new products, prasugrel and ticagrelor. Whatever happened to easy drug names? Carl do you want to go through this?

Carl Jeffery, Pharm.D.: We brought this before the Board because there is, in your binder, some criteria, but there are newer agents, Effient, is also available. This is the other branded product that is commonly prescribed. So to level the playing field, we wanted to bring this one up with criteria that would mirror the Brilinta. None of the criteria for the Brilinta would change, it is just the addition of these new criteria. The top line if you're looking at the claim count, the top one is clopidogrel, all the other ones are down below. Same with the by paid amount, clopidogrel is the top, and then Aggrenox then Effient then Brilinta. Part of the reason we are pulling out just the Brilinta and Effient because they are second line agents compared to the Aggrenox, aspirin and the clopidogrel are all first line

Paul Oesterman, Pharm.D., Chairman: So there has been no change to the prior authorization criteria, you are just going to add a second agent?

Carl Jeffery, Pharm.D.: That is correct.

Paul Oesterman, Pharm.D., Chairman: I will ask for a motion to approve the proposed addition of the Effient product to the existing proposed prior authorization criteria.

Larry Nussbaum, MD: I move we accept these criteria.

Paul Oesterman, Pharm.D., Chairman: Dr. Nussbaum has made the motion, do we have a second?

Dave England, Pharm.D.: Second.

Paul Oesterman, Pharm.D., Chairman: Dave England has seconded. We have a motion and a second, any discussion? If not, we will ask for a vote, all those in favor of the approval, say "Aye."

Board votes unanimous: "Aye."

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

Our next topic is regarding the presentation on botulinum toxin and information from that. Do we have anybody in the audience to speak on that? Please step forward and tell us who you are and what company you are with and remember you have a five minute limit.

Deirdre Monroe: Good evening, my name is Deirdre Monroe and I am a Senior Medical Scientific Manager with Allergan, the manufacture of Botox. I am here tonight to provide comments on the botulinum toxin policy, billing guide and the PA. First we want to thank the Board for all the work that has been done on these documents and I only have four recommendations. Our first two recommendations are with respect to the PA. The first recommendation to add language that we provided to the PA criteria that will address the difference between the billing guides lists of covered ICD-9 diagnosis codes vs. the PA criteria list of covered indications. By stating that the PA list of medications is not a comprehensive list of indications for which the botulism toxins are covered, and that providers should refer to the ICD-9 diagnosis codes in the billing guide for the complete list. Our second recommendation is to consider adding our recommended or similar safety language to the PA to assure providers utilize appropriate product labeling and scientific literature to select the appropriate drug and dose regimen for their patients. The third recommendation, is to add two statements to the botulism toxin policy in the Medicaid Services Manual Chapter 600 attachment, the first statement will help identify where providers can find a complete list of covered indications and also provides safety language with respect to the appropriate use of these medications and in order to avoid serious adverse events. This is similar to the PA recommendations that we just made. The second statement would be added to the description section of the policy, in order to reinforce that the different biologicals of the botulism toxin family are not interchangeable, and to help avoid medication errors. This suggests the statement has been adapted with revisions from the language included in pages 1-2 of Nevada's Overview Summary Section of your botulism toxin report. Our fourth and final recommendation is to add ICD-9 diagnosis codes to the billing guide that are consistent with the FDA approved indications for the Botox covered listed in the PA criteria and these ICD-9 codes we are asking to be added are following FDA approved indications, overactive bladder, neurogenic detrusor activity, prophylactic treatment of chronic migraine, and upper limb spasticity. To give some background on our request to add our safety language around the non-interchangeable products in the botulism toxin class along with the physicians utilizing appropriate product labeling, etc., is part of the communications component of the 2009 agreement still in effect with the FDA where we were asked that this type of information be on as many communication vehicles as possible. Finally, per the discussion at the July DUR Board meeting, we have also submitted the appropriate ICD-10 codes for the FDA approved indications for the botulism toxin class. So I thank you for your time and consideration for our recommendations and if you have any questions?

Carl Jeffery, Pharm.D.: Just for the reference for the Board real quick, this is the letter that I handed out, it has "Allergan" in the upper left corner. It has all the information that she presented.

Coleen Lawrence: Thank you for all the information that you have sent and presented. This is one of those policies that we actually have policy in Chapter 600 right now that is in our physician manual. As a recap from our last meeting, we didn't have policy in chapter 1200, which is our pharmacy manual, but we had some in our physicians manual. So our team was looking at it behind the scenes and honestly with everything else that was going on with Health Care Reform, we have not been able to approach everything behind the scenes to align the two policies. Carl I think you have an attempt to look at what we would do with coverage and limitations. What you have is Chapter 600, which is currently existing policy for the physician's manual. What we would do, is need to decide where to house this policy, because we don't want it in both manuals because it is a duplication and could be inconsistent. That was one that thing that when it was presented last time, it kind of sent up a red flag to us that we wanted to align them and have them in one place. So that is to bring everyone back up to speed where we were at

last time. And then, as our speaker mentioned, we have a list of ICD-9 codes, but we don't have, do we have that for them?

Carl Jeffery, Pharm.D.: They are in here, it was actually provided by the manufacturer.

Coleen Lawrence: Ok, great. So that is the third piece of this. In the billing manual for our providers, is the list of covered ICD-9 codes that we reference in our billing procedures. That gives you the full spectrum of what we are doing now.

Dave England, Pharm.D.: Looking at this and the comments made about the interchangeability, I didn't notice that this was saying that they are all interchangeable, they have the same indication for, like for cervical dystonia, if we can use one product over another, that is the physicians decision on which one to use not necessarily us telling them which one they can use. Is there something I missed in the interchangeability?

Deirdre Monroe: Yeah, it is in their package label for each of them, that their biologic activity is not interchangeable, so products are not directly interchangeable. You have to follow the product label for each of those doses.

Jeff Zollinger, DO: So 50 units of Botox is so much different than 50 units of Myobloc.

Dave England, Pharm.D.: I didn't get the impression we were saying they were interchangeable, I was just saying if you have this diagnosis, you could use that dose with that product, and not have to substitute. I just want to be sure, I thought maybe I was missing something.

Jeff Zollinger, DO: Can I just make a comment on product monitoring. Are we saying here that Botox is an approved treatment for chronic migraine?

James Marx, MD: That is the criteria for 15 days per month.

Jeff Zollinger, DO: Ok, so that is different from my experience, when I submit for approval for Botox treatment, I have done that on a number of patients, they will approve the code for the actual injection, but Medicaid will not cover the cost of the Botox.

Carl Jeffery, Pharm.D.: Right now it is only in the physician's manual. Coleen, can you speak on that?

Coleen Lawrence: I was looking at that.

Jeff Zollinger, DO: Is Medicaid paying for the actual Botox? Is that what we are saying here?

Coleen Lawrence: Right now, Chapter 600, where it says policy 6-11, that is for a physician's office, it is covered right now, for certain diagnosis. I was trying to…

Jeff Zollinger, DO: I think it is a 346.70 for chronic migraine.

Carl Jeffery, Pharm.D.: In the book is the most common diagnosis used, and chronic migraine is by far the most frequent use in here.

Coleen Lawrence: But right now it is not considered a current diagnosis for Chapter 600. If you look at the billing manual right now, it is not a current diagnosis that is covered. The mock-up that you were

given has the diagnosis that was added, but that is not the current policy that is covered. So that is why your authorizations are not being covered.

Paul Oesterman, Pharm.D., Chairman: Would it make more sense to be in Chapter 600 rather than pharmacy, since it is a non-cosmetic office administration? Not that I am trying to turf this.

Coleen Lawrence: That is to everyone here to discuss. It was a red flag the last time this was brought up. Botox was discussed and then that is why we wanted to bring it back up since we have Botox in Chapter 600 too, I wanted to bring it back up again because I didn't want to have two policies in two different areas.

Carl Jeffery, Pharm.D.: We have the ability in the pharmacy system to track this and put a prior authorization in place. You will see how almost all of these are given in a physician's office, which is appropriate, but we certainly have the ability to reject them in the point of sale system through the physician offices.

Coleen Lawrence: We don't pay for the Botox at all? We have some that we did pay for that were non-cosmetic?

Carl Jeffery, Pharm.D.: All of these, there are some paid claims for this. There is a chart of utilization, there are 30-40 claims that are coming through now.

James Marx, MD: Why would this be dispensed at a pharmacy? I am not clear on that. That's an opportunity for diversion I think.

Carl Jeffery, Pharm.D.: I think the scenario would anticipate, someone is picking it up at a pharmacy and then taking it to the physician's office for administration.

Chris Shea, Pharm.D.: The physician is not getting paid to buy the drug, you wouldn't want to buy the drug, get paid to administer it and then not get reimbursed for the drug. So maybe the physician is saying, I don't get paid for the drug, go get it filled at the pharmacy, bring it here and I will administer it. Is probably what is going on if there is no way for you guys to get reimbursed?

Jeff Zollinger, DO: It can be rather costly, so I wouldn't want to buy the Botox and do the injection, do the procedure, get paid for the administration and then not get paid for the drug. So that's where there is a discrepancy, it is approved, but Botox is not being reimbursed for the physician. So that is my question right now is that it is not an option for us.

Chris Shea, Pharm.D.: I know other situations like that, there are arrangements that physicians and pharmacies have, you have a pharmacy or you all agree on who they are going to use, you know when their appointment is, or if there was something worked out.

James Marx, MD: Not only diversion, but there is temperature criteria for its stability, so there are a couple concerns

Chris Shea, Pharm.D.: Right, there are a couple of drugs where the physician can work with the pharmacies to get the drugs

Paul Oesterman, Pharm.D., Chairman: We used to do this with chemo products all the time, that isn't that uncommon.

Chris Shea, Pharm.D.: Just so you're not stuck not getting paid for the drug.

Coleen Lawrence: So is this an appropriate drug to have dispensed at the pharmacy, or do we want to have it dispensed in the outpatient physician environment? And then we can work on coverage criteria.

James Marx, MD: I think that is where you want to go.

Coleen Lawrence: What is the appropriate delivery model?

James Marx, MD: I think putting it in the retail pharmacy is wrong and I think you may end up with some diversion to medical spas or beauty salons, I see that as a real issue.

Chris Shea, Pharm.D.: It makes more sense for physicians to get paid for the drug.

Dave England, Pharm.D.: Especially in light of the fact with all the difficulties that there are with some pharmacies, there are other drugs with a lot more use than these things. I could see restrictions being put on this for retail pharmacies. The wholesalers probably have to supply to them as well, but I don't see any reason why the administrator can't get reimbursed for the medication.

Coleen Lawrence: OK. What I hear is that there is a discussion to review the coverage criteria?

Carl Jeffery, Pharm.D.: Can we make it non-covered for retail outlets and only a physician administered drug?

Coleen Lawrence: Yeah, because you are going to have a physician administered outlet.

Carl Jeffery, Pharm.D.: But we can turn it off for POS.

Coleen Lawrence: We'll look at that option, and then we will look at the other coverage criteria because we have some expansion of some diagnosis. How about we do our homework on this side? And bring it back for the next meeting.

Paul Oesterman, Pharm.D., Chairman: So the action will be to table this until the next meeting.

Our next topic will be the review of buprenorphine and the buprenorphine/naloxone combinations products.

James Marx, MD: Did we need to approve that last action?

Paul Oesterman, Pharm.D., Chairman: There was no action. The agenda item was tabled from the last meeting.

Carl Jeffery, Pharm.D.: This one we actually accepted the proposed recommendations, but was asked to bring it back again this time to re-review it, so we can have more discussion. What is attached in here is the criteria that will be made effective April 1, 2014, and is in the handouts that I sent out with the "Draft" on it because it is still in the draft form. This is what was approved at the last meeting. I think there was some hesitancy about adding the Subutex only available to pregnant and lactating females.

James Marx, MD: For background, the recent, Subutex is discouraged because Subutex does have some abuse potential that the Suboxone doesn't have, so that was the reason for the encouragement in the regulation of the use of Suboxone and the Subutex. And that is why we had this, some people think that the incorporation of the Narcan with the buprenorphine is counterproductive in the transition process. That is why there was a cut over transition period.

Dave England, Pharm.D.: This is the question too, in the event we have a patient in these guidelines, it says approval good for one year, in most cases like in any of these treatment programs, not all patients are successful the first time through, if they have to go back through a second or third time, have we made adjustments in here about use, so if the patient fails, there is a specific time when the patient can start up again.

James Marx, MD: Part of the problem is that the PI actually states it is indicated for temporary sort of treatment program, and that has been an issue with a lot of the PBMs is that they are saying, what is the plan for treatment. I think the discussion at the last meeting is that there are some pretty good, powered, studies that show that most people, 96-97% of patients will revert if they go off, so that is pretty strong evidence that these people will be on this for a long time, and certainly the six year history of methadone and narcotic agonists show where patients are needed to have to methadone to maintain sobriety in terms of avoiding the other street narcotics. The Suboxone is probably going to be in the same class.

Dave England, Pharm.D.: That is what I just wanted to be sure in the event we have a patient that comes on this and falls off, and then wants to come back again, this isn't going to restrict them because they had a treatment failure.

James Marx, MD: I don't think that is how it works.

Carl Jeffery, Pharm.D.: That isn't how the criteria is. The PA is good for a year, so once they are approved, if they fall off, as long as their PA is still good within that year, they can get back on.

James Marx, MD: There are a couple other drugs in this class now, so I don't know if you want to make this a class type.

Carl Jeffery, Pharm.D.: Right, I think we have the criteria on here pretty generic, but you are right there are some generic medications out now, Subzolv.

Paul Oesterman, Pharm.D., Chairman: We should probably put that on the agenda next time, since it wasn't on the agenda for this time, we can't take any action on that.

Larry Nussbaum, MD: Last time we talked about taking off the counseling specific requirements on there.

Coleen Lawrence: I think that is encouraged.

James Marx, MD: The rational for that was that there was a study a year and a half ago now that actually, they thought patients with concurrent counseling do much better and actually they found they did exactly the same whether they were on the Suboxone or off. I think we came up with the criteria that it would be recommended and advised, but not be mandatory, which some of the PBMs are trying to make it mandatory, but the study doesn't really hold that criteria up. 96% of patients fail if they were on counseling or not, there was absolutely no difference in the rate.

Coleen Lawrence: Now we have it as encouraged in the draft criteria.

James Marx, MD: So we say it is encouraged.

Paul Oesterman, Pharm.D., Chairman: So at this point, we will bring this back next time for inclusion of new products also.

Carl Jeffery, Pharm.D.: But we are still going forward with the changes, right?

Paul Oesterman, Pharm.D., Chairman: This is what was approved last time. Ok, before we go to the next item, we will take a five or ten minute break.

[Break]

Paul Oesterman, Pharm.D., Chairman: We are going to go ahead and continue our discussion. Our next item on the agenda is a presentation regarding injectable epinephrine products. Anybody in the audience have a comment? Seeing none, we will go ahead and discuss this, Carl do you want to go ahead?

Carl Jeffery, Pharm.D.: The reason we brought this forward because there is a new product on the market called Auvi-Q, and at the last P&T Committee meeting, they had a demo device, it was pretty cool. It is an audible device if you are having an anaphylactic response, and it talks you through how to give the dose. It is pretty novel idea, but we believe it is limited use, so we don't know if it needs to be rolled out to everyone, so that is why we brought it here. In the packet I handed out was some proposed criteria that I put together, basically if someone is impaired somehow, if they can't see or comprehend the directions.

Paul Oesterman, Pharm.D., Chairman: Just looking at the criteria, I think grammatically, there is an extra word in there, the word, "has"

Carl Jeffery, Pharm.D.: Yep, you're right.

Paul Oesterman, Pharm.D., Chairman: I'm not familiar with this product, is it an adult only or is there a peds dose?

Carl Jeffery, Pharm.D.: There are two strengths.

Paul Oesterman, Pharm.D., Chairman: in theory then, a pediatric or young child could not breathe could get this?

Carl Jeffery, Pharm.D.: I don't know at what age you would want to patient to self-administer, even if it was giving you the directions. I don't think my almost 10 year old could do this, jab a needle in your leg.

Dave England, Pharm.D.: Trying to be politically correct, do you get your choice of language?

Carl Jeffery, Pharm.D.: That's a good question, I don't know.

Dave England, Pharm.D.: I wouldn't want to restrict it to just specific languages, some of our recipients can speak other languages, and not specific to English.

Paul Oesterman, Pharm.D., Chairman: What is our usage of epinephrine products?

Carl Jeffery, Pharm.D.: Over the past six months, 6 prescriptions, not real big.

Paul Oesterman, Pharm.D., Chairman: Six prescriptions for it? I'm just trying to figure out the cost, because it seems like there is quite a bit of fluctuation, from $25 to $862

Carl Jeffery, Pharm.D.: It's hard to judge, because the lower prices are copays, Medicaid is the secondary payer.

Darrell Faircloth: You say there is some utilization for the Auvi-Q?

Carl Jeffery, Pharm.D.: There was, there were six prescriptions in the last six months.

Dave England, Pharm.D.: Under the circumstances, it seems, the criteria is ok, it won't be first line, but if there is going to be an issue, it should be available. I move that we approve the PA criteria.

Paul Oesterman, Pharm.D., Chairman: Do you want this inability to comprehend be documented somehow?

Carl Jeffery, Pharm.D.: It is the physician's office that would be calling in the PA, so I think we can take their word for it.

Paul Oesterman, Pharm.D., Chairman: So we have a motion?

James Marx, MD: Second.

Paul Oesterman, Pharm.D., Chairman: And a second. Any further discussion? Seeing none, we will call for a vote, all those in favor of approving the proposed prior authorization criteria, indicate so by saying, "Aye."

Board votes unanimous: "Aye."

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

James Marx, MD: Is this available in multiple languages?

Carl Jeffery, Pharm.D.: I'm not sure.

James Marx, MD: I think to be federally compliant, you have to be language neutral, I wonder if this is compliant with that.

Dave England, Pharm.D.: That's what I was wondering, because our criteria does not say English Language, just has language issues, so if this comes in other languages, this wouldn't restrict this that way it is written.

Paul Oesterman, Pharm.D., Chairman: Our next item on the agenda is the presentation of the promethazine with codeine?

Carl Jeffery, Pharm.D.: Do you want to go back to the hypercholesterolemia?

Paul Oesterman, Pharm.D., Chairman: Yes, we can do that now, so we are going to go back to topic 4, item A, presentation of the antihyperlipidemics agents. Do we have anyone in the audience who would like to speak?

B Bottenberg: My name is B Bottenberg, and I am internist in Carson City. I have been practicing medicine here in Nevada for 20 years, I am certified in internal medicine and lipidology. One of my passions is preventing and treating vascular disease and cholesterol is probably the biggest factor in this. There is a disease called familial hyperlipidemia which causes very, very high LDL cholesterol, bad cholesterol, it is a devastating disease if you have it. As a rule, we get a gene from mom and a gene from dad, and with regards to cholesterol, if you get good genes from mom and good genes from dad, your LDL cholesterol if you take care of yourself is about 100. If you get a bum gene from one of your parents and a good gene from the other, as a rule your LDL is about 200. If you get two bad genes, your LDL cholesterol is about 400, give or take 100s. So if you get one good gene and one bad gene and your LDL is 200, you're at high risk for a heart attack in your 40's, give or take 10 years. If you get 2 bum genes, and you have an LDL cholesterol of 400, 500, or 600, 800, 1000, these are the people who have heart attacks as teenagers. They don't normally survive into their 20's very well. So this is a devastating problem if you get it. And if your child has it, we have very few options to treat it. One of the few things we can do is plasmaphoresis, which is almost like dialysis, and that is really tough because you have to fly or drive to another place, we don't have it here. There is a drug called Juxtapid which we can use for this. The standard drugs that we normally use for cholesterol don't really work for this. Right now, the gene defect that we have identified that causes familial hyperlipidemia, number around 1600. Right now Medicaid has limited the use of this drug to just 4 specific gene defects. To make the diagnosis of familial hyperlipidemia, we don't even do gene testing. It is expensive, it is not accurate. There are so many gene defects and different allele problems that the gene testing isn't even relevant. So I just propose that you remove the necessity to have one of the 4 gene defects in order to approve the drug. Only one in a million babies are born with this. It is not likely we are going to see this drug used very much. In order for me to prescribe it, I have to be registered with the pharmaceutical company, it can't be prescribed by just anybody. And for a pharmacy to dispense it, they have to be registered with the drug company as well. It's not going to be abuse, it isn't a drug that is going to be used very often. And I certainly don't want to be the physician that says, "Mr. Jones, I can't use this drug because your kid doesn't meet one of the 4 gene defect criteria." So I just ask that you remove that one criteria from the use of the drug.

James Marx, MD: What happens when you give these people high dose niacin? Does niacin have any effect on this?

B Bottenberg: Familial hyperlipidemia, the process of high cholesterol, the liver makes the cholesterol and then it sends these receptors out to grab it. Some people don't even make these receptors. Once the cholesterol goes in the blood stream, there is no way to get it out. Niacin kind of slows down the production of cholesterol, 15-20%, so when your cholesterol is 800, and you just dropped it to 700, we're not really getting very far.

Coleen Lawrence: So doctor, if you could stay there for a second for us, I would appreciate it. So we actually talked about this after we had the manufacturers talk to us afterwards last time and did some more research on it, and that is exactly what we found, it is really treated as a specialty drug. You have to register for the utilization of the drug, and it's highly managed. The drug itself and anybody that would

be utilizing the drug are managed afterwards, drug A and drug B are through two pathways with the manufacturers and the physician. We have proposed criteria when we first released this, but pretty much what we are going to propose is to lift all the criteria, and just to continue to manage and monitor the patients as we go forward.

B Bottenberg: If I might add, the FDA has approved us to use this drug, and they don't require us to do the gene testing either.

Coleen Lawrence: So when it first came to our attention when looking at this, we weren't aware of all the steps. After the last meeting after we tabled the discussion, and then we worked with the manufactures afterwards and doing further research we found out the additional steps and clinical pathways taken with this drug. That is our proposal, you have these in here, but that is because of the release of the information. So that is our recommendation now that we are here, it's come full circle.

Dave England, Pharm.D.: So for instance, the impression that I am getting, a lot of time, because these are limited by the manufacturer, you have to meet their criteria before you get this, so basically we are following their criteria. The other thing, Is there any rationale for using both of these at the same time? Should we limit it to just one?

BBottenberg: I think we should leave that up to a case by case basis. These are really desperate people and families. I don't have a lot of experience with this drug. I think it should be left up to a case by case basis.

Coleen Lawrence: You wouldn't have any clinical criteria, we would remove, we wouldn't have a policy on it, because the utilization of it, we would have very few. Yes they are very expensive, but they're going to hit our high-dollar amount report that we monitor monthly anyways. It is going to go through a specialty pharmacy review anyway, so we are going to be able to monitor them that way. Now that we know more about the process, it is just so unique honestly. So we will just monitor the use that way, and we have a different process to monitor. Personally, I don't think there is a rationale to have a policy on them. Maybe if they explode, and we have 10 new products on the market, then we can look at it again.

James Marx, MD: There is already a REMS program in place, so that what was the rationale, the REMS would take care of it. So we are just going to strike the criteria?

Carl Jeffery, Pharm.D.: There is nothing in place now, this was proposed.

James Marx, MD: So we don't have to do anything.

Paul Oesterman, Pharm.D., Chairman: Inaction will be our action. Out of curiosity, does the company that make these two products have a compassionate care programs? How would that follow Medicaid?

Nancy Martin: My name is Nancy Martin, I am a senior medical science liaison for Genzyme for the other product which is Kynamro or mipomersen. As Dr. Bottenberg mentioned, genetic testing isn't really a recommendation. So your question was about the compassionate use. We do have compassionate use programs. Right now, patients are required to be 18 years of age or older. One thing just in case the committee wasn't aware because this is pretty recent, the FH foundation, which is based here in the US, and the National Lipid Association, January 16th, filed for ICD-10 codes for both heterozygous FH and homozygous FH. So that might add a little bit more information, so now you would

have an actual diagnosis of homozygous FH. One final note, and even though it sounds as though this will be eliminated, I noted Kynamro is actually a once weekly injection, so it had 30 vials or prefilled syringes for 30 days, and that is actually almost a couple years' worth, so something to consider.

Chris DeSimone: Good evening, my name Chris DeSimone, and I am a national account manager with Agerion Pharmaceuticals. To your question about compassionate use program, Agerion pharmaceuticals does offer such a program for the labeled indication. I also wanted to add what we offer for government programs is a J-cap Program, where we cap the cost of the product on an annual basis and that is just an additional program. It wasn't asked, but it is something we offer to Nevada and Medicaid recipients. So compassionate use program to your question and what we call a Juxtapid cost assurance program.

Paul Oesterman, Pharm.D., Chairman: So just to wrap this up, it looks like we are not going to put any prior authorization criteria and will just be monitoring as we go. Back into sequence, our Promethazine with codeine. Last time we had a discussion about this and we had requested some additional usage data. Just a little background, promethazine with codeine is a cough syrup that has been around forever, at least 20 years. It is a very effective product, but unfortunately, has been found to work its way into illicit use and has some street names such as sippin' syrup, purple drink. Our concern was the utilization and I think, thank you for the further information, we have in front of us the usage of January 2013 through December 2013. Looking at this, it seems like there are several patients that have consumed or been prescribed some rather large quantities and I am just curious at looking at this as to the number of prescribers. Could it be the same prescriber or the circumstances?

Carl Jeffery, Pharm.D.: if you look at this other page, relating back to the recipient, here is the number of prescribers. You see prescriber 1, he or she prescriber 253 claims for 50,000 ml.

Paul Oesterman, Pharm.D., Chairman: If that is an emergency department physician, I'm ok with that. Someone out of their true scope of practice, I would be a little concerned.

Dave England, Pharm.D.: One the one patient with 24 claims and 2 doctors, where does this coordinate?

Carl Jeffery, Pharm.D.: If you look four pages back, then it starts by prescriber, I left their names off and assigned them a number.

Jeff Zollinger, DO: Pretty impressive.

James Marx, MD: So what are we going to do about this?

Jeff Zollinger, DO: What can we do about this?

Carl Jeffery, Pharm.D.: We can do a quantity limits, a certain number of milliliters per X number of days.

Paul Oesterman, Pharm.D., Chairman: I know there some years back where the physicians would use this as a liquid form of codeine, and the promethazine was just a side benefit, but now we have much more readily available, and better products for analgesic purposes. I would like to see us try to put together a quantity limit.

Coleen Lawrence: Would it help you if we looked at the top number and did a few demographics for you? Are they kids, adults, type of prescriber, and maybe the delivery model a little bit?

Paul Oesterman, Pharm.D., Chairman: I would like that information, but I don't want this to go on much longer.

Coleen Lawrence: Right, you could still make a decision, but if that helps paint a picture.

James Marx, MD: We need to start developing some criteria. I think there is some reasonable amount that we can come up with.

Carl Jeffery, Pharm.D.: We can start high and kind of ratchet it down as we go

Coleen Lawrence: And while you make that first line cut, then we can come back in addition to that and get you a little bit more because like you said, depending on who it is, maybe that will help you for the next level.

Paul Oesterman, Pharm.D., Chairman: Someone is getting almost 12000 ML in a year, that's a lot, I don't use that much gas in my car. In the number of prescriptions in an outpatient setting that I see, I think 8 ounces is a reasonable amount to give in a single fill.

Carl Jeffery, Pharm.D.: Do you want to limit 8 ounces per fill, or per 30 days, or 15 day.

James Marx, MD: this should last six months, this is a lot. The dose is 5ml, so we're not talking about 30 ml per dose or something like that.

Dave England, Pharm.D.: If someone is getting it for what it is used for, symptomatic treatment, then that should last you. So can we maybe limit to 8 ounces.

Carl Jeffery, Pharm.D.: Per fill or per number of days, per year?

Dave England, Pharm.D.: 8 ounces per month.

James Marx, MD: Looking at the, even down to the third page, you're at a liter a year, that's an incredible amount.

Dave England, Pharm.D.: if you have a chronic cough for that long,

Carl Jeffery, Pharm.D.: So we have 8 ounces per 30 days.

Paul Oesterman, Pharm.D., Chairman: 8 ounces per 30 days is a starting amount, let's stick with metric, so 240ml

James Marx, MD: You're going to allow 240ml per 30 days, that's like 50 doses

Chris Shea, Pharm.D.: That's still a lot.

James Marx, MD: Even if it is every 4 to 6 hours, even so. I say that if you're going to do something…

Paul Oesterman, Pharm.D., Chairman: What about 120.

James Marx, MD: And I certainly wouldn't allow a fill every month, if you're going to allow that much, then maybe three fills per year.

Paul Oesterman, Pharm.D., Chairman: So 120ml at a time up to three fills per year, does that sound reasonable?

James Marx, MD: That's 24 doses.

Paul Oesterman, Pharm.D., Chairman: 120 ML per fill, no more than 3 fills per year, without prior authorization.

Coleen Lawrence: What is the criteria?

Carl Jeffery, Pharm.D.: What would justify someone exceeding this?

Dave England, Pharm.D.: I can't think of a reason why someone would need more.

Chris Shea, Pharm.D.: There is no criteria.

Dave England, Pharm.D.: They have more issues than cough.

James Marx, MD: I will move that Paul's recommendation of 120 ml per fill up to three fills per rolling 12 month period be accepted.

Dave England, Pharm.D.: I guess if we have two prescribers.

Coleen Lawrence: Do we have any grandfathering or anything like that?

Paul Oesterman, Pharm.D., Chairman: Let's grandfather, and then is there a way to send out a newsletter?

Coleen Lawrence: We do a web announcement.

Paul Oesterman, Pharm.D., Chairman: Ok, a web announcement.

Carl Jeffery, Pharm.D.: We can do some messaging in the system too for the pharmacies before it turns on.

Paul Oesterman, Pharm.D., Chairman: So we have a motion.

Dave England, Pharm.D.: I'll accept the amendment.

Larry Nussbaum, MD: Second.

Paul Oesterman, Pharm.D., Chairman: We have a motion and a second. Any further discussion? Hearing none, all those in favor of the proposal of the limitation of promethazine with codeine to 120 ml per fill, no more than 3 fills per rolling 12 months. All those in favor, say, "Aye."

Board votes unanimous: "Aye."

Paul Oesterman, Pharm.D., Chairman: All those opposed say, "Nay" Motion carries. One additional question that I have is could we get utilization data? I doubt there is very much, but the promethazine VC, I don't think there will be very much use.

James Marx, MD: But the street value of the Activas, because that is the recognizable product.

Paul Oesterman, Pharm.D., Chairman: Because it is purple, that is what they recognize.

Ok, the last clinical presentation is the review of psychotropic drug use in children. Any public comment? Seeing none, we'll go ahead and address this by the Board. We did receive an additional handout with the breakdown in particular of zero to three age population. I know you have all had a moment to peruse this very carefully, the newborn that took 120 - 1mg alprazolam tablets, I'm impressed.

James Marx, MD: Weren't we also going to look at the anticonvulsants of patients who have a seizure diagnosis?

Coleen Lawrence: They have or did not have?

James Marx, MD: Either way, it would probably be easier to look at those that have the diagnosis.

Dave England, Pharm.D.: I think the question was that were these in conjunction with anti-seizure meds.

Carl Jeffery, Pharm.D.: I think for the sake of discussion, I don't know that we have any action behind this, it was just for the Board to review. It is something we want to keep tabs on.

Larry Nussbaum, MD: I thought we had talked about setting up a task force in order to look at the rationality of the psychotropic medications in children.

Coleen Lawrence: That is what we still have on our plate. Honestly, just this last two months, we have been buried.

James Marx, MD: So it would be like the psychotropic utilization in children or something like that.

Coleen Lawrence: Right. These little guys are going to be one of the main areas where we want to keep looking at. We want to keep the reports coming and not lose sight of them.

Paul Oesterman, Pharm.D., Chairman: I think if we can approach this and make an impact at the zero to three age, then we won't continue on it, but once they get started on it, looking at the trend lines, they're not taken off any meds, they continue to get meds added on.

Larry Nussbaum, MD: There are multiple issues here. How many patients are on how many different types of drugs, is just one of the things the task force would want to look at. Even having these numbers, and Nevada is the most stringent state by far for prior authorizations. It is the only state that has prior authorization for all psychotropic drugs for all kids under 18.

Coleen Lawrence: In the back, Carl provided a list of what other states are doing. It is a snapshot of what other states are doing. Some of them are actually a little bit more strict than us in some areas. We have the counseling side in there, we did well in the comprehensive look at the child. Some states are doing more of the enforcement on the requirement of enforcing the diagnosis and FDA indication, and we know what we are doing is more tell us what the diagnosis and or indication of the drug is. Obviously, that is why a lot of our smaller guys are getting through. It is different when you look at the different classes, at the different ages for ADHD vs. psychotropics vs. everything else.

Paul Oesterman, Pharm.D., Chairman: this information is all outpatient?

Carl Jeffery, Pharm.D.: We didn't split it out.

Paul Oesterman, Pharm.D., Chairman: I'm seeing Precedex.

Carl Jeffery, Pharm.D.: And it would be the same with the midazolam.

Dave England, Pharm.D.: I hope these aren't outpatient use.

Coleen Lawrence: The drug report that you gave though Carl, it is all..

Carl Jeffery, Pharm.D.: It is PAD.

Coleen Lawrence: So the physician administered drugs.

Dave England, Pharm.D.: I also am thinking a lot of the midazolam, is for outpatient procedures.

Carl Jeffery, Pharm.D.: It can be given in the physician's office too.

Dave England, Pharm.D.: Some of them don't make sense.

Carl Jeffery, Pharm.D.: It is just the high doses in the young, like the Abilify 10mg in a 3-year-old, Risperdal,

Larry Nussbaum, MD: Some of these are going to be seizure medication.

Paul Oesterman, Pharm.D., Chairman: I would like to see this come back with a detailed showing something like you did with the promethazine to make sure the use is appropriate. Coleen, you're going to put together a task force.

Coleen Lawrence: Yes.

Paul Oesterman, Pharm.D., Chairman: Anything else on the psychotropic drug use?

James Marx, MD: You know, Coleen, I just wonder if it would be possible to look at any ER data on a cross tab for patients that are on ant seizure medication and ER admissions for say like withdrawal type seizures. There's a hazard of having these people on that, and then if they are non-compliant, and then have subsequent seizure activity. I just wonder if it is something worth looking at.

Coleen Lawrence: We'll have to brainstorm on how to find them.

Carl Jeffery, Pharm.D.: We would have to run all the kids who received an anticonvulsant and then send it over to MMIS.

Coleen Lawrence: We could do that through the DSS data, it is just a matter of finding if that is a diagnosable admission. You would have to give me a set of ICD-9s.

James Marx, MD: I think we could do the 9's pretty easy, but the 10s would be pretty hard. I think we could come up with some codes.

Coleen Lawrence: And then it is a matter of if they have it coded correctly on the discharge. Just tell me story of what you're looking for and we'll work together on that.

Paul Oesterman, Pharm.D., Chairman: The next item on the agenda, the DUR Board requested reports. Carl, do you want to take us through these?

Carl Jeffery, Pharm.D.: The first one on here is the black box warning drugs. We picked some of the top ones that we thought would be the most impactful here. Dave I think you were the one that originally requested this report. I don't know if this is what you wanted to see.

Dave England, Pharm.D.: The question was more if are we seeing, how many of our black box warnings, not all 400 of them, but certain ones, do we see a lot of those in our patients, and do we have excessive adverse events and things like that. But this, I was trying to read through this.

Carl Jeffery, Pharm.D.: Capturing the adverse events is hard for us. I'm not sure how we would capture that.

Paul Oesterman, Pharm.D., Chairman: I'm curious about September and Metformin.

Carl Jeffery, Pharm.D.: It was a rebill, we recycled some claims. So I will continue to see if we can get some kind of data regarding this. Make it a little more useful, track if anything is related to that.

Dave England, Pharm.D.: I'll go back and read the minutes, I know specifically my concern was, we know there are a lot of black box warning drugs out there, are we really seeing that many issues with them? Having a black box warning, do they have much impact on our recipients. I know in the community practice world, the black box isn't as effective because they constantly come up.

Carl Jeffery, Pharm.D.: What about looking at products where a black box warning was added to see if that changes any prescribing trends? Some of those go back years.

Dave England, Pharm.D.: That might be a good thing to look at.

Carl Jeffery, Pharm.D.: The next several pages here are, the top ten by class by claim count and cost. By far the biggest number of claims is the opioid analgesics. Which is nothing out of the ordinary, 55,000 claims per quarter. The next one is by paid amount. Looking at the antipsychotics. We're really close to about a million dollars a month for Abilify. Abilify has a crazy amount of usage, but antipsychotics up here at top, then you get the chemotherapy and blood factor products. I don't know if the Board has any ideas on how to get our hands around the blood factor products and how to address this. We see a lot of utilization for the blood factor products, and I have no idea on how to address this. We can make sure all these patients are being appropriately managed.

Paul Oesterman, Pharm.D., Chairman: Can we get for next time a report of all the patients that are receiving blood factor products?

Carl Jeffery, Pharm.D.: Sure, we can look at that.

Chris Shea, Pharm.D.: Are we pretty consistent with other states as far as criteria goes?

Carl Jeffery, Pharm.D.: I can ask around other states, but I am not aware of any other states that address this either. It is such an individualized disease and so specialized, that I think it is hard to address.

Chris Shea, Pharm.D.: You're not going to withhold it.

Coleen Lawrence: The main thing is thing is clients that most states look at, doing a specialty pharmacy which in the future we will be doing, we have an option to going with one specialty pharmacy and have that case management in there. And then this April, the Division will be rolling out our care management option, and that will be based on acuity of the patients. So obviously, these patients will be rising to the top and it will be fee for service clients and that will give them an option and have that case management. But from other states, it is the same thing, they get managed through a specialty pharmacy or they get managed through case management. It comes down to compliance for their medication.

Paul Oesterman, Pharm.D., Chairman: Right now there is just…

Coleen Lawrence: We've looked at them before and they hit the top claim report, and not erroneous claims, if they are they get looked at that way. We just have to explain it to our audit staff every time, they can't believe the claims are that much.

Carl Jeffery, Pharm.D.: And the volume they bill, they bill by units, so it comes over with 100,000 units on a claim and they have trouble with that. The next two are just kind of more specific, I don't find as much use in these, you can see the top drug spend is the quinolone derivatives, this includes Abilify and some other. And then it kind of breaks it down a little more. By claim count, the same way. Then we move to the top 50 drugs on the next pages. We have quarter 2, 2013, our old friend Abilify at the top, $2.4 million for the quarter, we're seeing a lot of that, and then the hemophilia is close after.

Jeff Zollinger, DO: So what is the prior authorization for Abilify?

Carl Jeffery, Pharm.D.: The only criteria we have is for kids under 18, and it is pretty simple, they just have to have a diagnosis. Anybody over 18, there are no criteria. It is one of our preferred agents, so people can get that pretty easily. The number is a little misleading because we do collect rebates on the back end, but we don't report that here.

Paul Oesterman, Pharm.D., Chairman: Can we get a report next time of the age breakdown of the Abilify of over and under 18?

Carl Jeffery, Pharm.D.: Sure.

Paul Oesterman, Pharm.D., Chairman: It just seems like it is a large claim count, they average quantity per prescription, the average day supply would be a lot higher.

Carl Jeffery, Pharm.D.: Right, you would expect to see close to 30.

Larry Nussbaum, MD: Could you also pull it up by diagnosis too?

Carl Jeffery, Pharm.D.: Sure, I'll add that on there. I know a lot of this is driven, Chris could probably speak to it, but in a long term care setting, there are a lot of claims for 7 and 14 day because of CMS. That skews some of our numbers.

Chris Shea, Pharm.D.: You guys shouldn't see any of that.

Carl Jeffery, Pharm.D.: There are some pharmacies in Las Vegas that are, that bill this way.

Chris Shea, Pharm.D.: Obviously, you could have the eligible person under the age of 65, but that is not that many of claims.

Carl Jeffery, Pharm.D.: I agree that we shouldn't see that many.

Chris Shea, Pharm.D.: So maybe they are picking up the copays.

Carl Jeffery, Pharm.D.: I agree that we shouldn't see it, but we do.

Chris Shea, Pharm.D.: So they are billing…

Carl Jeffery, Pharm.D.: Seven days.

Coleen Lawrence: We can look at the location too. We can break it down, looking at the seven days and seeing if they are SNFs.

Chris Shea, Pharm.D.: That would be interesting to see if they are doing that.

Carl Jeffery, Pharm.D.: They have told me they send out seven days at a time, and at the end of the month, they reverse and rebill the amount that was actually used.

Paul Oesterman, Pharm.D., Chairman: A lot of raised eyebrows right now.

Chris Shea, Pharm.D.: To a Medicare recipient, that would be standard of practice.

Carl Jeffery, Pharm.D.: We don't have a lot of Medicaid patients as primary in a nursing home.

Chris Shea, Pharm.D.: You would see a few.

Carl Jeffery, Pharm.D.: Right, most of them are going to be Medicare D, and they may have a disability.

Chris Shea, Pharm.D.: The other thing in my opinion is billing back, because that would be a short cycle drug on Medicare D, maybe because of the drug and the type of fills they do.

Coleen Lawrence: Is it just a habit of dispensing?

Chris Shea, Pharm.D.: Right, it could just be their habit of dispensing that drug that way and their computer system may come up and tell them to send only 7 to 14 day, so maybe something simple like that. I hope it wouldn't be on purpose. I don't know maybe,

Coleen Lawrence: We can also go back to see if they are readjusting that too.

James Marx, MD: Going back to something that Paul said, something that really strikes me is the number of these items, for example, somatotropin is a daily drug, how would anybody get a 14 days supply out of these clients. It is not something you would use half the time, you use it every day. To me that indicates that there is something not quite right there. Looking at somatotropin, in the top third here, 17 days or 14 days. That really kind of jumps out at me. I just wonder how much of that is really being used, or if it is being used appropriately at all? I guess the omeprazole 23 or 24 is ok, I can buy that, but somatotropin for a half of month doesn't make sense. Celexa, 18 days, that doesn't make much sense.

Chris Shea, Pharm.D.: Duloxetine, 17 days.

James Marx, MD: These are daily drugs, how can they be…but look at famotidine, 24 days, that's a good drug.

Dave England, Pharm.D.: Where's the Naprosyn?

Carl Jeffery, Pharm.D.: I can dig into that.

James Marx, MD: You can see there is more compliance with metformin, 26 days, that's good, so they should all be like that, 26 or 28 days.

Paul Oesterman, Pharm.D., Chairman: Is there anybody else on the Board that would like to bring back next time with more detail? Top 50 is something we can look at.

Carl Jeffery, Pharm.D.: On the next one, get your magnifying glass out, it is a lot of data and I didn't want multiple pages. This DUR conflict code on the top is a compliance measure, it actually reports it, it doesn't stop the claim, but tells the pharmacy that the patient should have picked this up 8 days ago. It is just for reporting at this time.

Paul Oesterman, Pharm.D., Chairman: Just out of curiosity, let's take for example that second one, lisinopril, on compliance, does it show us anywhere on the report how many were picked up too late, and if we need to do something a little more for patient education to prevent them from having a stroke?

Carl Jeffery, Pharm.D.: It tells you, you see along the top, all the original paid, you can see how many are paid and rejected, for lisinopril, none were rejected because of this edit. 132 were reversed because of that.

Chris Shea, Pharm.D.: So they reversed them?

Carl Jeffery, Pharm.D.: It goes either way, so it could have been too soon. We don't know if it is too soon or too late, but still within their time frame, if it is hitting the too soon edit, it will be down here at the bottom.

James Marx, MD: Promethazine with Codeine is 0.41%, I know nobody is waiting on those.

Paul Oesterman, Pharm.D., Chairman: Is there a way to generate a report for late pickup of antihypertensive meds, say if we can do something to help patients be more compliant with those medications that we are treating the silent killer types of diseases, lipid, hypertension, diabetes.

Carl Jeffery, Pharm.D.: Let me take that away to see what I can find.

Paul Oesterman, Pharm.D., Chairman: Do we have any products that are going generic with a significant impact?

Carl Jeffery, Pharm.D.: The big one that did go generic already is the Cymbalta, it just went generic, and that is going to be big. We are hoping that will help us a lot. Off the top of my head, I can't think of anything else coming out right now. Detrol LA is already available, but that won't be huge.

Larry Nussbaum, MD: What did you see with Lipitor?

Carl Jeffery, Pharm.D.: I don't recall the number off the top of my head. I think it was pretty good. And to wrap things up real quick, the retro DUR, we have a couple projects, one that is still ongoing, and one we completed. Taking a look at people who are on multiple migraine medications, so we have the results on those. The next one we are working on is the zolpidem dosing recommendations that have come out, the shorter duration.

James Marx, MD: I don't see any mention in here of the complex sleep behavior which has become a bigger issue, there is no mention of that in here.

Carl Jeffery, Pharm.D.: For the RetroDUR?

James Marx, MD: I see some dose recommendations, there was actually a very well publicized case in Las Vegas where an attorney's wife who had been on anti seizure medicine was given a new prescription for Ambien, and apparently there was an FDA directive that came out in April of this year, and very poorly distributed that stated that the initial doses in women should not be more than 5mg. She got 10mg and got in her car, drove up an embankment and was nearly killed. Actually, she wasn't hurt at all, which was really amazing. I talked to a number of pharmacies and not a single pharmacy had any sort of conflict or red flag in their system advising on an initial fill for Ambien.

Carl Jeffery, Pharm.D.: That is one of the things we are addressing here, it is the last bullet point. They have the, "The FDA required the manufacturers of Ambien and Ambien CR, Eduluar and Zolpimist to lower the recommended dose." From 10 to 5 or 12.5 to 6.25 for the CR products. The responses we have received so far have been positive from the provider community. I think we are getting a lot of responses that say thanks for the information, but I'm not going to make any changes.

Paul Oesterman, Pharm.D., Chairman: I don't know, I'm interpreting this a little differently. I'm looking at the responses, a lot that had pushed back and granted if you get one patient lowered within the guidelines, but the middle bullet point where it says, "50 returned survey noted that the prescriber plans to re-assess…" I'd like to see the follow up to those 50. What happened with them. I guess I'm looking more for bottom line. How many patients were reduced from 10 mg dose to a 5mg dose.

Carl Jeffery, Pharm.D.: These are still preliminary, we haven't received all the letters back. We will pull that together for next time.

Paul Oesterman, Pharm.D., Chairman: Looking at the other survey, the migraine, What about the possibility of utilizing a prior authorization if the patient doesn't have any prophylactic therapy to point them in that direction. Member number 3, I was concerned with the provider says he is not taking Medicaid and doesn't prescribe. Where is this patient getting this medication from? Does he have his own prescription pad he filling out on behalf of someone? That was a big red flag that jumped out at me.

James Marx, MD: I think the other upshot of this is that, if there were only 4 people that gave this dose of butalbital combination, I guess that's not too bad, but this is probably a very small segment and this is probably the number one cause of rebound headaches and drug overuse, this medication to treat headaches. This combination has never really been effective for chronic use and probably contributes tremendously to rebound headache phenomena.

Paul Oesterman, Pharm.D., Chairman: Something else we could send out as a reminder or educational tool.

James Marx, MD: The patients do like it, they don't want to give up their Fioricet, it is a problem.

Carl Jeffery, Pharm.D.: Our next planned RetroDUR activity is looking at patients receiving Suboxone or Subutex who are also receiving an opioid. I'm always looking for other ideas

Paul Oesterman, Pharm.D., Chairman: What I would like to see is more results, how effective are we at the interventions that we make?

Coleen Lawrence: On the migraine one, we could look at the DUR utilization and see what is going on with those recipients to see what their average ER utilization is. That will quickly show us if we are managing it.

James Marx, MD: Are you talking in relation to Suboxone and Subutex patients?

Coleen Lawrence: For the migraine ones.

James Marx, MD: Oh yea, it's going to be horrible. That will be another Phenergan with Codeine.

Coleen Lawrence: And to start your outcome, you would need a baseline.

Paul Oesterman, Pharm.D., Chairman: So we can make a motion for the approval for the approval criteria for the Suboxone and Subutex and concurrent opioid use.

Carl Jeffery, Pharm.D.: Yes, that is in the works already.

Paul Oesterman, Pharm.D., Chairman: So can we get a motion to formalize that from the Committee

James Marx, MD: So moved.

Dave England, Pharm.D.: Second.

Paul Oesterman, Pharm.D., Chairman: So we have a motion to proceed with the drug utilization review that you are planning, all in favor indicate by saying, "Aye."

Board votes unanimous: "Aye."

Paul Oesterman, Pharm.D., Chairman: All opposed say, "Nay". Ok motion carries. Any other discussion before closing.

Chris Shea, Pharm.D.: Carl and I talked about it before, but could we re-evaluate the criteria for the PPI's?

Carl Jeffery, Pharm.D.: I think at this point, they are so inexpensive anymore and so commonly used, but we still have the clinical criteria in place to review if it is still necessary still.

James Marx, MD: For PPIs?

Chris Shea, Pharm.D.: Some of that is me being selfish where I practice, filling out prior authorization for mechanically ventilated patients and I'm getting denied for PPIs for these folks because it doesn't fit the criteria. It is just really tough to treat a G-tube patients where we are doing all the right things and they still reflux, and that doesn't fit in with the criteria. So we start an aspirin just so we can get the PA

approved. It is just such a huge game anymore with these drugs. There might be some abuse in some aspects, but for us with the ventilator patients.

Carl Jeffery, Pharm.D.: You can get around that with a fair quantity limit.

Chris Shea, Pharm.D.: Yeah, I'm not opposed to that, but what I'm told now is not with the standard of practice anymore.

Paul Oesterman, Pharm.D., Chairman: Ok, we can have that on the next agenda.

James Marx, MD: Maybe, I think what Chris is eluding to is patients in long term care really sort of a different animal than our typical outpatient ambulatory patient, and maybe some of those prior authorization requirements can be relaxed or changed so the long term care is treated a little differently.

Chris Shea, Pharm.D.: We fight with that all the time, and I try to explain to them, I write letters and they send me the same thing back. This is legitimate and this is tough for those folks.

Coleen Lawrence: I think that is something we are going to look at, like the Botox, some things need to be in different delivery models, regional pharmacy vs. physician's office, we'll bring some more proposals forward in that setting, and nursing facility vs. retail.

Chris Shea, Pharm.D.: Yeah, nursing facilities now aren't what they used to be, we're sitting there with ventilated, dialysis patients that are very complex patient that have an average length of stay of 20-30 days, we're trying to get them home and to maximize their outcomes.

Paul Oesterman, Pharm.D., Chairman: Any last comments from the public? Thank you for sticking it out with us. Our next meeting is scheduled for…

Carl Jeffery, Pharm.D.: April 24, 2014.

Paul Oesterman, Pharm.D., Chairman: Same time, same place.

Carl Jeffery, Pharm.D.: Yes, if this works for everybody.

Coleen Lawrence: Does everyone like this new time slot?

Chris Shea, Pharm.D.: Yes, works for me.

Paul Oesterman, Pharm.D., Chairman: We will formally adjourn the meeting, thank you everyone.

Meeting adjourned at 8:12 PM