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Meeting Minutes – September 26, 2013 P&T Committee

JW Marriott Las Vegas Resort and Spa
221 N. Rampart Blvd
Las Vegas, NV 89145
702-869-7777

Committee Members Present:

Shamim Nagy, MD; Constance Kalinowski, MD; Evelyn Chu, Pharm.D.; Weldon Havins, MD; Kevin Desmond, RPh; Michael Hautekeet, RPh; David Fluitt, Pharm.D.; Joseph Adashek, MD

Committee Members Absent:

Ronald Shockley, MD; Adam Zold, Pharm.D.;

Others Present:

DHCFP: Gabriel Lither, Deputy Attorney General; Coleen Lawrence, Chief Program Services; Mary Griffith, RN, Social Services Program Specialist;

Catamaran: Carl Jeffery, Pharm.D.; Kevin Whittington, RPh; Mariellen Rich, RPh, Susan McCreight, Rob Earnest, Pharm.D., J.D.

HPES: Beth Slamowitz, Pharm.D.

Others: Mike Crittenden, Pfizer; Akshaya Patel, Mylan; Danican Frantz, Mylan; Ken Wong, BMS; Raphael Wilson, BMS; Dave Croft, BMS; Fran Kaiser, Merck; Efrain Alton, Merck; Andi Stratton, Vertex; Kim Burns, Vertex; Diana Blanton, Astellas; Lisa Borland, Vertex; Sam Stone, Astellas; Charissa Anne, J&J; MaryKay Queener, J&J; Bret Ferguson, Pfizer; Sandy Sierowski, Pfizer; Mike Spelt, Pfizer; Doug Powell, Forest; Carla McSpadden, Forest; Robert Jaramillo, Forest; Danielle Walters, Sanofi; R Clark, Sanofi; Tom Brock, United Therapeutics; Scott Larson, BMS; Nidal Naser, GSK; Brian Streng, GSK; Julie Bertuleit, GSK; Eunmee Lee, Pfizer; Carol Eisner, Takeda; William Lan, Abbvie; Kim Lawrence, Forest; Krystal Joy, Otsuka; Kent Lamberier, Otsuka; Steve Farmer, Amgen; Vinson Lee, Amgen; Joe Brann, Novo Nordisk; Dana Cowell, NME; Kenneth Ley, Jazz; D McCale, Baxter; Helen Liao, Lilly; Jenny Blackham, Lilly; Patrick Moty, Supenus; Naresh P Singh, MD; Michael Schlopter, MD; Shane Hall, Purdue; Chris Almeida, Purdue; Lovel Robinson, Abbvie; Tom McGovern, Abbvie; Scott Stepia; Robert Maul, MD

I. CALL TO ORDER AND ROLL CALL

Call to order at 1:00 PM.

II. PUBLIC COMMENT

Shamim Nagy, MD, Chairwoman: We have some public comment before we start, please come forward.

Michael Schlopter: First of all let me thank you for letting me speak. My background is a practicing pulmonologist in private practice in Las Vegas for the past 25-27 years.

Weldon Havins, MD: For the record, could you please state your name?

Michael Schlopter: Yes, Dr. Michael Schlopter. I have been in practice in Las Vegas for the past 25 or 27 years. I have an active asthma COPD type practice. I'm here to speak about a medicine that I have used in my practice called Tudorza or aclidinium bromide. I have found several different patients in my practice that either cannot take what is on the market now, Spiriva. One aspect is the actual delivery device itself. I have several patients with severe arthritis and cannot maneuver the Spiriva device. When they switch to Tudorza, the actual device, they could actually administer the medication themselves. They realize significant improvement in their symptoms. Second.ly, I have a number of patients that do not respond to Spiriva, and when I switch them to this medication, Tudorza, they actually had clinical benefit. Additionally, there are some people who have breakthrough symptoms at night, nocturnal symptoms, and with the BID scheduled dosing with the Tudorza, those symptoms went away. So I would like to have that in my armamentarium as a choice, not as a substitute, but as a choice for some of my patients who do not respond or cannot take the medicine Spiriva. So I think you very much.

Shamim Nagy, MD, Chairwoman: As for your comments, we will take them into consideration when we get to that class. We will start our meeting now. We start with roll call.

Mary Griffith: Mary Griffith, DHCFP

Coleen Lawrence: Coleen Lawrence, DHCFP

Joseph Adashek, MD: Joey Adashek, MD

Weldon Havins, MD: Weldon Havins, MD

Kevin Desmond, RPh: Kevin Desmond, Pharmacist

David Fluitt, RPh: David Fluitt, Pharmacist

Michael Hautekeet, RPh: Mike Hautekeet, Pharmacist

Gabriel Lither: Gabe Lither, Attorney General's office

Shamim Nagy, MD, Chairwoman: Shamim Nagy, MD, Chair

Constance Kalinowski, MD: Connie Kalinowski, MD

Evelyn Chu, Pharm.D.: Evelyn Chu, Pharmacist

Beth Slamowitz, Pharm.D.: Beth Slamowitz, HP

Kevin Whittington, RPh: Kevin Whittington, Catamaran

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

III. Review and Approval of the June 27, 2013 Meeting Minutes

Shamim Nagy, MD, Chairwoman: Thank you, getting back to public comments. If none, we would like a motion for approval of minutes from the last meeting.

Michael Hautekeet, RPh: I make the motion to approve the minutes.

David Fluitt, RPh: I Second.

Shamim Nagy, MD, Chairwoman: All in favor?

Board votes unanimous, Aye.

Shamim Nagy, MD, Chairwoman: Motion carried.

IV. STATUS UPDATE BY DHCFP

Shamim Nagy, MD, Chairwoman: Now Status Report from DHCFP.

Coleen Lawrence: Good afternoon, for the record, my name is Coleen Lawrence, I am Chief of Program Services for Nevada Medicaid. I would like to welcome everyone to the annual pharmacy and therapeutic PDL review. This review is an effort to be in compliance with the Division's Nevada Revised Statute regarding Annual Review of our Preferred Drug List. If you have never been to our annual review, hold on, it's a good time. Before we get started, I want to give everyone some information to show how successful this program has been. This year actually marks the 10th year anniversary since our legislation approved the Preferred Drug List. For those of you that have been here for the whole ten years, it has been a long time. It is very successful and we do appreciate everyone's cooperation with this. Here are some fun facts for our Preferred Drug List and our P&T Committee. We have been through three Governors, and we've had three official separate committees. Here are the really fun facts. For the fee for service population in 2003, pharmacies serviced 77,000 recipients for an

approximate total of $99 million. If you look at 2013, we grew to about 96,000 recipients and paid $127 million in total expenditures. If you look at about a 20% growth, it is only a 3% growth in case load growth. So our pharmacy program has been amazing. I really appreciate the collaboration we have had with our volunteers on the P&T Committee, and our collaboration and partnership with those who have helped us in the past 10 years. We are definitely an icon and are asked by other states all the time how we are so successful in our program. How do we not fight among all our stake holders? We attribute it to our communication and transparency. So we are very proud of that. With the more efficient systems we have, and changes with the ACA, we are at about 49% of collections with our OBRA rebate, and about 12% with our supplemental rebates, so we definitely have a stellar program. So moving to some meeting reminders, we say this every year, if this is your first meeting, welcome. We have some ground rules for a successful annual review. If you have seen our agenda, you know why we have to enforce these rules. When we first started this, we only had 40 classes to review. Every year, by statute, we must review all the classes, so it wouldn't just be a gentleman's agreement we look at all the classes every year. So we look at our PDL as long as we have a Board. Now, we have more than 40 classes, so we need to get through this. Here are some ground rules. Please, if you're coming up for public comment, we are going to be using our projector to show you what we will be reviewing in each class. We have a very regimented process on our agenda and we are very regimented on how we go through each class. We will be showing you throughout the process what we will be reviewing. There is nothing hidden, you will be able to see what we will be reviewing. Please keep your discussion to only items that the Committee has not heard or seen before, new items or material only. They have these magic brains and they remember everything you have said before. If they hear it again, they will tell you. We will be enforcing time limits very strictly. We will be letting you if your five minutes is up. The items we will be reviewing today are very clearly marked on the agenda. Our classes that have new clinical information that has come out since the last time the class has been reviewed before, so we will be bringing those back up. Items that have been asked to be re-reviewed by a committee member or items the State is choosing to re-review. The last section, this is a whole list of classes that we don't feel need to be reviewed because we just reviewed them and we don't need to go through the process again. However, the committee may review this list and say they want to pull something out of the class and ask to be reviewed at the next meeting or a future meeting. One other quick reminder, please remember to keep things in context, this is for the Medicaid Fee for Service program only. This does not apply to the managed care programs. And the last thing, I just want to ask if there are any physicians here to speak who need to get back to their practice?

Shamim Nagy, MD, Chairwoman: Ok, thanks Coleen.

Any questions for Coleen? Any public comment now?

V. ANNUAL REVIEW - ESTABLISHED DRUG CLASSES

A. ALZHEIMER'S AGENTS

Ok, we now move on to Annual Review of Established Drug Classes.

Alzheimer's Agents. Public comment?

Carla McSpadden: Good afternoon, my name is Carla McSpadden. I am a pharmacist that works for Forrest Labs and I'm here to talk about Namenda XR, the new once daily extended release version of memantine product. Let me first remind you that Alzheimer's dementia is increasing in prevalence, in fact Nevada is just one of six states that will experience a doubling of people with Alzheimer's by 2025. According to the Alzheimer's Association, 29% of people with dementia are dual eligible, which is why this disease should be of interest to State Medicaid departments. Namenda XR offers a new treatment option to these patients because of the extended release properties, Namenda XR has a longer T-max than the IR formulation, which afforded them the opportunity to push the dose up to 28 mg, 40% higher than the 20mg daily dose with the IR, while minimizing the potential for adverse events since there is no sudden dose dumping into the blood stream. Now while there are no head-to-head studies between Namenda XR and IR, there was a kinetic study performed and they learned that the higher daily dose of the XR did result in a higher Cmax and a higher AUC than the IR. So what we've got with the Namenda XR is slower absorption, a higher daily dose and higher blood concentrations of the drug. So the 24 week pivotal study that led to the approval of Namenda XR required combination therapy with an acetyl cholinesterase inhibitor, which of course has a different mechanism of action. Previous memantine studies involved donepezil, but this is the first randomized clinical trial to show the additional benefit of memantine on top of any the acetyl cholinesterase inhibitors.

Weldon Havins, MD: Let me ask a quick question here. Are we considering the XR today?

Carl Jeffery, Pharm.D.: I was actually just discussing this with Kevin, we just noticed there is an error in the slide here. Namenda is on the wrong side, we are actually proposing to keep Namenda and Namenda XR as preferred. That's our proposal to keep it that way. I'll explain it more when I get up there, but right now Namenda is preferred, but we want to keep it preferred and make sure we call out and include the Namenda XR on the preferred side.

Carla McSpadden: So, in regards to cognition, those receiving Namenda XR plus a cholinesterase inhibitor ended up with about a 2.5 point improvement in their SIP score, where those receiving only a cholinesterase inhibitor stAye.d right around their baseline level. The CIVIC Plus was the other primary endpoint, which looks at overall health status, the Namenda XR group had scores in the high 3's, indicating slight improvement verses those with placebo had essentially no change throughout the study. The study did also evaluate activities of daily living and behaviors which are probably equally important in this population, unfortunately, I don't have time to share all these results, but please do ask questions if you have any. Adverse events were similar between groups, dizziness, headache and diarrhea were the most common. Contraindications and warnings and precautions are exactly the same for XR and IR, so no difference there. Just like with the IR, a four-week titration schedule is recommended new to the product, but patients already on Namenda can be switched over directly to Namenda XR the following day. There is no dose titration or dosing protocol or anything. There is however a dose adjustment for patients with severe renal impairment. That was true for regular Namenda and that is a

creatinine clearance of less than 30 and that dose would be 14mg daily. Even though it is extended release, the capsule can still be opened and sprinkled on apple sauce to aid those who have difficulty swallowing at the end stages of the disease. So Forrest is pleased to offer a new extended release formation of a proven treatment option for patients with Alzheimer's disease. It offers a higher dose, 28mg with a slow absorption which minimized the potential for adverse events and it offers once daily administration which may be helpful for those patients that only have care giver assistance coming in to help with their meds once a day. And it is another positive study, which many promising Alzheimer's agents have not been able to achieve and this is years after the Namenda IR studies were conducted which means a different patient cohort is now experiencing positive clinical benefits with memantine. So we are asking that Namenda XR be considered a preferred agent just like Namenda IR on the formulary.

Shamim Nagy, MD, Chairwoman: Thank you. Any questions?

Any other public comments? No?

Dr. Jeffery, would you please go ahead with the review?

Carl Jeffery, Pharm.D.: As I stated earlier and I apologize for the error on the slide, but we'll get that corrected. But to go into the review, I think we all have a good understanding of the pathophysiology of the disease that works with the two different mechanisms that are currently available to help treat it, the acetyl cholinesterase inhibitors and the NMDA inhibitor that we just heard about, Namenda. Right here we show what the current PDL is, and I'm not going to read them now. But what brought this class up for review is that Cognex is no longer available, it was pulled off the market, so that is one of the reasons that prompted us to discuss this today. Without going too much into the clinical nature of these medications, there is really little new information that has become available for the Board to review. At this point, I would like to make the recommendation that the Board consider these products clinically and therapeutically equivalent.

Weldon Havins, MD: I have a question about the Namenda XR, are you including the Namenda XR, are you adding that on?

Carl Jeffery, Pharm.D.: When we get to the voting of what is on the preferred list, our intent was to include all forms of Namenda on the preferred products. When we publish the actual preferred drug list, we can make sure to call that out to make it specific.

Shamim Nagy, MD, Chairwoman: So that is IR plus XR?

Carl Jeffery, Pharm.D.: Yes, that is right.

Kevin Desmond, RPh: I make the motion that these products are therapeutic equivalents.

Weldon Havins, MD: Second.

Shamim Nagy, MD, Chairwoman: All in favor?

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

Dr. Jeffery, could you present the updates to the PDL?

Carl Jeffery, Pharm.D.: So I will try to make this as clear as possible for the record so when this gets typed and published that we know for sure. As proposed here, the PDL will remain donepezil, donepezil ODT, the Exelon Patch, the Exelon Solution, and then the rivastigmine caps. In addition to this, we will keep the Namenda and the Namenda XR as preferred. So the slide here isn't completely accurate. The remaining products would be non-preferred.

Shamim Nagy, MD, Chairwoman: So we are moving Namenda to preferred.

Weldon Havins, MD: I move we accept the proposed list including Namenda as preferred.

Michael Hautekeet, RPh: Second.

Shamim Nagy, MD, Chairwoman: All in favor?

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

B. ANALGESICS: Long Acting Narcotics

Next we will be discussing Analgesics: Long Acting Narcotics. Any public comment?

No comments, Dr. Jeffery.

Carl Jeffery, Pharm.D.: On the slide, we have the current PDL as published, we have the Duragesic patches, the brand name, Kadian, which a branded morphine sulfate extended release and morphine sulfate extended release, the generic for MS Contin tablets. Everything else is considered non-preferred in this class. When we get into the clinical aspects, they are all very similar in how they work with the exception of one agent that we wanted to include in this class and what prompted us to bring this class up. Nucynta ER, technically is more chemically related to a tramadol product, but the way it is compared and how it is used is more similar to other regular opioid analgesics. We wanted to pull the Nucynta ER into this class as well and all the others, there is very little new information that I wanted to call out or feel it is necessary to share with the Board at this time. All of them are opioids that decrease pain. With that, Catamaran would like to recommend that the Board accept these as clinically and therapeutically equivalent.

Shamim Nagy, MD, Chairwoman: Any questions?

Michael Hautekeet, RPh: On one slide you have fentanyl patch and another you have Duragesic, so are we talking about talking about fentanyl patch for the preferred or the Duragesic.

Carl Jeffery, Pharm.D.: For this step, our intent was just to review for clinically and therapeutically equivalence.

Michael Hautekeet, RPh: I make the motion that we consider these clinically and therapeutically equivalent.

Evelyn Chu, Pharm.D.: Second.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

Dr. Jeffery, now the review to update the PDL.

Carl Jeffery, Pharm.D.: One of the big changes we wanted to make here, and it really isn't that big of a change is that on the previous published list we had Kadian as a preferred agent and it has a pretty low market share, it wasn't the driver we thought it would be, so we would like to recommend that Kadian be moved to non-preferred and also with Nucynta ER, the way it is currently in the tramadol related products and is considered non-preferred. All we are doing is moving it from that class to this one, so Nucynta ER would remain non-preferred.

Weldon Havins, MD: What does the PA required mean?

Carl Jeffery, Pharm.D.: There are clinical criteria on the Duragesic patches that the DUR Board has established, so the recipient has to meet those criteria before getting those.

Joseph Adashek, MD: So there is only one long-acting agent right now you can get without PA?

Carl Jeffery, Pharm.D.: Right, only the extended release morphine.

Kevin Desmond, RPh: So back to Mike's question about why Duragesic is preferred and not the fentanyl patch. What is the rationale for that?

Carl Jeffery, Pharm.D.: It's been on the market long enough and it comes down to best interest of the state.

Shamim Nagy, MD, Chairwoman: Any other questions?

David Fluitt, RPh: I sort of see it as a critical question, what is the prior authorization process for Duragesic vs. the fentanyl patch?

Carl Jeffery, Pharm.D.: its class wide, the PA criteria is for both the brand and the generic product. It doesn't matter if it is brand or generic.

David Fluitt, RPh: I'll make the motion to move the Duragesic patch to non-PDL.

Joseph Adashek, MD: Why don't we just add the fentanyl to preferred?

Kevin Desmond, RPh: The motion is to add the fentanyl patch to the preferred drug list.

David Fluitt, RPh: I second that.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

C. ANTI-MIGRAINE AGENTS: Triptans

Going to the next topic, anti-migraine agents, triptans.

Any public comment? None.

Dr. Jeffery.

Carl Jeffery, Pharm.D.: We now have the triptans class here. Right now we have the Maxalt, Maxalt MLT, Relpax and sumatriptan as preferred, and all the others are non-preferred. What brought this up is that we wanted to clarify what all was included in the sumatriptan class, so we wanted to call out the different dosage forms on the PDL. Then that brought up some other opportunities to work with some other manufacturers. Again, similar to some of the other classes, the triptans are an established class. I think they have been presented clinically again, they are all equally effective on paper. David and I were talking a little bit about this before the meeting, from a pharmacist perspective, we look at it on paper and they all have similar effects and the studies all show they are equally effective vs. placebo. Very few head-to-head studies show that one is any better than another. There are a few, but the power isn't really there to really hang your hat on one. With that information, Catamaran would like to make the recommendation that the Board consider these products clinically and therapeutically equivalent.

Shamim Nagy, MD, Chairwoman: Any questions? Do we have a motion?

Michael Hautekeet, RPh: I make the motion to accept these as equivalent.

Weldon Havins, MD: Second.

Board votes unanimous: Aye.

Carl Jeffery, Pharm.D.: After we had the opportunity to update the sumatriptan, we have included the tablets, nasal spray and the injection. Most people start with the tablets, they don't like moving to the injection unless there is some nausea related to the migraine, then these other agents are available. Working with these products, the addition of Zomig orally disintegrating tablet, the ZMT, to propose that as preferred, and then to move the Maxalt, all the forms, to non-preferred, which is a change from here. We feel this isn't a really hard change

because most patients take them on an episodic basis, they don't take them routinely. And so this change wouldn't be very drastic for them. Catamaran recommends that Zomig ZMT be added as preferred and to move Maxalt to non-preferred.

Shamim Nagy, MD, Chairwoman: Any discussion?

Joseph Adashek, MD: What if people have been on Maxalt and then it changes to non-preferred so now they have to choose Zomig or…?

Carl Jeffery, Pharm.D.: Well, we can discuss this with the Board. One of the options we have is to put a grandfather clause in there, so if the recipient has had in it X number of days, 30, 60, 90 days in the past, then they would not need to get a prior authorization for this. Or we can do a hard cut over. In agents like this, I feel it is reasonable to ask them to move to a preferred agent. When it is something like we have talked about before, if it is an agent they are established on and takes them a while to titrate to a dose, it is harder for them to switch. But with these types of agents, it should be pretty easy to switch.

Joseph Adashek, MD: I would still like to make a motion that we grandfather Maxalt in for at least 90 days, so people that are used to Maxalt and get relief from it can still get it. I motion we grandfather Maxalt in.

Weldon Havins, MD: I second.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

Weldon Havins, MD: Do we need to have a motion to accept the PDL? I make a motion to accept the PDL as proposed with the grandfathering addition to Maxalt.

Michael Hautekeet, RPh: So they will be grandfathered if they have been on it for 90 days?

Carl Jeffery, Pharm.D.: Let me clarify what I mean with grandfathering. If a patient walks into a pharmacy with a prescription for Maxalt, if they have had one paid claim within the past 90 days, it will bypass the PA. So even if they got it 89 days ago, it will pay without PA.

Weldon Havins, MD: I think there was a motion and a second.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

D. ANTIPARKINSON'S AGENTS: Non-ergot Dopamine Agonists

Moving to the next class, Antiparkinson's Agents – Non-ergot Dopamine Agonists.

Public comment? None.

Dr. Jeffery.

Carl Jeffery, Pharm.D.: We have the current PDL, last year we put Neupro as preferred, which is the patch, 24 hour patch you put on once a day. That really is the only one that is a little bit different than the others. The others are by mouth, dopamine agonists. Nothing new, it's an established class, no new drugs or new information. We have the pramipexole, ropinirole, ropinirole ER which are all generics. At this point, Catamaran would like to recommend the Board consider these clinically and therapeutically equivalent.

Michael Hautekeet, RPh: I make the motion to accept that they are therapeutically equivalent.

Weldon Havins, MD: Second.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries. PDL recommendation?

Carl Jeffery, Pharm.D.: So this might be kind of a sensitive change too. We have run the numbers, and the Neupro we made preferred last year, and it really didn't drive the utilization like we hoped, so with that we would like to make the proposal to move that back over to non-preferred to drive the use toward the remaining preferred agents that are proven and effective. So we have pramipexole, ropinirole and ropinirole ER on our preferred list. Like I said, for Neupro, utilization is pretty low, we have fewer than 10 patients currently on Neupro, it is up to Board if you want to grandfather those recipients, or if we should encourage a switch. My recommendation is to grandfather these patients in.

Shamim Nagy, MD, Chairwoman: Any discussion.

Joseph Adashek, MD: I would like to grandfather at least those 10 patients, do you have to make it 90 days or can you always grandfather these recipients? If they are stable on that Parkinson's drug, do we want to keep them on it forever?

Carl Jeffery, Pharm.D.: The reason we choose 90 days is that typically that gives them a chance to be able to get it again. But if they are not getting it routinely and they stop it for greater than 90 days, they really should be re-tapered up to a new dose.

Joseph Adashek, MD: Right, if you find a Parkinson's drug that works for someone, you probably want to keep them on it, for at least for those 10 patients, we should grandfather those in, if they're stable on it, they should be able to stay on it. Otherwise, it should be non-preferred. I guess that is a motion.

Michael Hautekeet, RPh: I second the motion.

Board votes unanimous: Aye.

Gabriel Lither: Just for the record, we are talking about grandfathering in for 90 days for these recipients?

Joseph Adashek, MD: No, I said forever.

Gabriel Lither: Forever?

Joseph Adashek, MD: Right, if they are on it, they should be able to stay on it.

Gabriel Lither: I understand, but when you, "Let them stay on it." If they're currently on it to let them stay on it. You're saying if they were taking it and then stopped for three years and they start again, they don't need a PA?

Joseph Adashek, MD: No, that isn't what I meant.

Coleen Lawrence: So what happens is if they have been on it sometime in the last 90 days, even if they have had a 30 day break, then they do not have a prior authorization requirement. However, your prior authorization for everyone still has to be looked at the same as your prescription within a year, the prior authorization needs to be looked at for medical necessity. So that will still need to be reviewed, just as a physician you need to review it. So we can't say that you will always have unlimited access, but if they have had it in the last 90 days, then they do not have to get a prior authorization and that drug will be available. The only limitation we have is to have people get a prior authorization.

Joseph Adashek, MD: Typically, people don't take a big break off Parkinson's drugs,

Coleen Lawrence: Right, so it won't be an issue for them, if they have had it within the past 90 days, they will still be able to get it.

Gabriel Lither: That's fine, I was just kind of concerned since we were having the grandfathering with this class and the last class that as we go forward, I was afraid it might create some other issues, that is would be indefinite.

Coleen Lawrence: Right, it is not indefinite, it is just that we always do a look back of 90 days like we normally do.

Shamim Nagy, MD, Chairwoman: So what is the 90 day clause again?

Coleen Lawrence: So the 90 day clause is what we typically call a look-back 90 days within our system. If there has been a paid claim within the past 90 days within our system for this specific drug that we are looking at then they will be able to have that drug without a prior authorization through the preferred status.

Shamim Nagy, MD, Chairwoman: Is there a time limit on that?

Coleen Lawrence: As long as they have had it within the past 90 days.

Carl Jeffery, Pharm.D.: They will be able to get it indefinitely as long as they have had at least one fill within the past 90 days forever, then they will be able to get it.

Shamim Nagy, MD, Chairwoman: Ok, thank you.

Weldon Havins, MD: I move that these three drugs plus the Neupro for 90 days be considered PDL.

Joseph Adashek, MD: Second.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

E. CARDIOVASCULAR: Antihyperlipidemics, Statins and Statin Combinations

Next class, Cardiovascular Antihyperlipidemics, Statins and Statin Combinations.

Any public comment? None.

Dr Jeffery.

Carl Jeffery, Pharm.D.: We have a new agent in this class, Liptruzet, is a new agent that is a combination of the active ingredient in Zetia which is ezetimibe, and atorvastatin which is the active ingredient in Lipitor. That is what prompted us to discuss this today. As far as statins go and their combinations, this is an established class that has been available for years. A lot of good things have come from this class. We've got currently preferred high potency and low potency, really the only new information that has come out within the past couple years is that simvastatin 80 shouldn't be used in any new patients. Other than that, everything is pretty standard on what kind of literature is available. Again there are head-to-head trials comparing these and almost everything comes out with getting one manufacturer says it works best for them and then another says their product is better. In the end, it comes down to clinician preference and what is going to work best for the patient. So with that Catamaran would like to recommend to the Board that these products be considered clinically and therapeutically equivalent.

Shamim Nagy, MD, Chairwoman: Any discussion? If not, do I have a motion?

Michael Hautekeet, RPh: I make a motion to accept them as equivalent.

Joseph Adashek, MD: Second.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

Update to PDL list.

Carl Jeffery, Pharm.D.: So the only change we want to make here is to include the new combination product, the Liptruzet, which wouldn't be first line any way since most people start

with a single agent first and then move on from a single statin to a combination, so we have the Liptruzet as non-preferred, everything else is staying the way it was.

Shamim Nagy, MD, Chairwoman: Any questions? Any discussion?

Michael Hautekeet, RPh: I make the motion to accept the recommendation from Catamaran.

Evelyn Chu, Pharm.D.: Second.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

F. DIABETIC AGENTS: Meglitinides and Combinations

Shamim Nagy, MD, Chairwoman: Next class of medications, Diabetic Agents, Meglitinides and Combinations.

Any public comment? None.

Carl Jeffery, Pharm.D.: We have the diabetic agents, the Meglitinides and combination products. And really why we brought this up is for housekeeping because Starlix was included in another class and it really does belong in this class, so this is strictly housekeeping to include this in here. The other agents on here as you can see are Prandin and Prandimet as the only ones listed. There are two agents which are nateglinide which is the generic Starlix and then Prandin and then a combination product with metformin Prandimet. These products work very similar to a sulfonylurea and have good data to support the use of these, but no comparative studies to say that one is better than another. With that, we would like to recommend that the Board consider these products clinically and therapeutically equivalent.

Shamim Nagy, MD, Chairwoman: Any discussion or comments? Do I have a motion?

Kevin Desmond, RPh: I make a motion that the drugs in the class are therapeutically equivalent.

Michael Hautekeet, RPh: Second.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion approved.

Update to the PDL?

Carl Jeffery, Pharm.D.: This is another class that falls into the NRS limitations where we are limited to making the products available before June 30, 2010 as preferred, so we recommend that everything be considered preferred.

Weldon Havins, MD: I move that the four drugs listed be considered PDL.

Joseph Adashek, MD: Second.

Joseph Adashek, MD: Aye.

Weldon Havins, MD: Aye.

Kevin Desmond, RPh: Aye.

David Fluitt, RPh: Nay.

Michael Hautekeet, RPh: Aye.

Shamim Nagy, MD, Chairwoman: Aye.

Constance Kalinowski, MD: Aye.

Evelyn Chu, Pharm.D.: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

GASTROINTESTINAL AGENTS: Pancreatic Enzymes

Shamim Nagy, MD, Chairwoman: Next class, Gastrointestinal Agents, Pancreatic Enzymes.

Any public comment?

William Lan: Hello, my name is William Lan global medical affair for Abbvie. Thank you for the opportunity to speak to you today about Creon. Please review the full package insert at www.rxiv.com for safety and efficacy data. Creon is available in 3000, 6000 12000, 24000 and recently approved 36000 lipase unit strengths. Today we will share two key points for Creon. Creon is the first FDA approved delAye.d pancreatic enzyme to be marketed in the US. And the only one indicated for the treatment of exocrine pancrease deficiency (EPI) due to cystic fibrosis, chronic pancreatitis and pancreaectomy. Two studies evaluate the safety and efficacy of Creon in adults and children with EPI due to CF and one study evaluated Creon in adults with EPI due to chronic pancreatitis and pancreaectomy. The primary efficacy endpoint was the mean difference in the coefficient of fat absorption, CFA, between Creon and placebo. Statistically higher CFA's were seen with Creon compared to placebo in all three studies.

Gabriel Lither: Sorry to interrupt, but Creon is on the proposed PDL as a first agent. You might want to keep it very brief, of course of you can use your time, but I don't know if I have ever seen the Committee take something that is recommended as proposed PDL and move to non-PDL.

Joseph Adashek, MD: Unless you go over your time.

William Lan: Got it, just one quick last point, Creon is not interchangeable for any of the other available products. Thank you.

Shamim Nagy, MD, Chairwoman: Any other comments?

Dr. Jeffery.

Carl Jeffery, Pharm.D.: This is our old friend. I think earlier this year and late last year we had this class on every agenda, so I think we have discussed it ad nauseam. Really, no new information has come out about it. The reason we brought it up is because we have to work so far out on the agenda, we thought there was going to be a change in the market place with these agents, and it turned out not to be the case. With this, we are not recommending any changes. Because these are all the same again, we have the same agents, just with different concentrations of the enzymes, we recommend that these be considered therapeutically and clinically equivalent.

Weldon Havins, MD: I move that we consider these drugs clinically and therapeutically equivalent.

Michael Hautekeet, RPh: Second.

Shamim Nagy, MD, Chairwoman: All in favor?

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

PDL updates?

Carl Jeffery, Pharm.D.: So again, we are recommending no changes at this time. Like I said, we anticipated some changes to the market place that didn't pan out, so we recommend Creon and Zenpep remain preferred.

Michael Hautekeet, RPh: I make the motion to accept the recommendation from Catamaran.

Evelyn Chu, Pharm.D.: Second.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

G. IMPETIGO AGENTS: Topical

Shamim Nagy, MD, Chairwoman: Next class, the Topical Impetigo Agents.

Any public comment? None.

Carl Jeffery, Pharm.D.: Since I think it has been awhile since we last discussed this, there has been some new information and some new changes. There is Altabax, which is a newer product, it is considered preferred right now. But it has a little bit different action than

mupirocin does, it is only really indicated for methicillin susceptible staph aureus , MRSA. It is kind of limited on its use and it is reserved for treatment of only those bacteria. Other than that, it is indicated to treat impetigo. Centany is a branded product of mupirocin cream and ointment, so that is why it is in there. But all these products work the same way, are generally equally effective unless you are treating MRSA. But Catamaran would like to recommend to the Board that these be considered clinically and therapeutically equivalent.

Shamim Nagy, MD, Chairwoman: Any discussion? Do we have a motion?

David Fluitt, RPh: I make the motion that these be considered clinically and therapeutically equivalent.

Michael Hautekeet, RPh: Second.

Shamim Nagy, MD, Chairwoman: Voting.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Updates to PDL?

Carl Jeffery, Pharm.D.: Because of what I just mentioned with the Altabax being limited to only MRSA, we would like to make that non-preferred since it is not first-line anyway and limit the preferred products to the mupirocin ointment. The only change is moving the Altabax to non-preferred.

Shamim Nagy, MD, Chairwoman: Any discussion?

Michael Hautekeet, RPh: On the Bactroban, there is no age restriction is there?

Carl Jeffery, Pharm.D.: No, there is not age restriction.

David Fluitt, RPh: On the mupirocin, do you see any core issues with the nose and the colonization of MRSA.

Carl Jeffery, Pharm.D.: Yeah, I think our intent with this is to just look at impetigo, we didn't really get into the MRSA colonization within the nose because, you're right, there is some evidence to say that they do use the nasal swabs in the case of nosocomial infections, and I think it is all related to the Medicare rules, that say if someone acquired MRSA in the hospital, then they don't pay the bill. So everyone is getting treated with the Bactroban. The outcomes don't show justification in my mind, it doesn't really reduce any kind of infection, people are colonized and that is how it is, that's the reading that I have done anyway.

David Fluitt, RPh: So just a point of clarification, are the ointment and cream bioequivalent, in terms of therapeutic value?

Carl Jeffery, Pharm.D.: I haven't seen any therapeutic difference between the ointment and the cream, I think it comes down to preference.

Shamim Nagy, MD, Chairwoman: Do I have a motion for approval?

David Fluitt, RPh: This one makes sense to me, I make the motion we approve as presented.

Kevin Desmond, RPh: Second.

Board votes unanimous: Aye.

H. OPHTHALMIC ANTIHISTAMINES

Shamim Nagy, MD, Chairwoman: Next class is Ophthalmic Antihistamines.

Any public comment?

Carl Jeffery, Pharm.D.: Ophthalmic antihistamines, I think, was it last…I can't remember when we last talked about this, maybe December when there was a new product available. But we have all sorts of once a day and twice a day antihistamines for the eye. All have been shown to be equally effective and or ineffective depending how you see it. All benefit itchy eyes and conjunctivitis that we see in some of the patients. Really no studies that call out one being better than another, I think it is all patient and doctor specific on what they want to prescribe. Because we are not seeing any huge differences between these products, we would like to recommend that the Board consider these clinically and therapeutically equivalent.

Weldon Havins, MD: I move that we consider these clinically equivalent.

Michael Hautekeet, RPh: Second.

David Fluitt, RPh: I know this is out of order, but the Emadine, where is that? Emedastine.

Carl Jeffery, Pharm.D.: You're right, it is not listed on the slide. We can also include that in the therapeutic equivalent vote.

David Fluitt, RPh: Ok, that's fine.

Weldon Havins, MD: Did you say Emedastine?

David Fluitt, RPh: Yes, called Emadine, as a brand name.

Carl Jeffery, Pharm.D.: There are two that sound very similar, epinastine and emedastine. So, David is right, there is one that is missing on the slide.

Weldon Havins, MD: So the motion would include the one that is missing.

David Fluitt, RPh: I move that with the addition of emedastine that we consider these clinically equivalent.

Michael Hautekeet, RPh: Second.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

Updates to the PDL?

Carl Jeffery, Pharm.D.: We wanted to drive the market share to two products that are on the preferred list. Alaway which is an over the counter available product and Pataday, which is a once-a-day product. We feel by having these two products available gives patients and doctors flexibility for what they need. We would consider the Emadine as non-preferred on this list. When this list gets published, we would have the Emadine as non-preferred.

Weldon Havins, MD: I move that we consider Alaway and Pataday be considered for thePDL.

Kevin Desmond, RPh: Second.

David Fluitt, RPh: I have a comment. One thing that I picked up on in the studies is that you have two agents that are pregnancy category B, is it possible to include one of those on the PDL, which would be Emadine or the Lastacaft.

Joseph Adashek, MD: I'll be honest with you, as a maternal fetal medicine specialist, I don't think it matters.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

I. PEDICULOCIDES / SCABICIDES

The next class of medications, the Pediculocides and Scabicides.

Public comment?

Rachel Clark: Hi, my name is Rachel Clark and I am a medical science liaison with Sanofi Pasture, and I wanted to thank you for putting Sklice on the proposed PDL list, and with that I just wanted to ask if you had any questions? Thank you.

Carl Jeffery, Pharm.D.: Ok, this is another topic from about a year ago. As was mentioned, Sklice was not included in that list when we reviewed last time. Since then, nothing else has really changed except for the addition of Sklice. All the other agents we talked about a year ago, and the mechanism of action and we can review that if you want, but at this point, I would like to recommend that the Board consider these clinically and therapeutically equivalent.

Shamim Nagy, MD, Chairwoman: Any discussion?

David Fluitt, RPh: Is lindane available still? I know it isn't available in California.

Carl Jeffery, Pharm.D.: I thought it was, but then I call myself a real pharmacist anymore because I don't see it.

David Fluitt, RPh: Ok. I do make the motion that these be considered clinically and therapeutically equivalent.

Michael Hautekeet, RPh: Second.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carried.., updates to PDL?

Carl Jeffery, Pharm.D.: The only thing we wanted to add here is the Sklice as proposed PDL. And David, to your point, I don't remember if you were here when we discussed this last time, but we talked quite a bit about the toxicity of the lindane and that is why it is non-preferred. Even if it is available, no one uses it. We didn't want to make any other changes except the addition of the Sklice to the preferred drug list.

Weldon Havins, MD: I move that we accept the five drugs listed on the PDL

Michael Hautekeet, RPh: Second.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

J. RESPIRATORY: Inhaled Corticosteroids/Nebs

Shamim Nagy, MD, Chairwoman: Next class, Respiratory Inhaled Corticosteroids.

Any public comment? No.

Dr. Jeffery.

Carl Jeffery, Pharm.D.: This is another one of our old friends. We talked about this maybe a little bit over a year ago. This is another one that when we created the agenda, we thought there were going to be some changes in the market place, but that turned out to not be the case. Or that isn't exactly true, to drive the utilization we would like, we would have to switch so many members over, we didn't feel it was appropriate for us to do that. For this review, we have several inhaled corticosteroids, all shown to be effective and really established in the clinical outcomes and the guidelines for the treatment of asthma. The only restriction on this is an age restriction on the budesonide nebulizer solution, so we limit those to four and under, but no restriction on any of the others. Catamaran would like to make the recommendation that these be considered clinically and therapeutically equivalent.

Shamim Nagy, MD, Chairwoman: A motion?

Michael Hautekeet, RPh: I make the motion that we accept these as therapeutically equivalent.

Weldon Havins, MD: Second.

Board votes unanimous: Aye.

Carl Jeffery, Pharm.D.: Catamaran doesn't recommend any changes at this time. Again we thought there were going to be some changes in the market place. All would be considered preferred except for Alvesco, which was non-preferred to start, so we are just keeping it the same way.

Weldon Havins, MD: I move that we keep the same set of drugs on the PDL.

Joseph Adashek, MD: Second.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

K. RESPIRATORY: Intranasal Rhinitis Agents

Shamim Nagy, MD, Chairwoman: The next class of drugs, the Intranasal Rhinitis Agents.

Public comment? No.

Dr. Jeffery.

Carl Jeffery, Pharm.D.: The intranasal rhinitis agents. Right now we have just the two agents listed, the Astepro and the Azelastine, which is the generic Asteline as preferred. The Astepro and the Astelin are very similar agents, then we have Dymista which is a combination product of azelastine and fluticasone. But because these are all similar agents in how they work, Catamaran makes the recommendation that the Board considers these clinically and therapeutically equivalent.

Michael Hautekeet, RPh: I make the motion to accept that these products are clinically and therapeutically equivalent.

David Fluitt, RPh: Second.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries., moving on to the update of PDL.

Carl Jeffery, Pharm.D.: The only change we wanted to make here is to include the Dymista and the Patanase onto the preferred list, but move the generic azelastine to non-preferred. Mostly this is because this is not a big plAye.r in the market place. I had one patient tell me using

Astelin was like injecting gasoline in to their nose, so I don't think a lot of people like the azelastine.

Joseph Adashek, MD: I move we accept the recommendations.

Weldon Havins, MD: Second.

Board votes:

Joseph Adashek, MD: Aye.

Weldon Havins, MD: Aye.

Kevin Desmond, RPh: Aye.

David Fluitt, RPh: Nay.

Michael Hautekeet, RPh: Aye.

Shamim Nagy, MD, Chairwoman: Aye.

Constance Kalinowski, MD: Aye.

Evelyn Chu, Pharm.D.: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

Weldon Havins, MD: I just wanted to ask why you voted nay?

David Fluitt, RPh: I didn't see any reason to put the Dymista as preferred, because I see the differentiation, at least in my mind, that the H1 antagonist and the corticosteroid, I think you should start with a single agent first and then add another one if needed.

Michael Hautekeet, RPh: I don't think I would start with the first agent being a combo, I would start maybe with the Astepro, then if that doesn't work, we have a choice.

Weldon Havins, MD: Do you have a motion to change?

Shamim Nagy, MD, Chairwoman: Are you comfortable with this? We could make an amendment.

David Fluitt, RPh: I'll change my vote to "Aye.".

Gabriel Lither: No pressure. The one thing we want to remember is that we are moving fast, but don't be shy, jump up and say something for discussion before the motion or after the motion. Express things like that. In this particular matter, the motion passed with a majority and we can move on.

L. URINARY TRACT ANTISPASMODICS

Shamim Nagy, MD, Chairwoman: Urinary Tract Antispasmodics.

Public comment?

Carl Jeffery, Pharm.D.: The current class, we have Detrol LA, oxybutynin tabs and syrup, Sanctura XR, Toviaz and Vesicare all considered preferred with the remaining non-preferred. With the exception of a relatively new agent, Myrbetriq, it works a little differently. Most of the other ones stop the contraction of the detrusor muscle by the cholinergic system, where the Myrbetriq uses the muscarinic receptors to relax the muscle a little bit. Because the Myrbetriq is relatively new, it is not established into the guidelines yet, so right now, there really is no guideline to say that it is preferred over any of the other ones or in the literature. There are no head-to-head superiority studies. With that information, Catamaran would like to recommend that these products be considered therapeutically and clinically equivalent.

Shamim Nagy, MD, Chairwoman: Any discussion? Do I have a motion?

Michael Hautekeet, RPh: I make the motion to approve these therapeutically and clinically equivalent.

Kevin Desmond, RPh: Second.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries. PDL update please.

Carl Jeffery, Pharm.D.: Catamarans recommends that we include the oxybutynin ER on the preferred list. One of the changes we wanted to make here too is to move the Detrol LA to non-preferred. I think this is consistent with what we are seeing in the market place anyway with the people switching from the Detrol LA to the Toviaz which is what is being promoted. Detrol LA and Toviaz are similar agents, but there are fewer side effects with Toviaz. We are recommending that Myrbetriq be considered non-preferred, just because it is not established in the guidelines at this point there is no reason people shouldn't try one of the more traditional agents first before they move to the other ones. So Catamaran makes the recommendation that oxybutynin, all forms of the generic, including the ER tabs, Sanctura XR, Toviaz and Vesicare be considered preferred.

Kevin Desmond, RPh: Is there not an oxybutynin XL in the generic.

Carl Jeffery, Pharm.D.: There is, it is the on list here.

Kevin Desmond, RPh: Ok, the ER and XL are the same?

Carl Jeffery, Pharm.D.: Yes.

Shamim Nagy, MD, Chairwoman: Any other questions? Do we have a motion?

David Fluitt, RPh: I make the motion that we accept the proposed list as PDL.

Weldon Havins, MD: Second.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion Carries.

VI. ANNUAL REVIEW – ESTABLISHED DRUG CLASSES BEING REVIEWED DUE TO RELEASE OF NEW DRUGS

A. ANAPHYLAXIS: Self-Injectable Epinephrine

Shamim Nagy, MD, Chairwoman: Moving to the Annual Review of Established Drug Classes being reviewed due to release of new drugs, Anaphylaxis, Self-Injectable Epinephrine.

Public comment? None.

Review of the drug class.

Carl Jeffery, Pharm.D.: For this class, they are all the exact same ingredient, it is just how they are administered that is a little bit different. What brought this is up is that Twinject is no longer available and there is a new product available that is Auvi-Q. I haven't personally seen one, I have read about it, it is a little device about the size of an iphone that gives you verbal directions. You push a button and it reads through the directions to administer a dose. Kind of a novel idea and maybe it has its population, but it is still epinephrine, it still reaches the same result. So, Catamaran recommends that these products be considered therapeutically and clinically equivalent.

Weldon Havins, MD: I move that we accept these five products as clinically and therapeutically equivalent.

Joseph Adashek, MD: Second.

Shamim Nagy, MD, Chairwoman: Any discussion? Voting.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

Carl Jeffery, Pharm.D.: Our recommendation for preferred is to just keep the Epipen and Epipen Jr as preferred. I think there may be a place for the Auvi-Q and I think for maybe the visually impaired or for those who can't read or some other limitations, but they should be able to qualify for the non-preferred. Epipen and Epipen Jr. are the old standby that we would like to recommend as preferred.

Michael Hautekeet, RPh: With Auvi-Q, one of the things I have noticed is that the needle is a little bit shorter than Epipen, so when you inject it, it is a little less painful. And a lot of times when you have people that get into a crisis, they start to panic and they press the button and they start to hear a voice that is reassuring and calming. Especially for the younger people, there is voice that can guide you how to do it. A lot of times, it is the kids that are allergic to whole bunch of stuff, like peanuts. The Auvi-Q I think would have a good place on the preferred list, I think it would help more of the kids. So I would like to make a motion to include Auvi-Q in the proposed preferred list. Maybe with age restriction if that would work.

Weldon Havins, MD: Age restriction for what, minors?

Michael Hautekeet, RPh: Yeah, for smaller kids.

Weldon Havins, MD: Is that your motion?

Kevin Desmond, RPh: For a certain age?

Michael Hautekeet, RPh: Yeah, any child who is allergic to something and suddenly their throat is closing up, they press the button, there is a voice telling them to do this and this, and I think it could be beneficial.

Joseph Adashek, MD: Want to make an age of around 16?

Michael Hautekeet, RPh: Yeah, 16 or something like that.

David Fluitt, RPh: What is its indication?

Michael Hautekeet, RPh: I don't know.

David Fluitt, RPh: Is it indicated for 12 and above?

Carl Jeffery, Pharm.D.: What is the age when a kid can self-administer this? Realistically, how old is a kid before they can self-administer this?

Michael Hautekeet, RPh: They should be able to do it on their own. I know this because I have friends with kids that are very allergic and they have to put this on their leg and press on it, where as you have a device which is this size, it is a lot less scary and the thing talks to you. For me, I think it is…

Unknown Audience Member: Here is a demo product, it's not live, just pull this.

[Demonstration of product use]

Joseph Adashek, MD: Is this made for adults and kids?

Weldon Havins, MD: But you would want to restrict it to just kids?

Carl Jeffery, Pharm.D.: From our perspective, if you're going to make it preferred, I wouldn't put an age restriction on it.

Michael Hautekeet, RPh: Ok, let's just make it preferred.

Kevin Desmond, RPh: I second.

Shamim Nagy, MD, Chairwoman: Any other discussion or comments?

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries.

Weldon Havins, MD: Was the previous motion ok or do we need another motion for the age?

Gabriel Lither: I think his previous motion was to add Auvi-Q without age restriction, so we are fine.

B. DIABETIC AGENTS: DPP-4 Inhibitors and Combinations

Shamim Nagy, MD, Chairwoman: Going to the next class, the Diabetic Agents, DPP-4 Inhibitors and Combinations.

Public comment? None.

Carl Jeffery, Pharm.D.: We have one new product with a couple combinations in this class, the alogliptin or Nesina also in combination with metformin and pioglitazone. This falls into the same other three base products in here, it is hard to tell by looking at what we have here because there are all sorts of combo products and for some reason when they add something else, they have to completely change their name. So we have the Januvia and the Onglyza are others in here. As far as the studies go, there has been a lot of new data out here. There are a few head-to-head trials. There have been a few cases where, the way the study is designed is they take all three drugs within the same study and compare them to placebo, then they compare where each one is going, so it isn't a direct head-to-head study, so it is kind of frustrating that they don't compare them that way. But what we see is a significant benefit over placebo, but like the sitagliptin shows slightly better results in the fasting plasma glucose than some of the other ones, but then there is a new one that shows similar efficacy.

Weldon Havins, MD: Are these part of the statutory regulation?

Carl Jeffery, Pharm.D.: We have looked at that and you're right, they do fall within that class, so if any of them are available on the market before June 30, 2010, we have to consider those preferred, but there have been several agents that are actually available on the market after that date, so we can make those non-preferred, and we'll get to those shortly. No huge difference between the studies here. Within the single agents, they are all available as a once-a-

day drug, and once they start adding other drugs like metformin then it turns into a twice-a-day unless it is extended release. So it is dependent on the other drug. Having that information with the clinical trials, we recommend to the Board that these be considered clinically and therapeutically equivalent.

Shamim Nagy, MD, Chairwoman: Any discussion?

Weldon Havins, MD: I move that we consider this list of drugs clinically and therapeutically equivalent.

Joseph Adashek, MD: Second.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries. I have this letter here, is the gentleman here, but he doesn't want to testify.

Carl Jeffery, Pharm.D.: So with the NRS in mind that limits our dates, we have checked these and the new agent and some of the other ones, we would like to drive the utilization toward these agents on the preferred drug list here, trying to push people toward those products, and make these non-preferred. Right now they are all preferred, so this could be an adjustment for some patients, so I will open it up to what the Board thinks about grandfathering people that are on these. I could see that if a patient was stabilized on their medication that it would be difficult to change in the middle of a stream. Catamaran recommends as preferred Kombiglyze XR, Onglyza, Januvia, Janumet, Janumet XR, and Juvisync as preferred and the other as non-preferred.

Shamim Nagy, MD, Chairwoman: Any discussion or questions?

Joseph Adashek, MD: So all the non-PDL now were all PDL before?

Carl Jeffery, Pharm.D.: Yes

Joseph Adashek, MD: Obviously, there are many people on those five drugs together and doing well.

Carl Jeffery, Pharm.D.: Yeah, I don't have the utilization, but probably a good percentage.

Joseph Adashek, MD: I would like to make the motion that we accept the recommendations…

David Fluitt, RPh: I have some other discussion first. Can you tell me why the Juvisync was considered for the proposed PDL?

Carl Jeffery, Pharm.D.: Some of it was driven by the date it was released, so if it was available before June 30, 2010, our hands are tied, it has to be considered preferred, and that is Nevada Statute.

Joseph Adashek, MD: I would like to make a motion that we accept the recommendation for PDL and grandfather those patients that are stable on the non-PDL medications.

Weldon Havins, MD: That is if they are currently on it.

Joseph Adashek, MD: Yes assuming they are not going to take a break from their diabetic drugs.

Weldon Havins, MD: Second.

Board votes unanimous: Aye.

C. DIABETIC AGENTS: Other Agents

Shamim Nagy, MD, Chairwoman: Ok, next class Diabetic, Other Agents

Robert Maul, MD: Hi my name is Bob Maul, I have worked at UMC for the past 25 years and I really thank you for allowing me to stay away from my wife today. She is taking archery next week. I have a different clientele coming out of University Medical Center, they usually don't have a place to stay, they may or may not have a Clark County medical card, they may be pending Medicaid, they are homeless, they are drug addicts, they are hypertensive non-compliant diabetics, probably on two different medications. And for them to take insulin is either they can't or won't, they have a psychosis or they feel they are going to get robbed if they do take insulin because of the insulin pens because they are a commodity out there on the street. I believe the Invokana fills a niche for these folks that will allow them to stay off insulin for a longer period of time and perhaps they will be more compliant with an oral medication. I wish it would be readily accessible for these men and women. That is my main concern for their well-being and if we could make it accessible under any circumstances would be much appreciated.

Joseph Adashek, MD: Why do you like this one over the others?

Robert Maul, MD: Because I can spell it. I have had, I have not used it myself, I have indirect experience by both firemen and police officers who I have referred to private physicians who are on limited duty because they are diabetics, newly diagnosed or have been diagnosed for a long time and the stigmata of taking insulin or they can't or won't take insulin, they did very well. Several of them have stAye.d off insulin, although it is an excellent drug, for months and months until they can be convinced that maybe insulin is the best way. But Invokana allows them to stay off the insulin and the stigmata of injections. Any my homeless folks, they get robbed. I have several patients I have seen that live in Fresno, that is a very poor community. And a lot of them are on this medication because they get robbed, they leave their medicines or people take them. I think this is a pleasant alternative to insulin at this moment in time for many of them.

Joseph Adashek, MD: The others are not insulin, why do you prefer this one over the others?

Robert Maul, MD: This one has a different mechanism of action. It's the minor or less metabolic side effects. There is no weight gain, it is just easier medication than insulin when you have to take insulin two or three times a day, do an accucheck, and maybe run out of chemstrips or maybe not even have them and borrow medications from the guy who lives two tents down from you on the street. Accessibility is very important to my clients be it on a prior authorization or directly. Thank you very much.

Michael Hautekeet, RPh: If I could give a little more insight to this drug. I am on this drug. The Invokana is completely novel mechanism of action. When we learn about diabetes, they always frown at excreting glucose in the urine, this drug will actually block the GLPT-2 receptor in the loop of Henle and prevent the reabsorption of sugar, because the tubule will excrete sugar, the GLPT-1 will excrete it then the GLPT-2 will reabsorb it. By blocking the site, the GLPT-2, you excrete sugar at up to 300 mg per day, so your blood sugars will drop. I am on the drug myself, so that is why I know about it. It is very interesting, it has lowered my A1C, and it is a totally different mechanism of action. The only side effect is, don't take it at night because it acts like a diuretic. So you run all day long. It comes in two strengths and most of the time, the 100mg for me is enough, and it is once a day. It is a really, I can tell from me personally, it has worked well for me. So I would like to make the motion to include Invokana in the…

Shamim Nagy, MD, Chairwoman: We're not done with Public Comment yet.

Marykay Queener: Actually, your personal comments are probably more impactful than mine, but I'll come up any way. Good afternoon, my name is Mary Kay Queener, I am a scientific liaison with the Health Outcomes Group at Johnson and Johnson. I am here to speak to you today about Invokana or canagliflozin, to consider adding it to the PDL. As you know and as you have heard testimony already, despite the large number of agents that are available, a lot of people cannot get to their A1C goal. Invokana is a first in class, unique mechanism of action. As you just said, it is a SGLT2 co-transport inhibitor, which is responsible for the sodium-glucose exchange. The result is that, as you said, that the glucose is normally filtered by the kidney in hyperglycemic patients would normally be reabsorbed, in this case is blocked. So the patient excretes that extra glucose. This is an insulin independent mechanism of action, can which can be advantageous, particularly in combination with other agents. It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type II diabetes. The dosing is as you said is 100mg once daily before the first morning meal, and in patients with inadequate control on the 100mg dose, they can go up to the 300mg dose provided their GFR is above 60. It has been studied in a large number of studies. Nine clinical trials in phase three, over 10,000 patients, it has been studied in three head-to-head trials, two against Januvia, and one against glimepiride. It was looked at in monotherapy, dual therapy, triple therapy and also in patients with high risk of cardiovascular disease, patients who are older and with moderate renal impairment. In every study it showed statistically significant improvement in A1C and it also decreased their systolic blood pressure and also caused weight loss, which is obviously a benefit in this patient population. As I said, all the studies were statistically significant in their A1C lowering at their primary endpoints of 26 to 52 weeks. The 100 mg dose had lowering of up to

0.91 and the 300mg dose had up to 1.2 points in A1C. In addition, it did show, the 300mg dose, was superior in A1C lowering compared to Januvia and glimepiride. Glucose excretion in the kidney accounts for most of the most common adverse events. As you mentioned nocturia, if you take it at night, in addition, mycotic infections and UTI's and volume related events were the most common adverse events. The instance of hypoglycemia is similar to placebo and in all the clinical trials, it was very low with the exception of in combination with insulin or with a sulfonylurea. In that case, if it is used in combination with any of those agents, the insulin or sulfonylurea may need to be lowered. In term of clinical trial adverse events, we did see a dose dependent increase in LDL which went along with a dose dependent increase in HDL and lowering of triglycerides. The HDL/LDL ration is unchanged, but we are continuing to look at long-term cardiovascular safety. As a part of our ongoing clinical trial program and post-marketing commitments, it can be used as monotherapy for patients who are intolerant to metformin or who are not meeting their goals on dual or triple combinations, including with insulins to improve their glycemic control. And based on all that, I would ask you to consider addition to the PDL for appropriate patients who have not achieved their glycemic control with diet, exercise and metformin or other agents that they are currently taking. I would be happy to answer any questions.

David Fluitt, RPh: Did you do any studies to see what the net effect on the A1C was? I have seen some other studies that drop it a 0.8 points, do you have any idea what that figure is? Do you see that there is a place for this medication to people who are not tolerant to metformin?

Marykay Queener: It was done as monotherapy, there was a monotherapy trial, and that actually had the largest A1C lowering, so the 100mg dose lowered the A1c 0.91 and the 300mg dose lowered it 1.16. And then all the other studies where in combination with background therapies, metformin or sulfonylurea and then adding on Invokana compared to other agents or compared to baseline agents.

Kevin Desmond, RPh: Is this ever considered for first line therapy? Or is it always metformin first and then metformin not tolerant or failure before the switch?

Marykay Queener: The indication from the FDA is when diet and exercise fail, similar to most of the other agents, but in terms of where we are positioning it, it would be a failure or intolerance to metformin following diet and exercise. The ADA has not come out with new guidelines to this point, since the approval back in April. The AACE has it as Second. line therapy after metformin along with the other branded agents. Thank you.

Carl Jeffery, Pharm.D.: Thanks for the good information on this product, lots of public comment. It is unfortunate that this is the first of several agents that are in the pipeline because right now it falls into the "Other" agents. I think that probably the next time we meet, or eventually when we meet again we'll have these in their own class of similar agents. So right now we have to limit the class with these other ones. Right now, the Precose we moved up to, so there are only a couple other agents in here. The other class is a pretty broad term when we talk about clinically and therapeutically equivalent, we just say that, yeah, they are all used to treat

diabetes. This is kind of a general class, but like I said, in a couple meetings, we will have them broken out into their own class.

Weldon Havins, MD: I move that we consider these medications clinically and therapeutically equivalent.

Evelyn Chu, Pharm.D.: Second.

Michael Hautekeet, RPh: We have two different classes, so as the "Other" Diabetic Agents, I Second. The motion as a second class.

Carl Jeffery, Pharm.D.: You think Invokana should be in its own class?

Michael Hautekeet, RPh: Yes, it should be its own class, but for now, we can just recognize that, yes, it has a different mechanism of action. So yes, I second. the motion.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion carries. Update to PDL?

Carl Jeffery, Pharm.D.: So because this is a new agent and it is still recommended that metformin be tried first, is really the reason we put it here as non-preferred. So this is our proposal is that the new agent be non-preferred, and keep the other ones the same.

Michael Hautekeet, RPh: It is a good drug, so I would like to make the motion to make Invokana as preferred, but after a trial of metformin, as an adjunct to therapy.

Joseph Adashek, MD: So you're saying if they fail one medication?

Michael Hautekeet, RPh: Well no, if we put Invokana as preferred, but as a second line therapy, they have to try metformin or something first and then they can get this.

Kevin Desmond, RPh: Wouldn't we leave it non-preferred then? And then have…

Joseph Adashek, MD: Basically, that is the definition of a non-preferred.

Coleen Lawrence: So you can make it non-preferred, and instead of having to go through two agents, they would have to go through one agent.

Joseph Adashek, MD: Or you could just make it preferred.

Michael Hautekeet, RPh: Let's just make it preferred.

Evelyn Chu, Pharm.D.: I second.

Joseph Adashek, MD: You second the preferred?

Gabriel Lither: So let's just get this clear…

Michael Hautekeet, RPh: Invokana as preferred.

Gabriel Lither: Ok we have a motion and a second.

Shamim Nagy, MD, Chairwoman: Any discussion?

Weldon Havins, MD: I have a question, if there is an FDA requirement or suggestion that you try metformin first, is that just standard of care? What if they order Invokana without going with metformin?

Michael Hautekeet, RPh: I think they can put metformin and Invokana together.

Weldon Havins, MD: So we will just leave it up to the physician?

Michael Hautekeet, RPh: Yeah, we'll just leave it up to the physician.

Shamim Nagy, MD, Chairwoman: And the protocol?

Michael Hautekeet, RPh: I don't know about the Invokana.

Evelyn Chu, Pharm.D.: I don't believe it is an FDA requirement, it is diabetes guideline that metformin is always first because it is cheap and it has good outcomes and good evidence, but it is not an FDA requirement.

David Fluitt, RPh: Dr. Jeffery, you mentioned that this represented a new class of medications and you said there are others coming down the pipeline which indicates to me that we will be looking at these at some future point. So strategically, is there any advantage of having this as proposed PDL as more agents become available?

Carl Jeffery, Pharm.D.: I think you bring up a good point, because as we have seen in other classes, once we make something preferred, it is hard to get that non-preferred again, where it is much easier to move the other way, moving the non-preferred to preferred.

Michael Hautekeet, RPh: But right now, this is the one that is available.

David Fluitt, RPh: There is a core therapeutic value to this medication, that all patients have access to in the non-PDL format. So we can take a look at maybe if someone fails on metformin or in addition to metformin, to use this medication for the superior impact on A1c levels for example.

Michael Hautekeet, RPh: There is a motion right?

Shamim Nagy, MD, Chairwoman: Yes we have a motion to make it preferred.

Joseph Adashek, MD: And it has been seconded?

Shamim Nagy, MD, Chairwoman: Yes, we have a second. So should we move to voting?

Joseph Adashek, MD: Aye.

Weldon Havins, MD: Aye.

Kevin Desmond, RPh: Aye.

David Fluitt, RPh: You say it is hard to move it back, I am undecided

Michael Hautekeet, RPh: Aye.

Shamim Nagy, MD, Chairwoman: Aye.

Constance Kalinowski, MD: No.

Evelyn Chu, Pharm.D.: Aye.

Gabriel Lither: Ok, how many "Aye." did we have? Five? Ok then it does not pass because there are 10 committee members and we have to have a majority to pass a motion, so with five, it does not pass.

Joseph Adashek, MD: Can we try to vote again?

Gabriel Lither: No, you can propose a different motion.

Coleen Lawrence: No, we had six "Ayes."

Shamim Nagy, MD, Chairwoman: Ok, so we do have six votes, the motion passes.

David Fluitt, RPh: It's a tough one, because I do see more coming in, and we do see a therapeutic failure. But as I understand it, as a non-preferred medication, we can still have access to that.

Joseph Adashek, MD: Dr. Kalinowski, your thoughts?

Constance Kalinowski, MD: My thinking was that, by keeping in non-preferred, then that supports the recommendations, it sort of requires people to try some first-line first, and if there is rationale, it passes.

Evelyn Chu, Pharm.D.: But we don't do that with Januvia. It is on the preferred list, we don't make them try metformin first.

David Fluitt, RPh: And we don't do that with the incretin mimetics, so we don't get to the other classes of medications, as far as the PDL, so it doesn't make sense to me. My objective is to make sure that we have access to it. And I do understand that it is one more phone call to get it. It's too late to change my vote now, it passed.

D. OPHTHALMIC NON-STEROIDAL ANTI-INFLAMMATORY AGENTS

Shamim Nagy, MD, Chairwoman: Moving onto the next class, the Ophthalmic Non-steroidal Anti-inflammatory Agents.

Public comment? None, Dr. Jeffery.

Carl Jeffery, Pharm.D.: So we brought this up before the Board because there is a new product, Ilvero, is another non-steroidal anti-inflammatory into this class. The same active ingredient as Nevanac, but a different strength, it is a 0.3% instead of 0.1%. I don't think there is a recommendation of one over another, they are all used right around operations, perioperatively. So the guidelines are not specific on which one to use and all of them have been shown to be safe and effective for the treatment of either pre-cataract surgery or some of the others. So with that information, we would like to recommend to the Board to consider these products clinically and therapeutically equivalent.

Weldon Havins, MD: I move that we consider the list clinically and therapeutically equivalent.

Kevin Desmond, RPh: Second.

Shamim Nagy, MD, Chairwoman: Any discussion? Voting

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion approved. Update to PDL?

Carl Jeffery, Pharm.D.: So this is one where we just include the new agent as non-PDL. I don't think there are any other changes, everything else is the same.

Weldon Havins, MD: I move that we keep the drugs on the PDL.

Joseph Adashek, MD: Second.

Shamim Nagy, MD, Chairwoman: Any discussion? Voting.

Board votes unanimous: Aye.

VII. ANNUAL REVIEW - DRUG CLASSES WITHOUT PROPOSED CHANGES

Shamim Nagy, MD, Chairwoman: Motion approved. Public comment?

Robert Jaramillo: Good afternoon, my name is Robert Jaramillo and I am here to talk about the respiratory inhaled anticholinergic agents, in particular talking about aclidinium, also known by the brand name, Tudorza. Aclidinium is only the Second. long acting anticholinergic agent available for the treatment of COPD, an important option seeing how COPD is now recognized as the third leading cause of death in the United States. And the 2011 Gold Guidelines also recognize long-acting muscarinic antagonist agents as first-line medications to improve symptoms as well as quality of life patients who have moderate to very severe COPD. Tudorza is

indicated by the FDA as a long-term maintenance treatment of bronchospasms associated with COPD, including chronic bronchitis as well as emphysema. Unfortunately, there still continues to be an unmet need in the treatment of more than the 24 million Americans that have COPD. And some of these unmet needs can come for the medications themselves, including safety and tolerability, efficacy as well as ease of administration. Three pivotal studies involving more than 1900 patients of 12 and 24 week duration led to the approval of aclidinium, a couple clinical points from these studies. Tudorza was able to show statistical significant improvement from baseline through the end of the studies in trough FEV1 bronchodilation. It ranged from 72 to 128 ML, showing it maintains bronchodilation over 24 hour period. Also, aclidinium has a very quick broncho-dilatory effect of 155ML within a half an hour and reaching its maximum peak of 263ML within 3 hours. And it shows it has a very durable and persistent effect, not only in peak and trough bronchodilation, able to show it has the same bronchodilation on day 1 of the very last days of the trials of the 12 and 24 week studies. Safety and tolerability of Tudorza was also established in three 40 to 52 week long-term studies. The recommended dose of aclidinium is 400 mcg twice daily. And being dosed twice daily, Tudorza was able to show statistical significant improvement of nighttime symptoms including breathlessness, cough and wheezing, an issue with over 90% of patients who have this disease. And Tudorza was also able to show a statistical significant reduction in the total daily use of rescue medication, 30 less puffs per month compared to placebo. And as for new data to share with you, a comparative six week trial looking at the efficacy and safety aclidinium and tiotropium, Spiriva, was recently published in the journal of Chronic Obstructive Pulmonary Disease. Aclidinium was able to show a similar trough and peak FEV1 bronchodilation to tiotropium at both day one, throughout the trial as well as the very last day of the six week study. As well, it duplicated it's statistically significant improvement in nighttime symptoms including phlegm, shortness of breath, wheezing and coughing. Aclidinium is a dry powder that is delivered through a breath actuated device called Presair and was designed to help with compliance as well as ease of administration. It really has a three easy step process and first, the 30 day supply is self-contained in the device. First you remove the protective cap, press the green button, this is just the display so it's not green, and then you take an inhalation. It also has an auditory and visual mechanism to let the patient know they received the full dose. There is a clicking sound, also a colored window that changes from green to red to let the patient know they received a full dose. There is also a locking mechanism that prevents double dosing, and a dosing counter that also locks out when no more drug is available. I know this can be an issue with some of the other devices that are available for COPD. I also want to mention some information. Again, from the six-week trial is that they looked at the preference of the patients, and over 80% of the patients prefer the Presair device over the 10% for the Handihaler. Important safety and tolerability information to mention, aclidinium has less adverse events than placebo. The most common were headache at 6.6%, nasal pharyngitis at 5.5% and cough at 3%. And due to its low systemic adverse events, its anticholinergic side effects were less than 1%, including cardiovascular events. So in conclusion, Forrest thanks the committee for their consideration for adding aclidinium to the preferred drug list. Aclidinium is recommended first line by the GOLD Guidelines as maintenance therapy as well as can offer another choice to your members when there may be issues with safety and

tolerability as well as ease of administration with the same bronchodilation that we see in the class. So I'll stop and ask if there are any questions. Did you want me to pass around the device?

Carl Jeffery, Pharm.D.: I just want to comment real briefly on this, we have this on the agenda for the December meeting. So I think the Board is free to make a decision if they want to discuss this now. It is not on the agenda now. Because there are also some changes with the availability of another product. This will be on December's agenda.

Naresh Singh: Good afternoon, my name is Naresh Singh, I am a practicing pulmonologist. I have been practicing here for about 23 years. Dr. Maul actually was a senior resident and changed me from obstetrics and gynecology to internal medicine. I'm on faculty at the University of Nevada School of Medicine and at Toro and I am a speaker and have been in the past for every inhaler, in every class. This is the anticholinergic, currently the only long-acting anticholinergic you have is Spiriva. Spiriva is a great drug, the problem is with 16% dry mouth, you have to individually peel the capsule off, open the device, insert the capsule into the device and then squeeze and then inhale it, and then open the device and then dispose of the capsule without using your hands so you don't have contaminated powder. I have patients in nursing homes and I have patients with Parkinson's disease that cannot go through all those maneuvers. I work out of University Medical Center and I am a co-director of the pulmonary department, so I have a fairly large population of Medicaid. You already heard Dr. Schlopter early on advocating that there are some patients who benefit from Tudorza, so you saw the device, how plain and simple it is and in fact, yesterday, I had a nursing home patient with Parkinson's and this is the device we were able to use. And so there is a study in Chest that twice-a-day dosing in some patients does have improvement over once-a-day. If you screw up one dose, you're locked out for the rest of the day. You get 30 pills. With twice-a-day dosing, there is a benefit, and there are some people who have a reduction in their sympathetic tone at night, and therefore an increased unprotected parasympathetic tone where twice-a-day dosing works better. And so for those patients, I advocate and recommend and ask the committee to consider adding Tudorza to the Medicaid formulary. Thank you.

Shamim Nagy, MD, Chairwoman: Thank you very much. I'm sure Catamaran and the Board members will keep that in mind for the next meeting. Coleen, do you want to say something.

Coleen Lawrence: No, I'm just kind of curious, we were just looking at our current Preferred Drug List. I think there might be some confusion. The physician said there was only one choice right now.

Carl Jeffery, Pharm.D.: For long-acting. Spiriva is the only long-acting anticholinergic preferred, the others are all non-pdl.

Coleen Lawrence: Ok, so if it is your choice, we can bring this back again in the future.

Shamim Nagy, MD, Chairwoman: Ok, in the future, we will bring this back.

Joseph Adashek, MD: When will it come up? Can we put it on the agenda for the next meeting?

Shamim Nagy, MD, Chairwoman: Yes.

Joseph Adashek, MD: Do we need a motion to do that? I make a motion to put this on the agenda for the next meeting.

Michael Hautekeet, RPh: Second.

Carl Jeffery, Pharm.D.: Is there any other public comment? I think we need to vote to accept the recommendation to keep the remaining classes unchanged. There are 64 classes, and they are all listed in the agenda, the classes on the preferred drug list where we are recommending no changes at this time.

Weldon Havins, MD: Unless there are other specific reasons to review these, I move that we accept Catamaran's recommendation that we maintain the PDL with this drug classes.

Joseph Adashek, MD: I second.

Board votes unanimous: Aye.

Shamim Nagy, MD, Chairwoman: Motion approved.

VIII. REPORT BY CATAMARAN ON NEW DRUGS TO MARKET, NEW GENERIC DRUGS TO MARKET, AND NEW LINE EXTENSIONS

Carl Jeffery, Pharm.D.: We will be sure to bring back the inhaled anti-cholinergics in December. The only thing we have left is the RxInsights that is in the back of your binder, it gives a little foresight into what's coming. I think the last couple meetings, this has been a little underwhelming, but this one has some really good information of some new agents that are coming out. We have several new generics that are coming out that I think will impact us and our future decisions. There is a generic now for the 18mg Concerta, where there were other strengths, but not the 18mg. Again another one for the repaglinide which is the generic Prandin, and it has a 180 day exclusivity, that means one generic manufacture has the rights to produce that for 180 days before any other generic manufacture can start making it. The Retin-A Mircro, Trilipix, Aricept 23 and Roserem have all been approved. This Roserem is a little bit sketchy because they are currently in litigation and trying to get it off, so it probably won't be available until 2019, but it is still listed in here. That was it for my presentation.

IX. REVIEW OF NEXT MEETING LOCATION, DATE, AND TIME

Shamim Nagy, MD, Chairwoman: Thank you Dr. Jeffery.

Location and date for the next meeting?

Carl Jeffery, Pharm.D.: December, the third Thursday so we don't interfere with the holiday week, December 19. For me, this location works well, I would like some feedback from the Board members, I know it is off the beaten path for a lot of you. So far the JW Marriott has treated us well.

Joseph Adashek, MD: It's good for me.

Weldon Havins, MD: Me too.

Shamim Nagy, MD, Chairwoman: Any public comments? No public comments. Meeting adjourned.

Meeting adjourned at 3:05pm.