Nevada Medicaid
Pharmacy and Therapeutics Committee
Draft Meeting Minutes

The Division of Health Care Financing and Policy (DHCFP) Pharmacy and Therapeutics Committee conducted a public meeting on June 26, 2014, beginning at 1:00 p.m. at the following location:

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

Committee Members Present:
Michael Hautekeet, RPh; Mark Decerbo, Pharm.D.; David Fluit, RPh; Adam Zold, Pharm.D.; Evelyn Chu, Pharm.D.; Shamim Nagy, MD, Chairwoman, MD;

Committee Members Absent:
Weldon Havins, MD; Amir Qureshi, MD, Joseph Adashek, MD; Constance Kalinowski, MD

Others Present:
DHCFP: Gabriel Lither, Deputy Attorney General; Coleen Lawrence, Chief Program Services;
Catamaran: Carl Jeffery, PharmD; Kevin Whittington, RPh
HPES: Beth Slamowitz, Pharm.D.
AGENDA

I. CALL TO ORDER AND ROLL CALL

Meeting called to order at 1:00 PM.

Roll Call:
David Fluit, RPh
Evelyn Chu, PharmD
Mike Hautekeet, RPh
Adam Zold, PharmD
Gabe Lither
Shamim Nagy, MD
Mark Decerbo, Pharm.D.
Coleen Lawrence, Chief Clinical Policy Team, Nevada Medicaid
Kevin Whittington, Catamaran
Carl Jeffery, Catamaran

II. PUBLIC COMMENT

None

III. FOR POSSIBLE ACTION: Review and Approval of the March 27, 2014 Meeting Minutes

Review and approve March 27, 2014 Meeting Minutes

Michael Hautekeet, RPh: Moved to accept meeting minutes.
Board votes unanimous, Aye.
Minutes approved.

IV. STATUS UPDATE BY DHCFP

Coleen Lawrence: Provided updates on:
• Director, Mike Willden has been appointed Chief of Staff of Staff for Nevada. The previous administrator for the Division of Healthcare Services, Romaine Gilliland, will now serve as the Director.
• P&T annual review will be in November as required by statute.

V. ESTABLISHED DRUG CLASSES

A. CARDIOVASCULAR: ACE Inhibitors and Diuretic Combinations

Public Comment: None

Carl Jeffery – Catamaran: New Liquid product available – Enalapril - comes with a packet of Ora-Sweet that you mix together and then give to the patient. Comes in a powder, makes a solution when mixed with the Ora-Sweet. It comes all prepackaged and is ready to go. Other than that, I’m not going to get into the details about ace inhibitors. There’s really no special studies done on just this one. Nothing that I’m aware of has changed with ace inhibitors recently. It’s just another one that falls into the treatment. With the Enalapril, guidelines just recently came out. Current guidelines recommend the ace inhibitor. I think this may be a topic that we talk about in the future, but right now nothing that I’m aware of has really changed as far as the treatment guidelines, or new clinical information. It’s really only going to be used for kids. I think what we want to avoid is it being used in nursing homes for the ease of the nursing staff that could easily crush a pill up and give it via a tube that way. So Catamaran would like to make the recommendation that the board consider these clinically and therapeutically equivalent.

David Fluit, RPh: Motion to consider clinically and therapeutically equivalent.
Adam Zold, Pharm.D. : Second.
Board votes unanimously: Aye.

Motion approved.

Carl Jeffery: Our recommendation is to make the Epaned the new version of the liquid Enalapril as non-preferred. Our logic behind this is if a child does need this for some reason, it would be easily justified if medical necessity would be able to override the non-preferred criteria. This would also potentially limit it for use in the nursing home if it wasn’t really necessary.

Michael Hautekeet, RPh: One of the problems I see in the pharmacy is that we have a lot of compounding prescriptions for Enalapril for children. Could we update your recommendation to accept it and put an age limit on it, to make it preferred for children under 4 or 5, because compounds are not covered by Medicaid, trying to get it through the doctors, we can’t get ahold of the doctors.

Carl Jeffery: I mean it’s up to the board’s discussion I guess.
Adam Zold, Pharm.D. - Agrees with age limit.

Michael Hautekeet, RPh – Motions to add Epaned on the preferred list for ages of less than 5 years.

Adam Zold, Pharm.D.: Second.

Mark Decerbo, Pharm.D. – Do we have past precedent of setting age restrictions?

Carl Jeffery: We do. There are some other ones for example Xopenex is that way.

Further discussion question related to swallow studies where patients who have had strokes are unable to swallow medication.

Board member wanted to ensure that this medication will still be accessible to those patients.

Carl Jeffery: So basically, if Mike’s motion is approved, how it would go is, if a prescription came in for the Epaned, for a child who is 5 or under, the claim would go through without any prior authorization. It would just go right through. If they were older than 5, it would stop for non-preferred. At that time, they would have to call. If it was somebody who had difficulty swallowing, they could call and make that medical justification of why they need this product over something else.

Michael Hautekeet, RPh: Amends motion to make Epaned preferred for 10 years old and younger.

Adam Zold, Pharm.D.: Second.

Board Votes unanimously: Aye.

Motion carried.

B. CENTRAL NERVOUS SYSTEM: Oral Anticonvulsants, Misc.

Public Comment:

Dr. Bratman: Epilepsy is a serious neurological condition characterized by unpredictable seizures, which vary in type and severity, and can be extremely disruptive, to the patient and the lives of their caregivers. There’s a high degree of variability in the response rates to medications for this condition. In a seminal study by Quan and Brody, they showed that 53% of patients with epilepsy did not respond to their initial epilepsy medication. In addition to that, 36% of patients with epilepsy, seizures remained uncontrolled, despite being on more than two epilepsy medications. Therefore, today there is still definitely an unmet need in this class for epilepsy patients. On November 8th, 2013, the USFDA approved Aptiom for the use of adjunctive treatment of partial onset seizures. Aptiom, or the generic is recognized by the FDA as a new molecular entity, also a unique active ingredient, and structurally distinct from any other drug. The approval of Aptiom was supported by the results of three phase three randomized placebo control trials involving more than 1,400 patients. The patients in these studies
experienced partial onset seizures at baseline despite being on up to three concomitant epilepsy medications. In the pool of data analysis for Aptom, on the 800 mg and 1200 mg doses, given once daily, demonstrated significant reductions in standardized seizure frequency vs. placebo over 12 weeks, which was the period studied in our trials. Also, at 1200 mg, 41% of patients experienced seizure reduction of 50% or more. The most common adverse reaction in patients taking Aptom at doses of 800 or 1200 mg were dizziness somnolence, nausea, headache, diplopia, vomiting, fatigue, vertigo, ataxia, blurred vision, and tremor. These are all adverse events that were seen in 2% or more than placebo. The incidents of adverse events during titration were less frequent for those patients that began the initial dose at 400 mg as compared to those patients that started at 800 mg. Aptom is available in 200, 400, 600, and 800 mg tablets which can be taken whole or crushed, with or without food. The recommended starting dose for safety reasons is, in most patients, 400 mg once daily. After one week, dose should be increased to 800 mg, once daily, which is the recommended maintenance dose. If patient needs additional therapy after one week at 800 mg, they can be increased to 1200mg, once daily. Lastly, Aptom is not a scheduled medication.

Clinical Presentation:

**Carl Jeffery:** New anti-epileptic on the market – Aptom, or eslicarbazepine, indicated for adjunctive therapy for partial onset seizures. Mechanism of action is not exactly known, but they think it has something to do with the inhibition of the voltage gate and sodium channels. Catamaran would like to make the suggestion that these are clinically and therapeutically equivalent.

**Michael Hautekeet, RPh:** Motion to consider class clinically and therapeutically equivalent.

**Evelyn Chu, Pharm.D.** Second.

**Board votes unanimously:** Aye.

**Motion carried.**

**Carl Jeffery:** Catamaran would like to make the recommendation that Aptom be considered non-preferred because it is not first lane. It is adjunctive therapy. If there was no preferred drug list at all, there would still be two or three agents down the line before they got to this one. As the board looks at it, we can make this listed as non-preferred and that would maybe guide the therapy toward more first line therapy agents.

Questions:

Information for other agents in this class?

**Carl Jeffery:** We really don’t have any new information for these other agents. The class is open if you see some other agents on there, but our hands are a little bit tied on this class because any agent that was available before June 30, 2010, we have to have preferred. The ones on the right side here are the ones that have come out afterward that we can make non-preferred. It just so happens that all of them are indicated for adjunctive therapy as well. That’s why we’ve made that decision in the past. Just for consistency we can have this that way as well.
Adam Zold, Pharm.D.: Motion to accept recommendations for PDL making Aptiom non-preferred.
Michael Hautekeet, RPh: Second.
Board votes unanimously: Aye.
Motion carried.

VI. NEW DRUG CLASSES

A. DIABETIC AGENTS: Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors

Presenter:
Dr. Kannon: Dr. Chuck Kannon – Endocrinologist- works as the Director of Diabetes Center in the Redrach Medical Group at 5701 Charleston. 97% of his patients are people with diabetes. A sizable number of them, over 35-40% have some form of Medicaid plan or another. As challenging as it is, some days, at the end of the day, I feel like I’m at the epicenter of the unraveling diabetes tsunami that is sweeping this country. Las Vegas is a microcosm of that. Also I’m learning from my experience with our patients who are on Medicaid, that diabetes is not an equal opportunity villain. It seems to be those who are at the lower rungs of the economic ladder this disease is more capricious. To give you an example, when I used to work elsewhere, in silk stocking districts, the average referral of A1C was under 10. Now my average referral of a patient who comes to me with type 2 diabetes, who has Medicaid, is 12 or above. And you can keep wondering, for the obvious reasons. You can blame it on noncompliance. You can blame it on, yes, physician apathy. You can blame it on not having enough access to healthy food, and you can also blame it on lack of specialists. But the one thing you cannot blame it on is lack of access to diabetes medications. Thanks to this group, thanks to the wisdom and foresight, virtually every drug for treatment of type 2 is made available to our patients with type 2 diabetes and clearly, all of us our grateful for that. In the same realm, people keep asking, why do you have to have so many pills to treat one single disease? The reason for that is reasonably straight forward. Unlike type 1, where the entire problem is total and irrevocable loss of insulin, it’s not that way for type 2s. It’s got multiple ideologies. 8 to be exact. And we will call it, cleverly, the (garbled) of reasons why people get diabetes type 2. So we’re looking for drugs that work in very many ways and hit the disease at multiple fronts. Towards that end, last year, this committee okayed the approval of making one of the first SGLT2 inhibitors available to people with diabetes sometime about a year ago. The first in its class, canagliflozin, or Invokana, was approved by this committee last year. I’ve now been using this in our patient population, for more than a year. As we all know, this drug works by making the kidney excrete excessive glucose. Remember, in old days, having glycosuria was bad news. This is exploiting the ability of the kidney to promote glycuresis. The nice thing about the mechanism is no matter what other treatment you are on, whatever pills you are on, whatever insulin you are on. When you are out of control, adding a drug that flushes away the glucose, it’s almost like using the kidney to flush more. If you think glucose is a toxin, you’re detoxing now with the use of this class of drugs. Invokana has caught on for almost a year and universally, the big advantage that we see is the weight loss. Everyone agrees today that the treatment of type 2 diabetes is just not lowering the glucose, in fact it’s lowering the body weight. In fact there is even a clever term for this disorder now. It’s no longer diabetes. It is Diabesity, indicating that unless you lose weight, no matter what else you do,
that’s the core of the problem. And so far, from what I’ve seen, Invokana, as a SGLT2 inhibitor, effectively does that and brings down the A1C on all other treatments you can layer it on. The side effects are very few, but these are important to discuss, such as genital mycotic infection, volume depletion, and so on. It’s a small price to pay for the big payload at the end of the road. I thank you for having introduced and made it available. We just hope that it will continue to be made available to our patients who are enormously benefiting by the largess of availability. Thank you much and if you have any questions I would be happy to answer them.

Dr. Wynn: Doctor Carolyn Wynn – Medical Science Liaison with AstraZeneca – Farxiga. Newly approved drug in the SGLT class for the treatment of diabetes. As he (the previous speaker) so eloquently described it is a selective SGLT2 inhibitor. Farxiga works in the kidney to remove glucose from the urine. It does this by blocking the SGLT2 transporter thus preventing the reabsorption of glucose back into the bloodstream. It is indicated for use with patients for treatment of diabetes, for those who are inadequately controlled through diet and exercise. It is not yet indicated for the treatment of type 1 diabetes or diabetic ketoacidosis. There are two doses available. There’s a 5mg dose and a 10mg dose. The recommended starting dose of Farxiga is 5 mg once daily, taken in the morning, with or without food. In patients tolerating Farxiga 5 mg once daily, who require additional glycemic control, the dose can be increased to 10 mg once daily. This medicine is not recommended for patients with moderate renal impairment, which is defined as GFRs of less than 16 mls per minute. For this medication to be beneficial, your kidneys need to function properly. This is why there is a caveat regarding moderate renal impairment. There have been about 24 clinical trials for Farxiga in the past 10 years. (Phase 2 and Phase 3 trails)

Over 11,000 patients worldwide were studied. Over 6,000 patients were actually treated with Farxiga. These patients covered the range of Type 2 diabetes progression. This includes patients who were drug naive, who failed oral agents, who are already on insulin, those who are elderly, history of cardiovascular disease, and that’s just to name a few. We know that there are many therapeutics available for the treatment of diabetes and we studied Farxiga in various capacities with these agents as well. I’m not here to give you a data dump of all 24 clinical trials, but I do want to give you a brief overview of what these entailed. We studied these in a placebo controlled setting in monotherapy, as an add-on to Metformin, Sitagliptin, Pioglitazone, Sulfonylurea, as add-on to insulin. Those include dual agents as well as triple agents. Also had active comparative trials, or “head-to-head” trials. That was in comparison to Metformin XR as well as in comparison to Sulfonylurea which are standards of care. Additional studies, of course, you have to consider special populations. I’ve already mentioned looking at patients with mild to moderate renal impairment. We also had two dedicated hypertension studies for patients who had a background of ACE and ARMS which, again, are standard of care for patients with diabetes. Overall, these clinical studies proved that Farxiga is effective in reducing A1C, with additional benefits of weight, as well as blood pressure reduction. And just to mention, we have been a long time in the making with these clinical studies and they ranged from 12 weeks to 4 years. So we have long term extension data as well that also shows that the A1C as well as the glycemic effects of Farxiga are sustained. Equally as important, is for me to share the safety considerations. Some of them have already been mentioned, of course symptomatic hypotension may occur, especially in patients with potentially moderate renal impairment, elderly patients, those on loop diuretics, those are a little
more volatile. It’s important to assess and correct that volume status before initiating this type of medication. In addition to that, we did note that there were an increased rate of genital mycotic infections. The symptoms were mild to moderate in intensity and patients usually responded to standard of care and rarely resulted in discontinuation. The last thing I wanted to point out is that we did see an imbalance in bladder cancer within our trials. And we do, within our label, recommended not to use in patients with active bladder cancer and caution the use for those with a history of bladder cancer because at this point in time, there isn’t enough data. If you have any questions, I’d be happy to discuss further. AstraZeneca would appreciate your consideration to add Farxiga as the second drug in the SGLT2 class to the preferred drug list

Michael Hautekeet, RPh: In Invokana, if the GFR is less than 45 and for Farxiga it’s less than 60. So that’s pretty much the only difference between the two.

Dr. Wynn: There are a few differences in the label. I will briefly speak on our moderate renal impairment study which is in our label. In that study we did look at patients within that moderate renal impairment group of 30 – 60. Within that study, looking at placebo vs. moderate renal impairment, we saw in our patients with Farxiga, a decrease efficacy. We saw a -0.29% A1C decrease. Equally, we actually saw patients in our renal impairment group who were on placebo have improvement as well. Because of that, we saw a numerical difference but it wasn’t statistically different. I think what we see, when we are looking at patients with moderate renal impairment, is that this drug works with the kidney. You need good kidneys for it to work at its best efficacy.

Mary Kay Queener – Clinical Pharmacist – Healthy Outcomes Group – Johnson and Johnson – Representing Invokana. Presented to board last year. Voice support for maintaining Invokana on the preferred list. Offer answers to any questions the board may have.

Vince Bera – Personal anecdote – diabetes and aspartame
About a year ago, I was rushed to the hospital as a diabetic, and the doctors told me I was fortunate to be alive. Why I wasn’t in a diabetic coma was perplexing to them. I was on insulin 3 times a day and in the evening, I sure all of you professionals here from the pharmaceutical companies know what I’m talking about, fortunately, I’m no longer on any medication whatsoever. What I hear going on here is that you’re trying to fix the problem that was created by the food industry, or certain chemical companies primarily aspartame. I see no one discussing aspartame and getting that out of our food chain, or food chain rather. Aspartame has changed its name. It is in just about every product that requires some sort of sweetening and now we have all of these great pharmaceutical companies trying to fix the problem that aspartame has contributed to. I am no longer a diabetic. I did lose about 40 pounds in the process. What I can attribute some of my success to is probably colloidal silver. Knowing a little about that, I discovered that colloidal silver does destroy a lot of diseases that are oxygen dependent. As a result it eliminates a lot of inflammation in many organs of the body. That’s my story. I think you should address those issues that pollute our food chain rather than approve more drugs, not that some of them are not successful. I’m sure that they are with all of the studies that they’ve done. I’m sure that they work on the problem, but you’ve got to fix the source of the problem first. Then maybe you won’t need all of these great people working in their labs, creating something that may never be needed.
Carl Jeffery: So we’ve got a new agent in this class, and this has been beat to death here about the mechanism of action and how this stuff works. It’s been covered a few times. I’m not going to go over it again. These agents are associated with weight loss and a lowering of blood pressure, so I think they have some benefits as well. I’d like to point out the indication for both of these new agents are the same in adjunctive with diet and exercise, so we’re not just treating with the medication alone. Farxiga, and again, these studies along with some of the newer ones have been talked about before, so I’m not going to beat this into the ground too much, but again: Large studies, these are some pooled data done alone and in combination. We’ve seen some pretty good results in here. Anywhere between 0.6 and 1.5% reduction to A1C, when it’s used alone, or up to a 2% when combined, and I think these studies were done with Metformin. As the doctor said before, they studied with Glimepiride, Pioglitazone, so there’s all sorts of studies that they did that show that adjunctive therapies are successful too. Showing one study to be non-inferior to the Metformin at the 10mg dose, which I think is a pretty significant study there too. As far as, and I know Mr. Hautekeet you referred to the differences there are. There are no head-to-head studies with this with the new Farxiga. That would be wonderful to see that, but I don’t see it happening in the foreseeable future. So at this time, we compare what we know about the Farxiga and the Invokana separately and look at those numbers and they’re pretty similar. As you’ve seen before, there’s really not that many differences. With that information Catamaran would like to recommend that these be considered clinically and therapeutically equivalent.

Michael Hautekeet, RPh: Motions to consider clinically and therapeutically equivalent.
David Fluitt, RPh: Second.
Board votes unanimously: Aye.
Motion carried.

Carl Jeffery: Catamaran would like to recommend that Farxiga be non-preferred, because the Invokana is already preferred. We broke these out into their own class, and so really, in order to add the step and get Farxiga and they try and for some reason they can’t tolerate the Invokana, or if they have some medical reason why they need the Farxiga, which, I’m not sure what it would be, but it would still be available to those patients. Basically Invokana would be the first lane. Some of this has to do with the anticipation of and the outlook as new products in the class come out.

Michael Hautekeet, RPh: Last year, when we talked about Invokana, I was just placed on Invokana, maybe a few weeks before. So it has been now almost a year and I have seen the improvement of the A1C. My feeling is that Invokana is a good drug. I hate to have just one available because, again, one drug doesn’t fit everybody. Even so Invokana and Farxiga may be similar on paper, but there are still chemical differences that could be beneficial to some patients where the Invokana doesn’t quite work correctly. I would make the recommendation to have Farxiga in the preferred because two drugs are better than none. I’ve seen how they work. Excreting sugar, everyone used to be scared of it. When I was placed on that drug. Besides the diuresis effect, the drug has to be taken in the morning; don’t take it at night. The sugar, it works good. I would make the motion to make both Invokana and Farxiga preferred.
No Second.

Need another motion.

**David Fluitt, RPh**: Motion to keep Farxiga as the non-preferred drug and keep Invokana as the preferred.

**Mark Decerbo, Pharm.D.**: Second.

**Board votes**: 5 Aye, 1 Nay.

Motion doesn’t carry, no sixth vote.

This will be discussed by the end of the year. Motion that this drug will stay non-preferred.

When new products are introduced they are automatically moved into the non-preferred class. This was a proposal for a new class. Invokana wasn’t put into this other class, this miscellaneous class. Our proposal was to make a new class with just these two agents. Now, since the motion didn’t pass, does that mean this new class….?

**Coleen Lawrence**: It just means that it stays by itself. Farxiga will remain in the non-preferred status. Invokana will stay in the preferred status.

**Michael Hautekeet, RPh**: Motion to create a SGLT2 inhibitor class by itself separate from the miscellaneous.

**David Fluitt, RPh**: Seconded.

**Board votes unanimously**: Aye.

**Motion carries**.

**Carl Jeffery**: For the clarification of the board, this is what the new miscellaneous class is going to look like. There is no action to be taken on this.

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**B. IMMUNOMODULATORS: Oral**

Withdrawn from the agenda.

**Public Comment**:

**Coleen Lawrence**: We’ve had a lot of comments come in about the different formularies between Medicaid paper service and the two managed care formularies come in. We’ve been reviewing them on the user service side of the house. One of the things we’ve been looking at is more on the cosmetic side of the formularies, on our side especially. As you all know I don’t have a lot of control of the coverage is on the managed care side, but we do have control over what we do. One thing that we are going to do
is revamp what our drug list looks like, so we can move our side of the house. That’s what we can do. We’re going to go through a chain of what ours looks like. And what we’re trying to do is shift some of our classes around, the titles, not the therapeutic alternatives that’s been voted by the board, but the higher categories. And we’re going to try to move toward what HPN and Amerigroup has used as their titles, so that way we can try to get a little more identical so that the look and feel will be the same.

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

Carl Jeffery: The Entyvio is a new drug for the ulcerative colitis that is currently available. This will be something brought up in one of our future classes. There’s a new intranasal testosterone that will be of interest. That will be brought up at least by November. A lot of patent expiration dates that will affect our drug list that we will be talking about in either the September meeting, or the November meeting. Some of the big ones that I’d like to highlight here are the Copaxone. This brings in the whole bio-similar discussion of whether these are interchangeable with the brand, or how that’s going to work. It will be interesting to see how this really plays out in the real world. Some of the big ones: Actinium and Nexium are some high utilization drugs that are going generic and are going to have some impact. Some big things coming down the pipeline that the FDA has given their initial nod to: Coming from Gilead for the treatment of Hep-C. It’s a combination of Sovaldi and another protease inhibitor. This is a once a day treatment, a fixed dose combination. We’ll see what the guidelines say with that one. That’s another big one that is coming out. With that, Bristol Meyers Squibb is getting into the game as well. They’ve got two new Hep-C treatment agents. Right now, initially with the information we have is for the genotype 1s. As with the Sovaldi, we’ll see if they get the additional genotypes, but that’s how it’s playing out right now. One more Hep-C agent here with AbbVie has another combination medication for the treatment of genotype 1 Hep-C. A lot of new players coming out. I think we’ve started to see just a little bit of warehousing again, so a little bit of a dip in the treatment of Hep-C with these. These are supposed to be available. The one from Gilead was supposed to be available in October 2014. These other ones just have the fourth quarter of 2014 listed. By the end of the year, these will be on the market, maybe not until the first of 2015. On the diabetes front, this is what I sort of alluded to before. We’ve got another SGLT2 product coming out from Lilly, a DPP4. It will be interesting to see how that one plays out on the market place. And then Purdue, the makers of Oxycontin, are working on a once daily, extended release, hydrocodone product that will probably make Zohydro obsolete. It’s an abuse deterrent.

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

September 25, 2014 at 1PM at the JW Marriott Las Vegas Resort and Spa.
IX. PUBLIC COMMENT

X. ADJOURNMENT

Meeting adjourned at 2:02 PM