BRIAN SANDOVAL
Governor

STATE OF NEVADA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH CARE FINANCING AND POLICY
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MICHAEL J. WILLDEN
Director

LAURIE SQUARTSOFF
Administrator

Nevada Medicaid
P&T Committee
Meeting Minutes

The Division of Health Care Financing and Policy (DHCFP) P&T Committee conducted a public meeting on November 13, 2014 beginning at 1:00 pm at the following location:

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

Committee Members Present:
Mark Decerbo, Pharm.D.; David Fluitt, RPh; Evelyn Chu, Pharm.D.; Shamim Nagy, MD; Weldon Havins, MD; Joseph Adashek, MD; Bill Evans, MD

Committee Members Absent:
Amir Qureshi, MD; Mike Hautekeet, RPh

Others Present:
DHCFP:
Coleen Lawrence, Chief, Program Services; Mary Griffith, RN, Pharmacy Services Specialist; Gabe Lither, Senior Deputy Attorney General;

HPES:
Beth Slamowitz, Pharm.D.

Catamaran:
Carl Jeffery, Pharm.D., Kevin Whittington, RPh

Others:
Jean Ritter, JCG/Silvergate; Nick Casalp, Reckitt Becker; Carey Avon, Zogenix; Brooks Hubbard, BIPI; Bill O'Neill, BIPI; Rob Bigham, Shire; Shane Hall, Purdue; Stephen Farmer, Amgen; Rupa Shah, Purdue; Marilyn Semenchan, Eisai; Danielle Walters, Sanofi; Barbara Glover, CF Center of Southern NV; Rudy Chamy, Jazz; Kirk B Lane, United Therapeutics; Tina Goodjohn, United Therapeutics; Sergio Gonzalez, Takeda; Sandy Sierawsky, Pfizer; Bret Ferguson, Pfizer; Don Cleveland, AZ; Kyle Peters, NNI; Dan Corell, NNI; Lee Stout, Chiesi;

Charissa Anne, J&J; MaryKay Queener, J&J; David Melikian, Mallinckodt; Dominic Cusau, Activas; Larry Curtis, Activas; Carol Riccoitti, Sunovion; Phil Walsh, Sunovion; Lovell Robinson, Abbvie; Aksunay A Pam, Mylan; Stephanie Roberts, Acorda; Abi Auen, Acorda; Deron Grothe, Teva; Zoe Henderson, Salix; Matt Bryant, Salix; Kim Jacoby, Lundbeck; Kyle Linhardt, Upsher-Smith; Suvy Garcia, Upsher-Smith; Jeff Kurszewski, Mallinckrodt; Lori Howarth, Bayer; Melissa Walsh, Novartis; Cathy Duce, Eisai; Soheyla Azizi, Eisai; Scott Larson, BMS; Craig Nakamura, Children's Lung Specialist

Call to Order and Roll Call

Meeting called to order at 1:02 PM
Joseph Adashek
Weldon Havins
Shamim Nagy
Gabriel Lither with the Attorney Generals Office
Bill Evans
Mark Decerbo
David Fluitt
Evelyn Chu
Beth Slamowitz with HP
Kevin Whittington with Catamaran
Carl Jeffery with Catamaran

Public Comment.

None

Administrative

Review and approve last quarter's meeting minutes

Motion to approve minutes.
Seconded.
Discussion: None.
Committee votes unanimous, "Aye."
Minutes approved.

Status Update by DHCFP

Coleen Lawrence – Chief Program Services DHCFP

This is our annual update for the Preferred Drug List for the Nevada Medicaid Fee for Service Program. We have this meeting once a year in accordance with our Nevada Revised Statue for our fee for service Preferred Drug List. If you have not joined us before, welcome.

You're in for a long meeting. Hold on. I'm going to lay out some ground rules. This is going to sound mean the first time I say this, but if you haven't joined us, you will appreciate these ground rules at about 4:00 today.

According to the Nevada Revised Statute, once a year we must review our entire Preferred Drug List. What we have done is we have separated our agenda into two parts. The first part of our agenda is the drug classes that we are going to review. How do we get there? We get there because our Chairman of the Committee has asked us to review the drug classes, or a member of our Committee, or there has been a substantial change throughout the year and our Committee members have said, "Let's review this for the next review." Or there is some new drug information that has come out within that drug class and somebody said "Hold off until the end of the year. Let's review it."

There's also a couple of classes in here that I believe that kind of got stuck in limbo since our last review and we said "Ok. Let's just wait until the next review class." Or there have been some negotiations that have been brought to our attention for review that is in the best interest of the state to review those specific drugs. That's how you get to the first half of the agenda.

The second half of the agenda is a very long list of drugs / classes and there are no substantial changes. So if you didn't make it to the first bucket, you have no reason for us to review those classes and therefore we are proposing no changes. So what we're saying is that we're going to take that one motion and we're going to say "We have no changes that we are proposing for these drug classes." And we're going to leave it just as we are. I know there may be something that may be coming down the pipeline. If you've been with us long enough, you know we are not the state that does not look at our Preferred Drug List. The reason why this annual review was put into place in 2003 was for protection, honestly. It was a safety net so that we wouldn't have a stale Preferred Drug List. I'm very confident in saying that we do not have a stale drug list. So if you're on that second half, you can come up during public comment and say "You know what? Although we're not hearing it today, I would appreciate if the Committee may look at this in the near future." Because we don't have the drug materials and the information to look at today. But it doesn't mean that we can't look at it next quarter. Or the quarter after that if something is coming down the pipeline.

So, some ground rules: We hear a lot of information every quarter. The Committee would appreciate that if you testify to information, please do not tell it to us again. They have a fabulous memory. Only testify on information that has not been testified in the past. New information only which will help the next ground rule.

You only have 5 minutes per entity, so choose who you are going to have speak wisely. And because of the very long agenda, those 5 minutes go by very quickly and we will be holding you to it today. We are going to be time keepers. The agenda is a very set, regimented process, so following comment, then Catamaran will go, then the Committee will have discussion, then we will vote. Those of you who have been with us long enough, you know we are very transparent about what we are going to do and what our proposals are going to do. Watch the monitor. Be wise about what you are going to testify on, because some doctors

may call you on it if you testify. That's pretty much it. We will move quickly. I don't mean to be rude, but if we drag too far, we will continue to move you further.

Last topic has nothing to do with this. How do you like the new program updates. If you guys have not heard, we have gotten recommendations from the Federal government regarding our VFC program. As long as we do not get any new information or new guidance from the Federal government, this next July, for the Nevada Check-Up Program, we will begin reimbursing for the vaccines under the VFC program. So we will be need all of your help. As of right now, we only pay the administration fee for the VFC program. This will be coming underneath the DUR program, for this review program, not the P&T, because that has nothing to do with us here today, but you know I like to get all the information about pharmacy out. So July 1st, 2015, for Nevada Check-Up only, we have to start paying for the and childhood immunizations, for Nevada Check-Up. So I will get more information out there. There will be web announcements like crazy, a large change for us.

We do have a new Committee member, Dr. Evans, who we welcome back to the P&T Committee.

Carl Jeffery: We have a proposal to update our TPL format to more align with the MCO structure that can reduce some of the confusion between the lists. It's not set in stone. Up here on the screen is how we're going to reorganize it. The biggest change is going to be how we categorize it. Right now it's just alphabetical by some random categories that we inherited over the years. So we're going to put those into subcategories. Now the drugs that have been classed are not going to change. If you guys have voted on that, we can't change them. Now we can bring that back down the road and review those classes, but that can be something else down the road. This is kind of a sample of how it will look, so you've got a subclass with cardiovascular and then within that beta blocker and calcium channel blockers. If you don't see calcium channel blockers then you will have preferred, or non-preferred and then over on the right of the list, it requires quantity limit or a PA restrictions, that either DUR Committee, or if there are other requirements. That's just a little foreshadowing on what we're going to do with the format.

Established Drug Classes, Central Nervous Systems: ADHD/Stimulants

Call for public comment.

Gabe Lither: Before we begin, Carl why don’t you take one moment to explain what’s up on the monitor there.

Carl Jeffery: Yeah, we put our proposed changes up here. So if something is in yellow here, it means it's new, that we're adding it to either side. If it's crossed out, it means we're taking it off there. For example were removing amphetamine salts extended release from the non-preferred side. So you just have to pretend that the right side is the non-preferred and that the left is the preferred side. So we're going to move the Adderall XR to not preferred and move the generic to the preferred. I think in the past we've given instruction that if you are somebody in the audience and you are going to talk about your product, and we have it up there as proposed as preferred, you probably don't need to come up and talk and save us all a

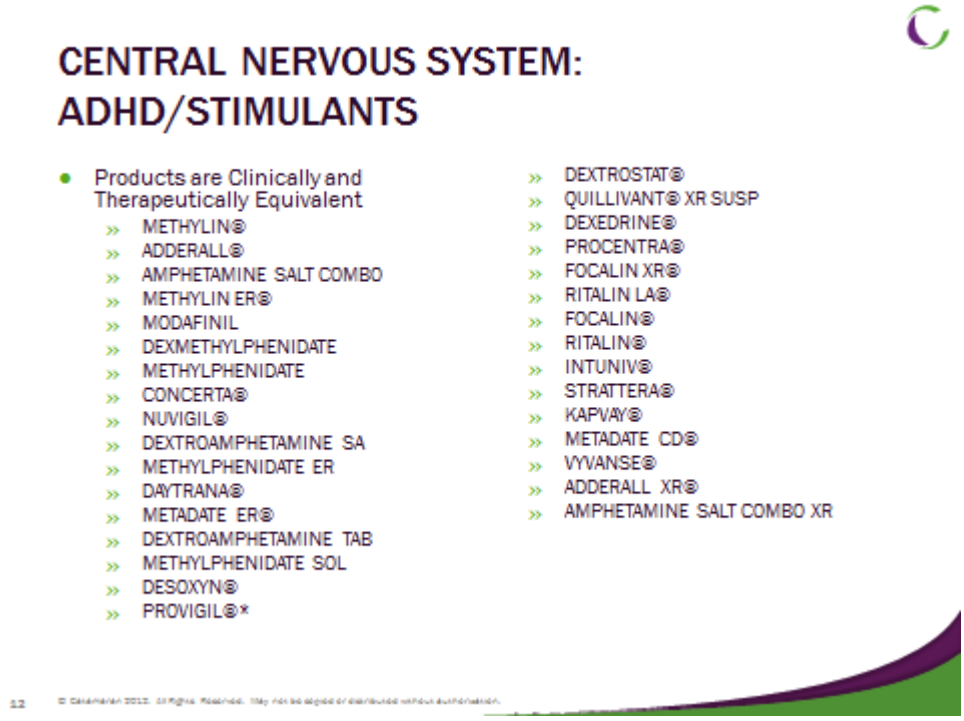
bit of time. Because if you come up and give a 5 minute spiel when your drug is preferred, there's a good chance this Committee may get a little irritated.

Chairperson Nagy - Any other comments? No. Ok, Catamaran

Carl Jeffery: We just got the review of the ADHD class. The biggest reason we're bringing this up, and I'll go back to the slide for just a second. We had a lot of confusion in the provider community about exactly what extended release methylphenidate products that are considered preferred because there is a generic for Concerta. There's a generic for Metadate. There's all sorts of generics, so we just wanted to get this clarified. This is the biggest reason why we brought it up. Now just a brief review of the clinical guidelines: There's really no one preferred agent. Every doctor and every patient is just a little bit different. It's very individual. Stimulants are still the number one choice with the non-stimulants like the Strattera and Clonidine and Guanfacine as a close second. And then in adults, methylphenidate is recommended as the first line. So Catamaran would like to recommend that the Committee consider all the drugs in this class as therapeutically and clinically equivalent.

David Fluitt: I make a motion that they be considered clinically and therapeutically equivalent.

Mark Decerbo: Second.



Voted: Ayes across the board.

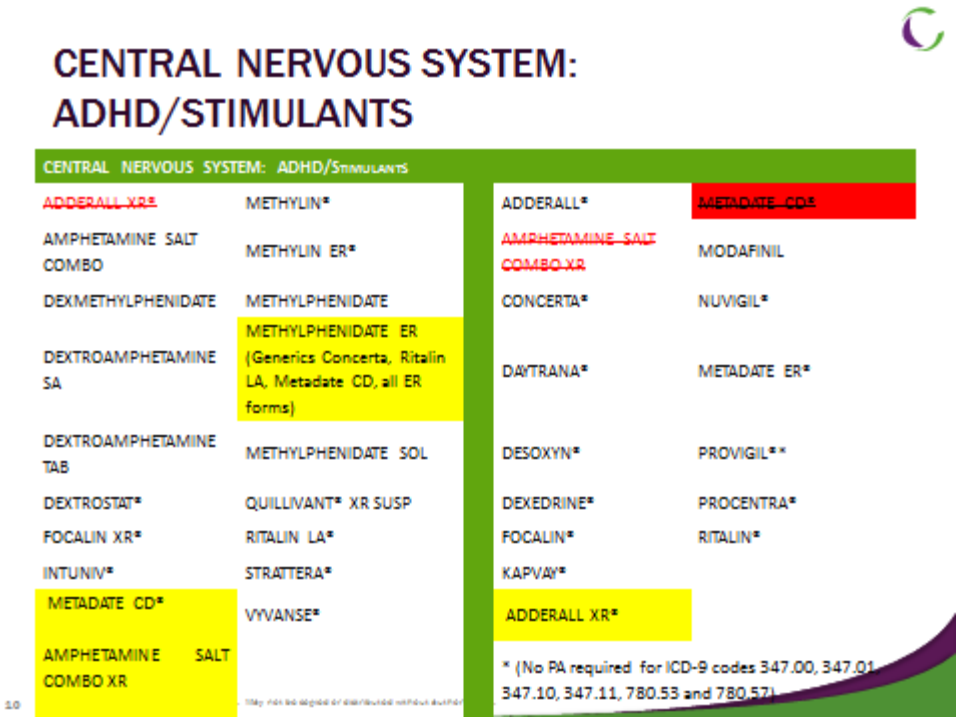
Motion approved.

Carl Jeffery: As it was updated here earlier, we want to clarify the methylphenidate ER to include every generic extended release product, regardless of what brand name it is associated with. That's one of our biggest changes here, to include all of those. The other one is to move the brand Adderall XR to non-preferred and to include the generic extended release. It's been out for several years. I think it's well accepted in the community as preferred. And then also the Metadate CD would fall in that class too with that extended release methylphenidate. It's kind of a branded generic.

Chairperson Nagy: Any questions, discussions? I need a motion.

Weldon Havins: I vote that we accept the current drug list that Catamaran is showing.

Joseph Adashek: Second.



Voted: Ayes across the board.

Motion approved.

Third generation Cephalosporin

Chairperson Nagy: Public Discussion? None.

Carl Jeffery: So we've got the third generation cephalosporin - This class of medications has been out and available and widely accepted and used across the Committee. A quick overview of what we're looking at here. There's two, the cefpodixime and the cefinir have a little bit more activity against the staphylococcus compared to the cefixime and the ceftibuten. There's no real big difference between these agents that have been shown

clinically. I think there's some that have maybe a slight advantage over the others. It is empiric therapy for any community-acquired pneumonia and this is also for otitis media in people with penicillin allergies.

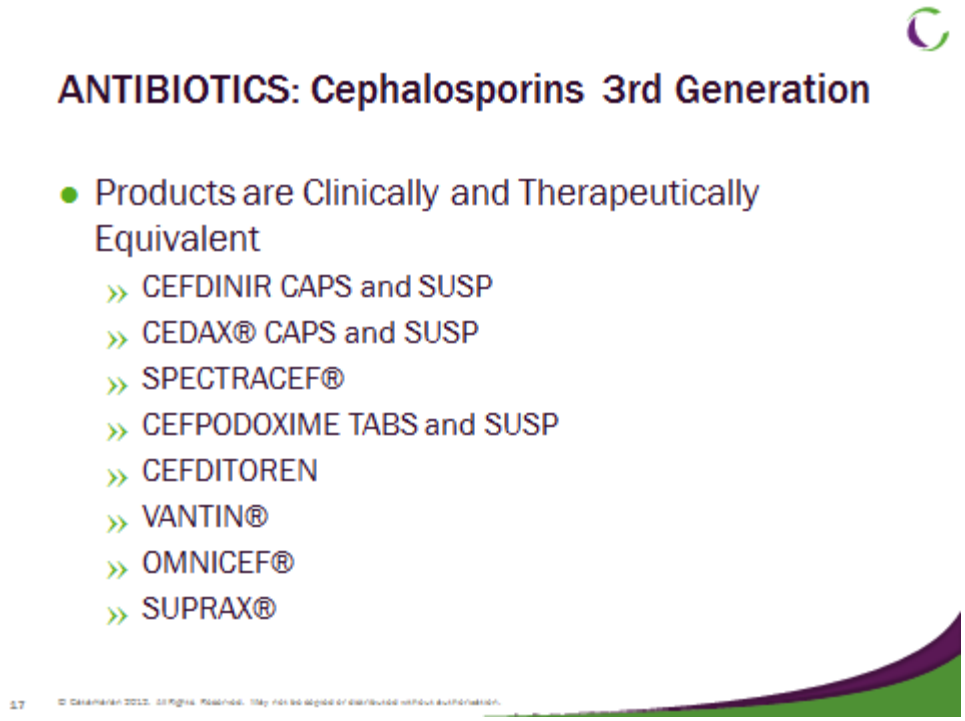
Catmaran considers the medications in this class therapeutically and clinically equivalent.

Chairperson Nagy: Any questions?

None. I need a motion forward.

Joseph Adashek: Move for equivalence.

Weldon Havins: Seconded.



Voted: Ayes across the board.

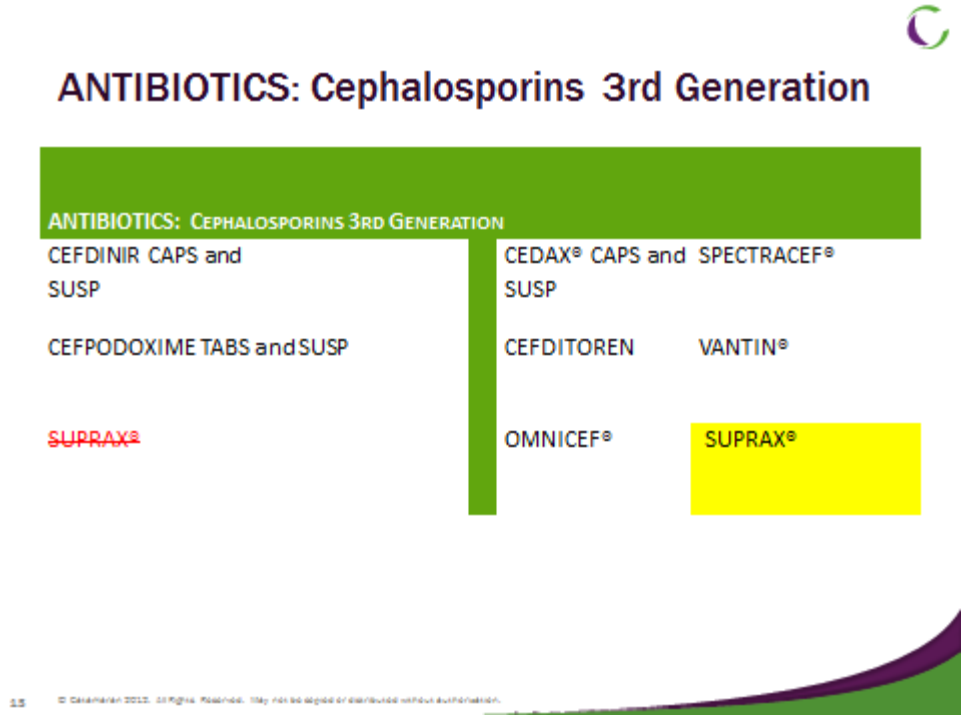
Motion approved.

Carl Jeffery: The only change we are recommending to update with this is to move the branded Suprax, which is only available as a brand currently, to non-preferred. This would leave the cefdinir capsules and the suspension and ceftizoxime tabs and suspension, so there's two different suspensions available for children too. Both of these have good coverage, so we don't think this will be an issue.

Chairperson Nagy: Need a motion for approval.

Bill Evans: Move to approve.

Joseph Adashek: Second.



Voted: Ayes across the board.

Motion approved.

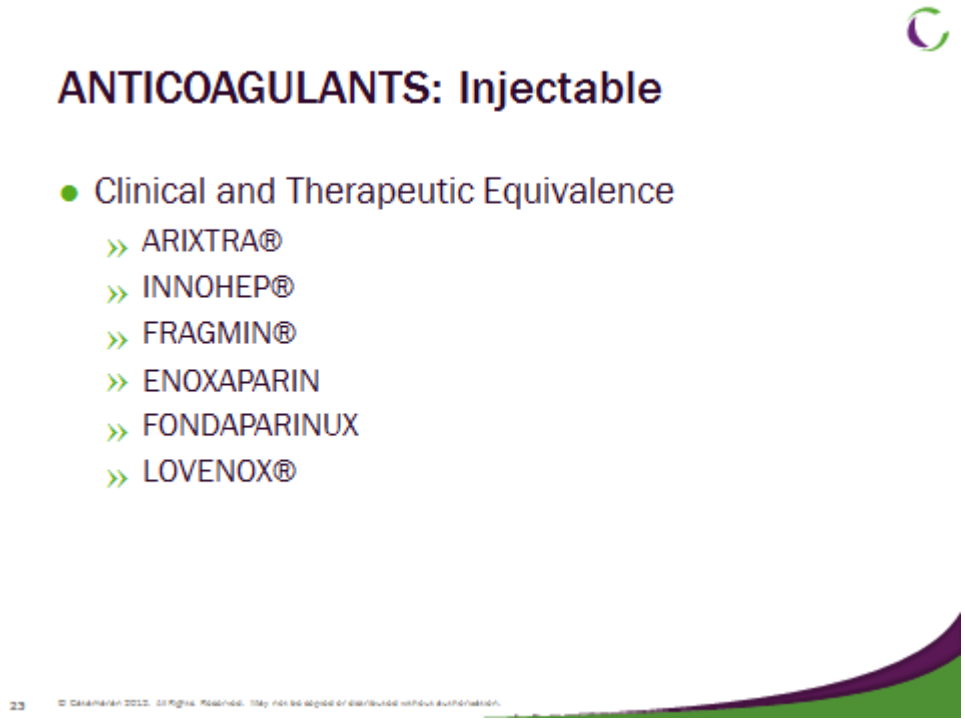
Anticoagulants - injectable

Public Comment: None.

Carl Jeffery: The injectable anticoagulants is the standard of therapy for the total hips and the total knees. They are still recommended over the other unfractioned heparins. VTE treatment is recommended with these, low molecular weight heparins and also DVT and PE treatment. Let's put up a little slide here with the different indications that each of the medications has. You can see it's kind of running all over the Committee. Catamaran would like to recommend that these products be considered clinically and therapeutically equivalent.

Weldon Havins: Move to be considered clinically and therapeutically equivalent.

Bill Evans: Seconded.



Voted: Ayes across the board.

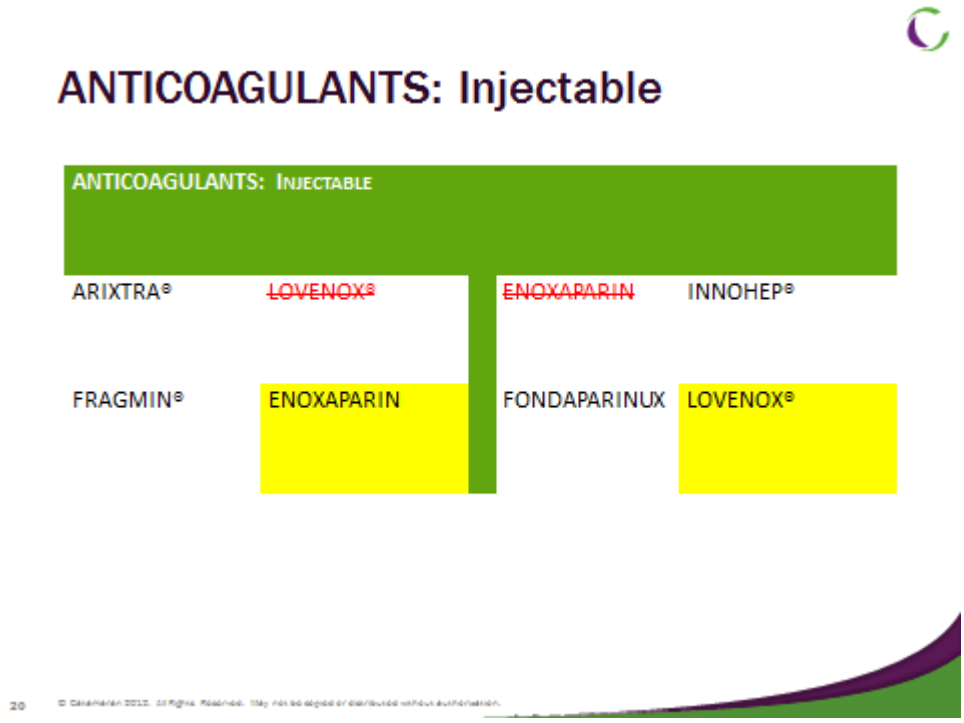
Motion carries.

Carl Jeffery: The only change we are making here is moving the branded Lovenox to non-preferred and the generic to preferred. We feel this will be favorable both for the pharmacy and providers who mostly stocked the Enoxaparin anyway in the pharmacy. This way it will make them happy.

Chairperson Nagy: Need a motion.

Joseph Adashek: Move to approve these recommendations.

Weldon Havins: Seconded.



Voted: Ayes across the board.

Motion carries.

Anti Migraine Medications

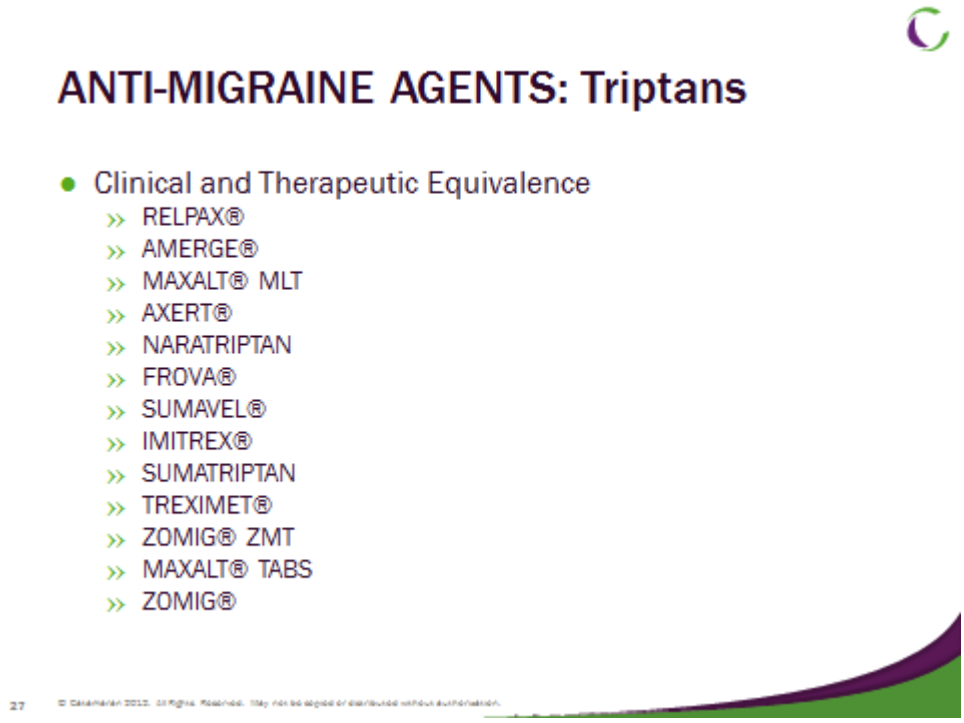
Public Comment: None.

Carl Jeffery: Catamaran brought this forward because we thought that there was going to be some changes in the marketplace that didn't happen, so we are actually not making any recommended changes with this. There's really nothing new with these triptans. I think you all know as providers, every patient has their favorite and every doctor probably has their favorite, so they are very individual. We would like to make the recommendation that these be considered clinically and therapeutically equivalent.

Chairperson Nagy: Need a motion.

Weldon Havins Move to approve.

Joseph Adashek: Second.



Voted: Ayes across the board.

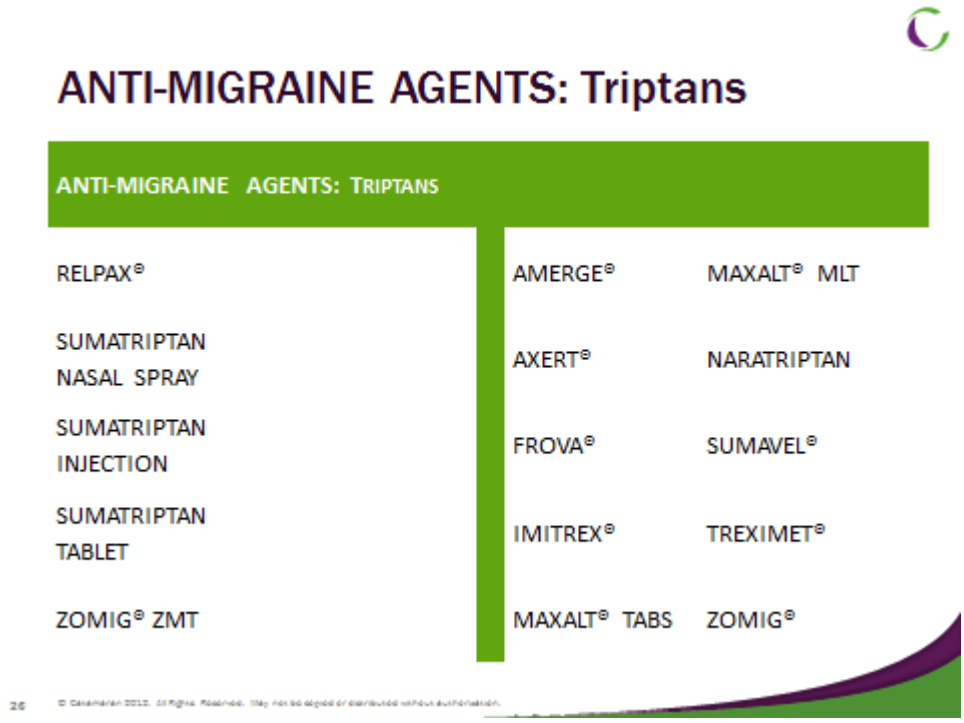
Motion carries.

Carl Jeffery: Catamaran recommends that there's no changes to the Preferred Drug List.

Joseph Adashek: Movement to approve recommendations.

Weldon Havins: Seconded.

Voted: Ayes across the board.



Motion carries.

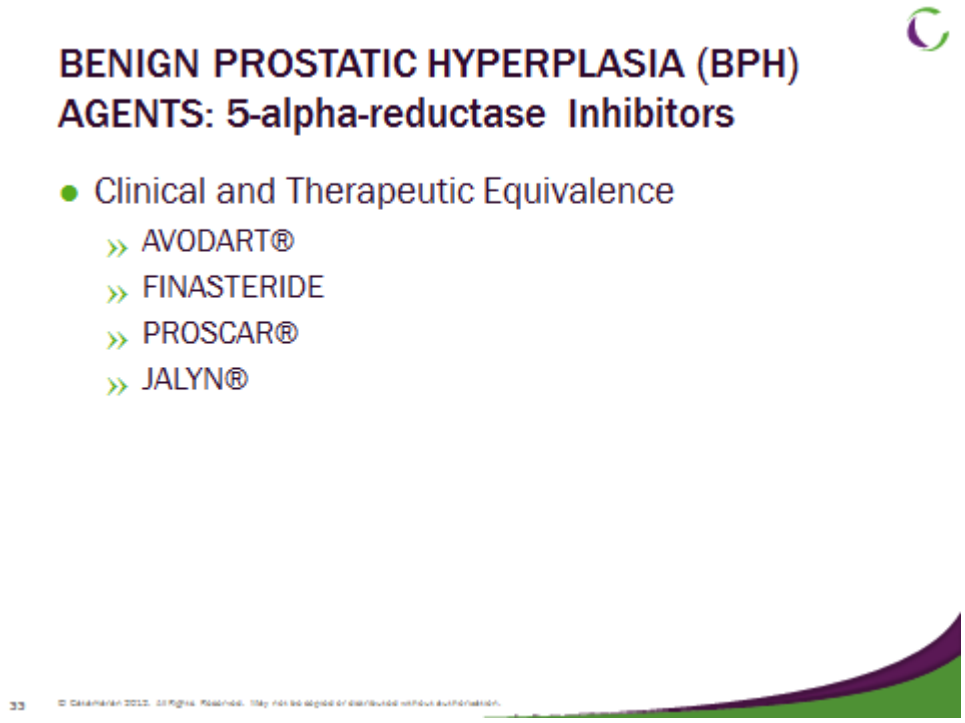
Benign Prostatic hyperplasia agents

Public Comment: None.

Carl Jeffery: There's a new combination product, Jalyn which is a combination of duteresteride and tamsulosin. It falls in that class, but when we look at the BPH agents as a whole, we can see the Avodart and the Proscar is up here and the Jalyn is down here with the combination with adding an alpha blocking agent in there. We already know how the other two agents work independently, so all this is a combination of the two. Catamaran recommends these products as being clinically and therapeutically equivalent.

Weldon Havins: Move to accept this recommendation.

Bill Evans: Seconded.



Voted: Ayes across the board.

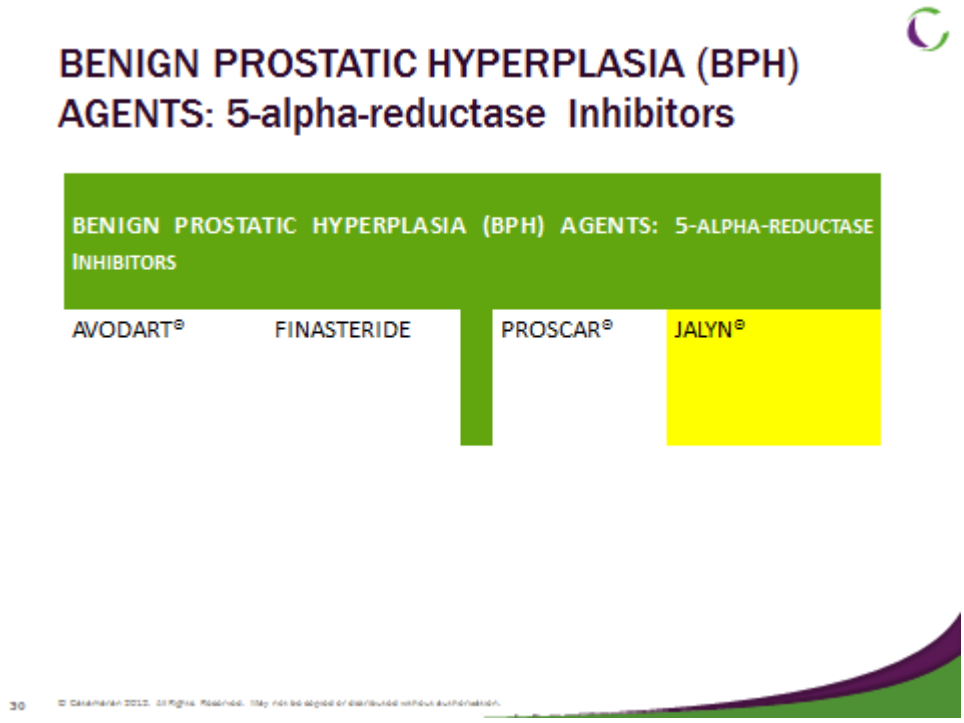
Motion carries.

Carl Jeffery: Catamaran's recommendation is the new combination product, Jalyn, be considered non-preferred. The rest of the class will remain the same.

Chairperson Nagy: Need a motion.

Joseph Adashek: Move to accept recommendation.

Weldon Havins: Seconded.



Voted: Ayes across the board.

Motion carries.

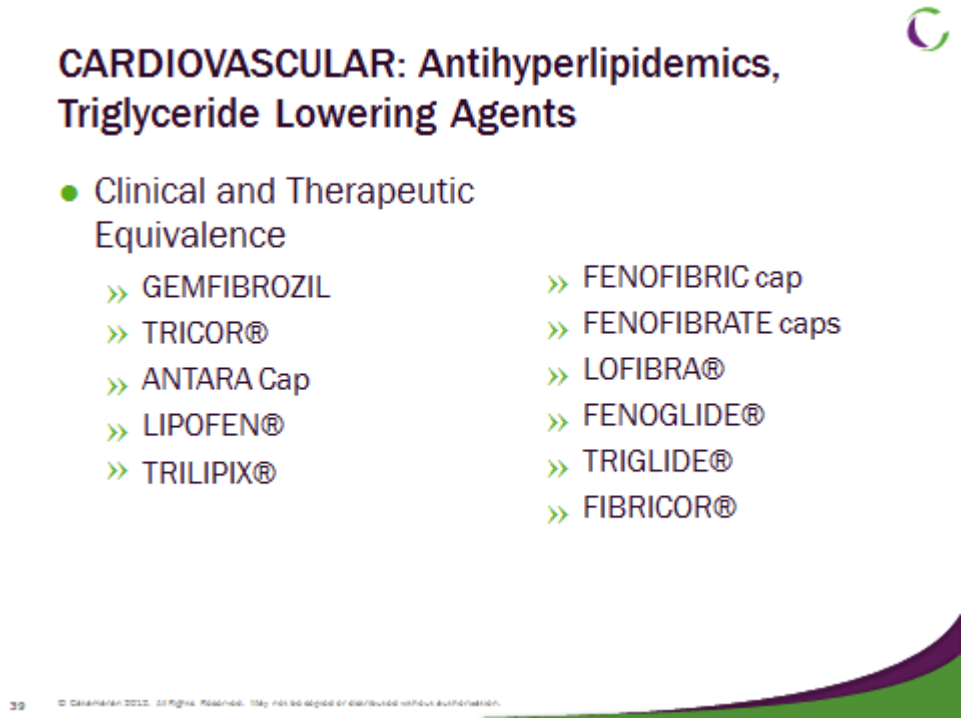
Fibric Acids

Public Comment: None.

Carl Jeffery: There's been a flood of generics on the market now with these. They're all kind of branded generics. They are all pretty much the same medication. We've got a quick overview of the clinical goal that fits with these. They do decrease the triglycerides by quite a bit and the HDLs and they can lower the LDLs by significant amounts. Really no demonstration of difference between the products. They've all been shown to be effective. There's been just a handful of head-to-head trials, but nothing really that stands out as being superior. It does still fall in to secondary or tertiary therapy after the Statin therapy is started. Here is a quick overview for the indications for these. Hypertriglyceridemia is probably the first one and just high cholesterol in combination. Catamaran would like to recommend that these be considered clinically and therapeutically equivalent.

David Fluitt: I make a motion that these be considered clinically and therapeutically equivalent.

Mark Decerbo: Seconded.



Voted: Ayes across the board.

Motion carries.

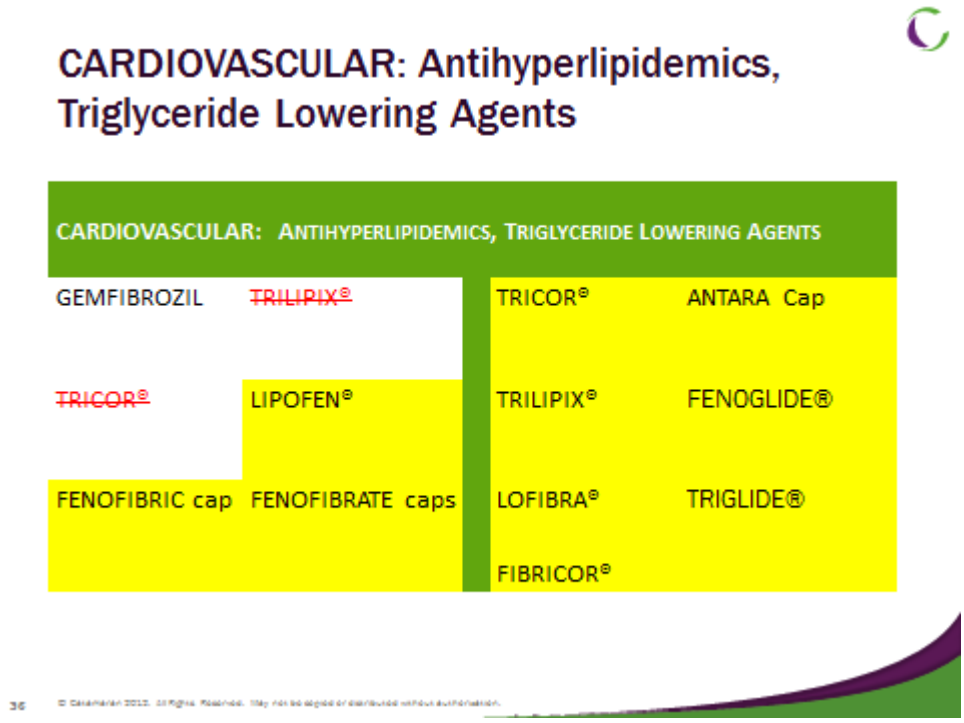
Carl Jeffery: Our recommendation is to move the branded TriCor and Trilipix to non-preferred. That's probably the biggest change. The other ones are all branded generics of the fenofibrate and the fenofibric acid. So we'll move these Lipofen, the fenofibrate capsules, and the fenofibrate caps to preferred and leave the TriCore, Trilipix, Lofibra, Fibricor, and Terrafenglide and Triglide as non-preferred.

Chairperson Nagy: Any questions, or discussions?

Need a motion.

Bill Evans: Move to accept the changes as presented.

Evelyn Chu: Seconded.



Voted: Ayes across the board.

Motion carries.

DPP-4 Inhibitors

Public Comment: None.

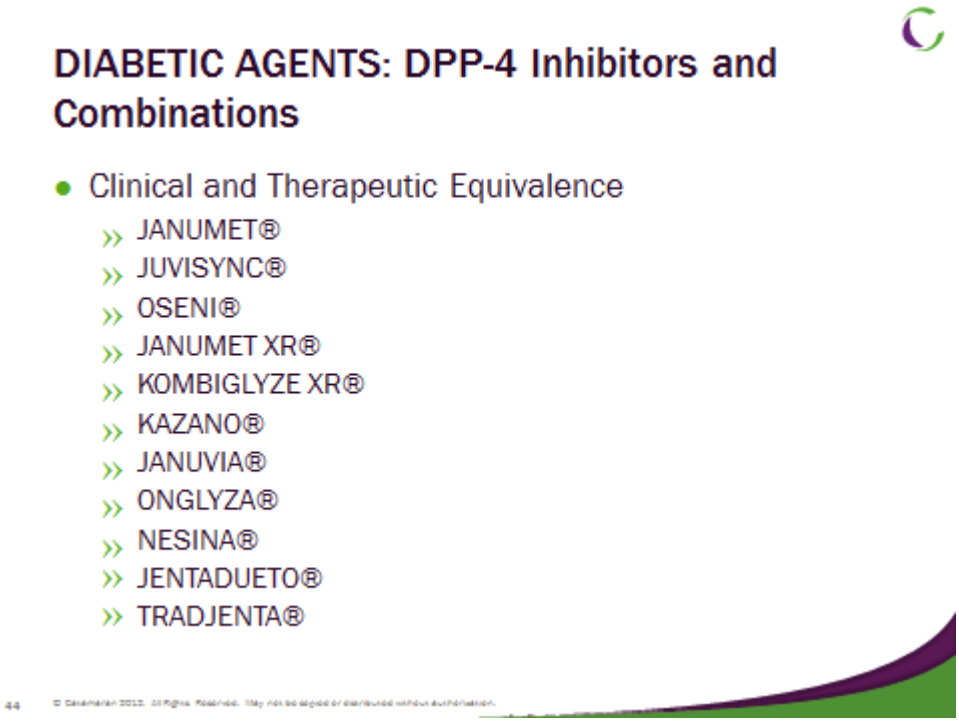
Carl Jeffery: DPP-4 inhibiters have lots of different products and lots of different combinations that are listed out here. We've voted on many of these last March. We moved some of these to non-preferred status. Lots of combinations with the Metformin. You can see the brand names on here. They all kind of blend together if you look at them long enough. The Diabetes Association recommends, Metformin first, unless somebody has a contraindication to it, but the DPP-4s are always up there in the top, as far as treatment with these. Again, there's been a handful of comparative studies, but really no single DPP-4 inhibitor has been shown to be significantly better than another. Catamaran recommends that these be considered clinically and therapeutically equivalent.

Chairperson Nagy: Any comments?

Need a motion.

Mark Decerbo: I move that the products be considered clinically and therapeutically equivalent.

Bill Evans: Seconded.



Voted: Ayes across the board.

Motion carries.

Carl Jeffery: Catamaran would like to make the recommendation that we make preferred the Jentadueto, which is a combination with the Metformin and the Tradjenta, and leave the rest of the class as is.

David Fluitt: We have some main concerns about cancer causing potential of Onglyza.

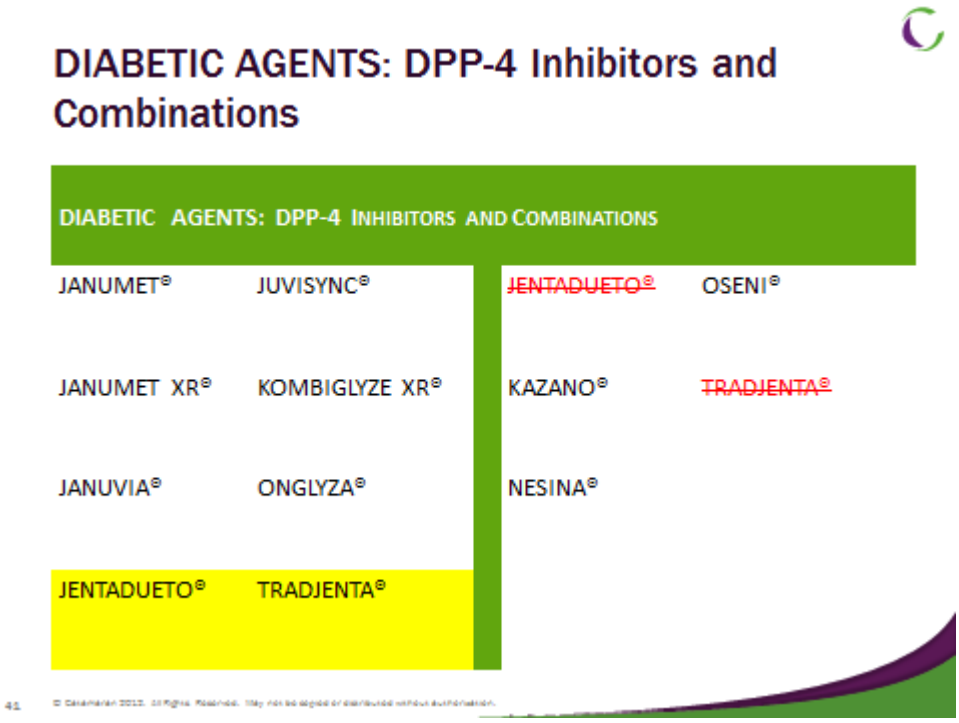
Carl Jeffery: This is something I'm not familiar with. Do you have some information?

David Fluitt: I'll have to be able to find it. So they went and had a trial to reducing the HbA1Cs. The initial effects of...never mind. I misread it.

Chairperson Nagy: No other comments?

Weldon Havins: Move to accept the recommendations.

Bill Evans: Seconded.



Voted: Ayes across the board.

Motion carries.

Electrolyte Depletors

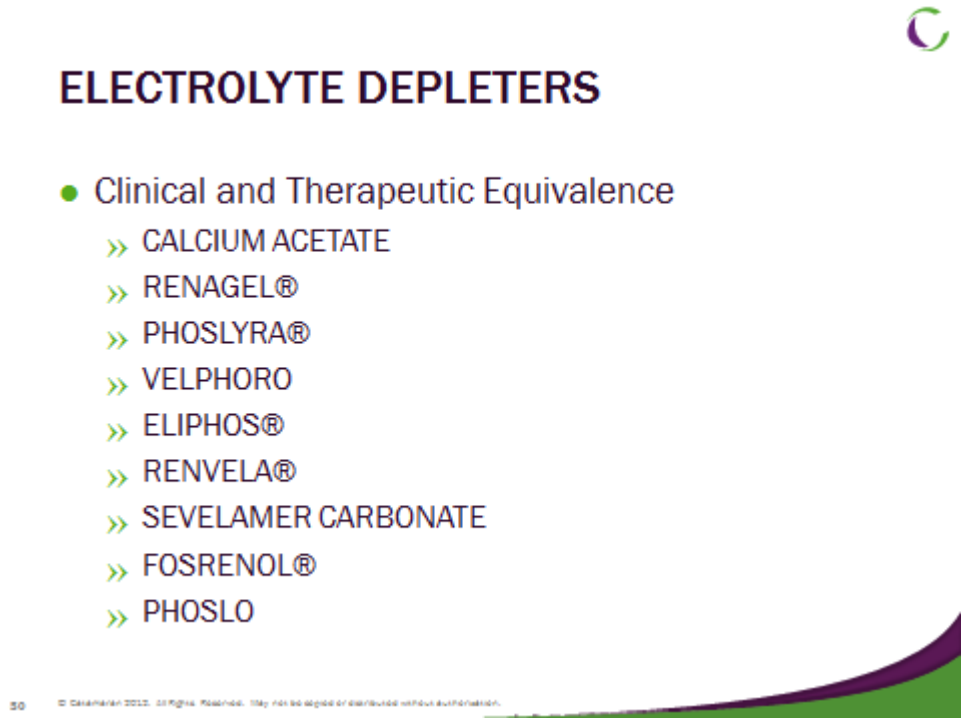
Public Comment: None.

Carl Jeffery: There's been several new generics on the market with these. Again, these are branded generics. We've got a quick breakdown of what each drug is indicated for and all for the end stage renal disease, people who are on dialysis, or not dialysis that have the high phosphorus. They help decrease the phosphorus in the blood. According to the NIH guidelines, we've got calcium acetate as the first one and then when you get up to the stage 4 and 5 you get into a non-calcium based, but usually the calcium acetate is the first drug of choice on these. Once they get into stage 5 with the kidney disease, if they are on dialysis, then you can get into the other ones, and even combine the agents until the achieving the phosphorus they need. Again, no head-to-head comparative studies showing one is better than the other. With that, Catamaran would like to recommend that these be considered clinically and therapeutically equivalent.

Chairperson Nagy: Any comments? I need a motion.

Bill Evans: Move to accept the recommendations.

Joseph Adashek: Seconded.



Voted: Ayes across the board.

Motion carries.

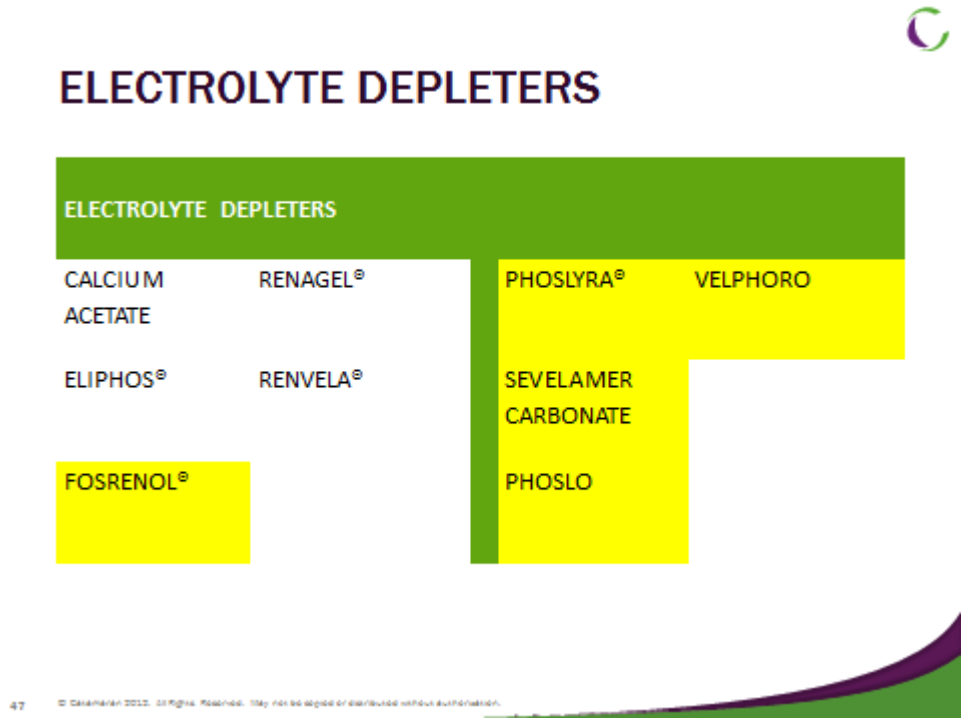
Carl Jeffery: So we're going to move, not very much around, there's a newer agent on the market, Fosrenol. It's been out for a few years. We're moving that to preferred. There are some newer medications that either we haven't reviewed yet, I think they have been available for a while now, but we've just never addressed them, and so we're going to put the Phoslyra, sevelamer carbonate, which is a generic of the Renagel, the PhosLo and the Velphoro as non preferred.

Chairperson Nagy: So we are making it non-preferred?

Carl Jeffery: Yes.

Weldon Havins: Move to accept Catmaran's recommendation of the preferred list.

Bill Evans: Seconded.



Voted: Ayes across the board.

Motion carries.

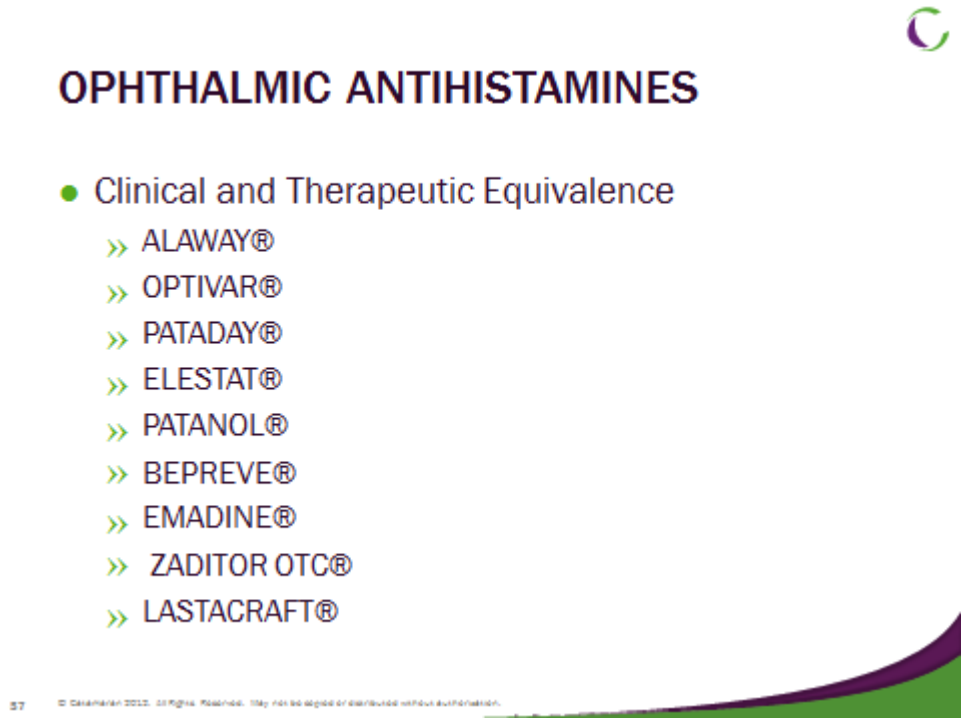
Ophthalmic Antihistamines

Public Comment: None.

Carl Jeffery: We've got ophthalmic histamines. Most of these are the same histamines for allergic rhinitis. I think there are maybe a handful of other things that they treat. Ketotifen is probably the newest one that's been introduced as an OTC on the market and that was probably a little over a year ago. Probably the biggest difference with this is how often they are prescribed, or how often they are given. The Lastacaft and the Pataday are just once a day whereas the other ones are typically 2-4 times a day. All are shown to be effective. Few head-to-head studies showing that some are better than others. Some would suggest that the Pataday, which is the patadine, may be preferred and better tolerated. Some studies have shown a significant difference between the symptom scores, but the overall clinical significance is not known. Catamaran would like to make the recommendation that these be considered clinically and therapeutically equivalent.

Weldon Havins: Move to accept the recommendations.

Bill Evans: Seconded.



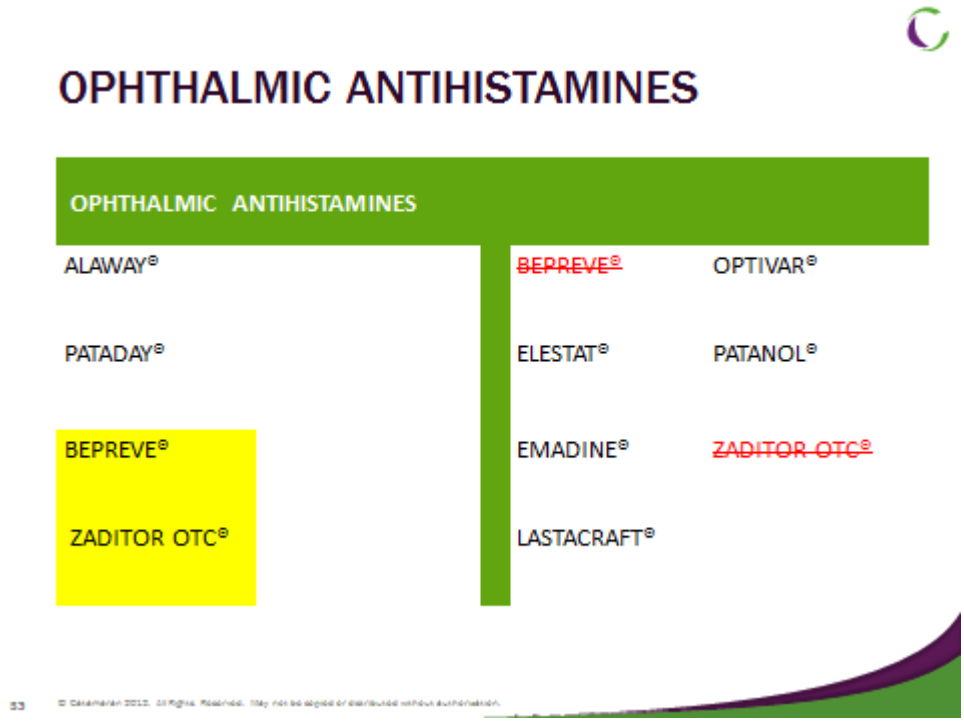
Voted: Ayes across the board.

Motion carries.

Carl Jeffery: So our recommendation for preferred is to move the Zaditor OTC, which is available over the counter now for Medicaid patients, they require a prescription from their doctor in order for Medicaid to pay for it, but it's still I think easy to get, well stocked. Then to move that Bepreve from non-preferred to preferred.

Weldon Havins: Move to accept the recommendations.

Joseph Adashek: Seconded.



Voted: Ayes across the board.

Motion carries.

Psoriasis Agents Topical

Public Comment: None.

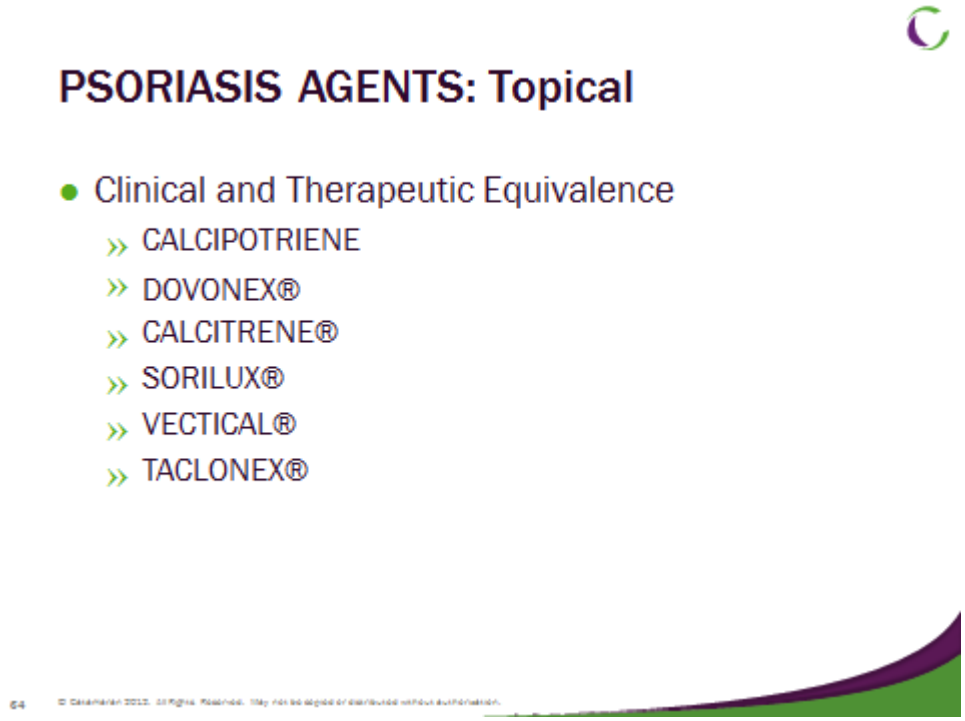
Carl Jeffery: Another flood to the market of new branded generics that are all on the same line of medications, just with a different name on them. We just wanted to clarify the class. In this class, we have some overlap with the acne agents. Tazorac is actually listed in the acne agents. Even though it's listed under review in here, it's not included into our PDL claims. We do have a relatively new combination product with active ingredient in the Dovonex with the betamethasone. Where you find these in the treatment algorithm is pretty far down there as far as the line of treatment. First comes the corticosteroids and then when you add one of these psoriasis agents, you still separate them out by twelve hours. So you put the corticosteroid on in the morning and then this other Calcipotriene on in the evening. Not only do you get the combination of putting them on at the same time, you have to be on this treatment for quite some time before you get down to this combination product. Again superiority in head-to-head studies have not been shown in these. Catamaran would like to make the recommendation that these products be considered clinically and therapeutically equivalent.

Chairperson Nagy: Any comments?

Need a move to accept.

Mark Decerbo: Move to accept the recommendations.

Bill Evans: Seconded.



Voted: Ayes across the board.

Motion carries.

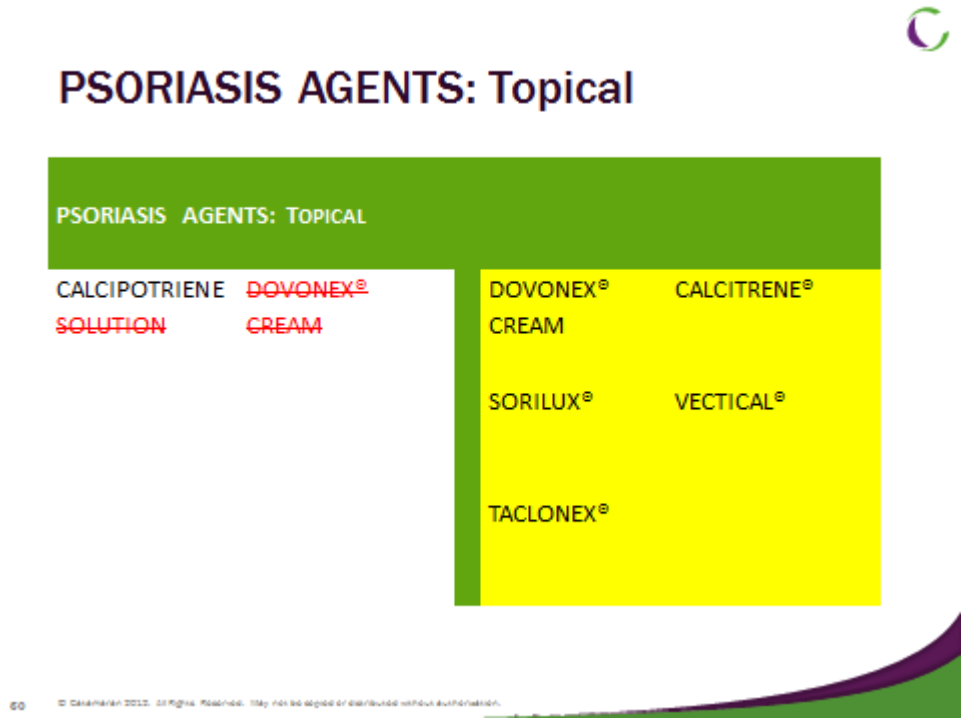
Carl Jeffery: Previously we had the Dovonex brand cream only on preferred. Now there's a generic cream available too, so we would like to have the generic available as preferred. It would move the Dovonex cream as non-preferred. And all the brand of generics out there that are similar products, make those non-preferred as well.

Chairperson Nagy: Any comments?

Need a move to accept.

Mark Decerbo: Move to accept the recommendations.

Bill Evans: Seconded.



Voted: Ayes across the board.

Motion carries.

Bisphosphonates

Public Comment: None.

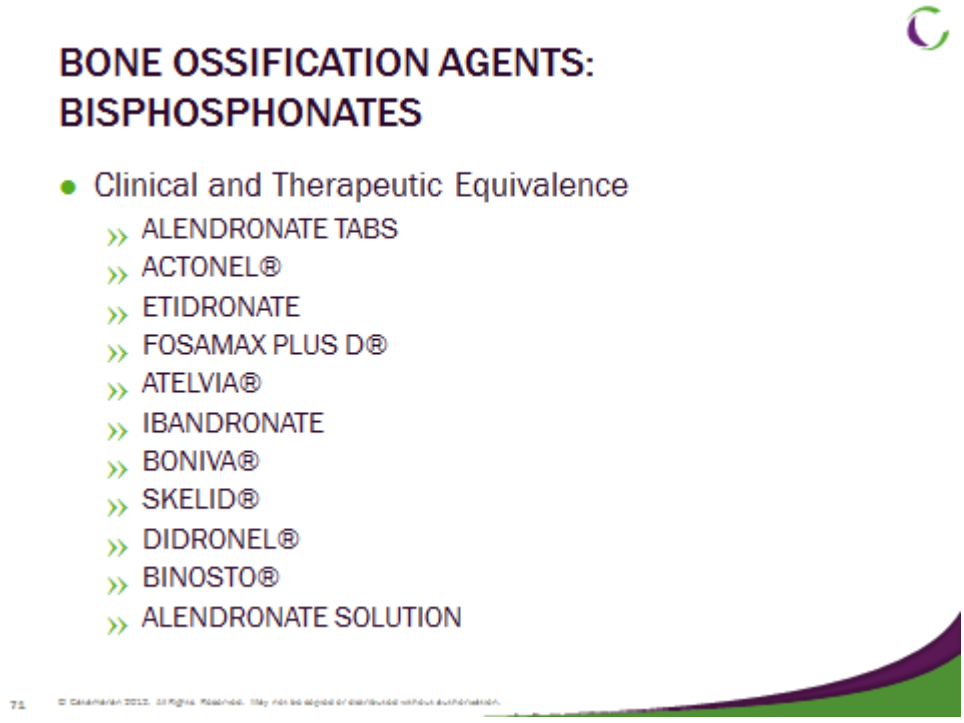
Carl Jeffery: What brought this up was the Binosto was added in here. Basically it's a Fosamax tablet, it's an effervescent tablet that dissolves so that you can drink it easier. A quick overview of all of these on here, the bisphosphonates, help stop the osteoclasts, the bone breakdown that leads to osteoporosis and fractures in the hips. So you can see the indication here, kind of all over the Committee. Everyone has their own little unique indication typically. We do have one combination product that is combining with vitamin D. That's the Fosamax Plus D. All are shown to significantly improve the osteoporosis outcomes in postmenopausal women and patients taking the prolonged glucocorticoid steroids. There really isn't any head-to-head data showing that one is much better than another. Catamaran would make the recommendation that these be considered clinically and therapeutically equivalent.

Chairperson Nagy: Any comments?

Need a move to accept.

Weldon Havins: Move to accept the recommendations.

Joseph Adashek: Seconded.



Voted: Ayes across the board.

Motion carries.

Carl Jeffery: Catamaran makes the recommendation that Binosto be considered non-preferred and with that we want to also include alendronate solution as non-preferred as well if patients need the solution, they should be able to obtain it without too much difficulty. It's still available for them.

Committee member: Just a quick question under the alendronate, does that include both the daily and weekly products?

Carl Jeffery: It is.

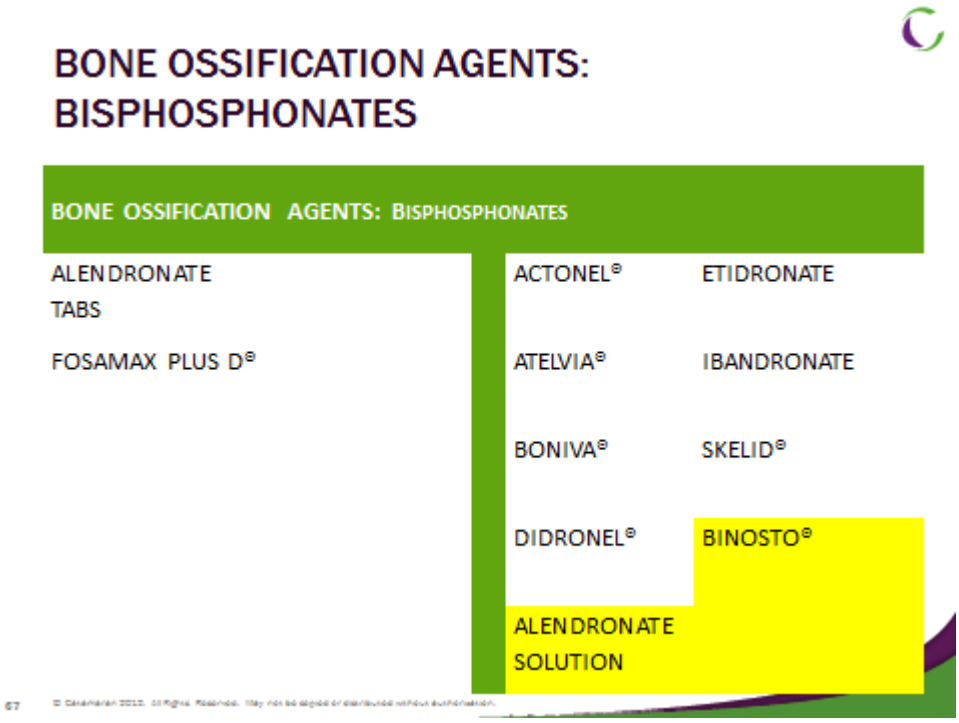
Chairperson Nagy: So they moving to the preferred list?

Carl Jeffery: I think they already are. Yes.

Chairperson Nagy: Need a motion.

Weldon Havins: Move to accept the recommendations.

Joseph Adashek: Seconded.



Voted: Ayes across the board.

Motion carries.

Antidepressants: SSRI

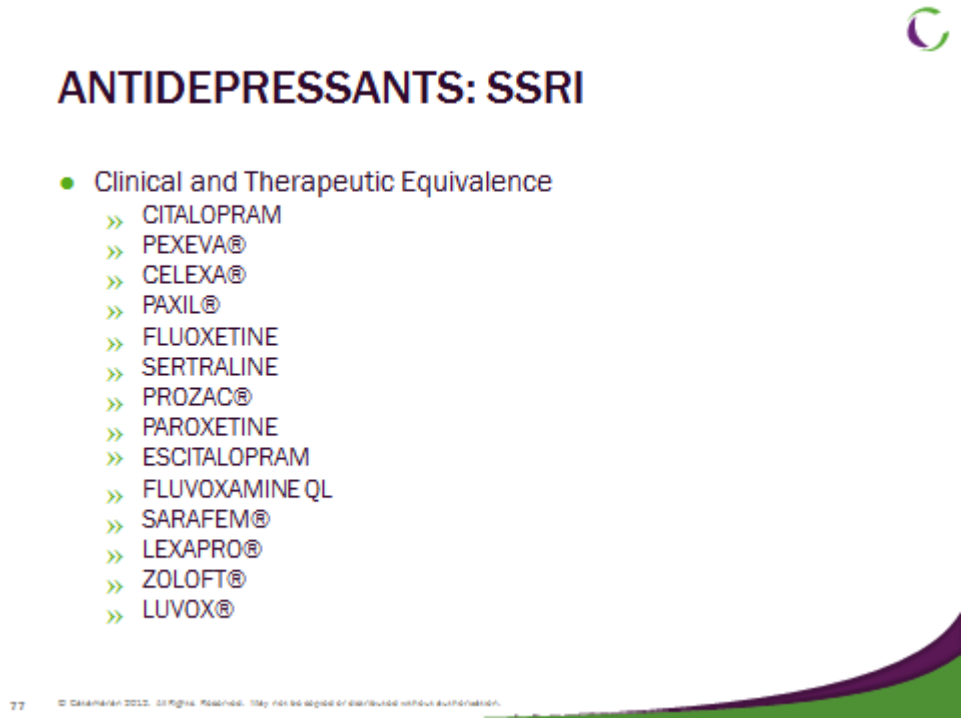
Public Comment: None.

Carl Jeffery: Just a real quick overview. SSRI has been an established class for a long time. There have been some new clinical literature and some new indications now that haven't been discussed here. Some of them have indications that are not discussed here. The guidelines for these are really selected by the individual products, patient, and the doctor, who are very much in tune with what works for their patients. It's an individual dose. Just because someone reacts to one, doesn't necessarily mean they are going to react to another one. Some studies show that there are some benefits with others, but they haven't been consistent across the Committee. I think these are pretty hard to show that. Catamaran recommends that these be considered clinically and therapeutically equivalent.

Chairperson Nagy: No comments? Then I need a motion.

Bill Evans: Move to accept the recommendations.

David Fluitt: Seconded.



Voted: Ayes across the board.

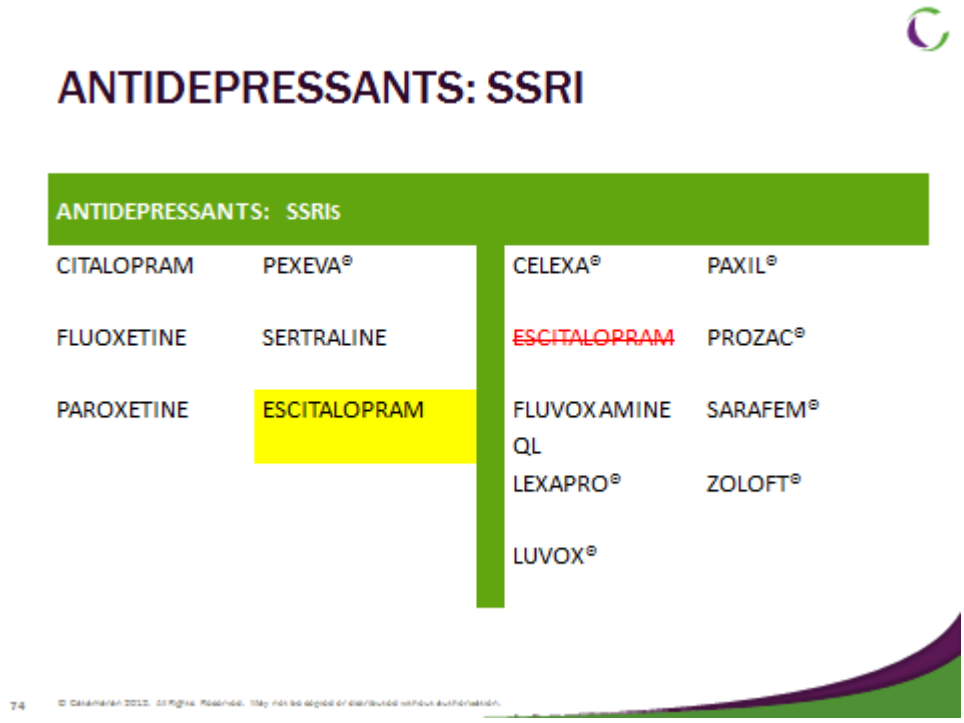
Motion carries.

Carl Jeffery: We have a really simple recommendation for this one. It's just to move the escitalopram, which is the generic Lexapro, to preferred from non-preferred. I think this will help a lot of patients, because it is probably one of our most requested preferred overrides.

Chairperson Nagy: Need a motion.

Bill Evans: Move to accept the recommendations.

David Fluitt: Seconded.



Voted: Ayes across the board.

Motion carries.

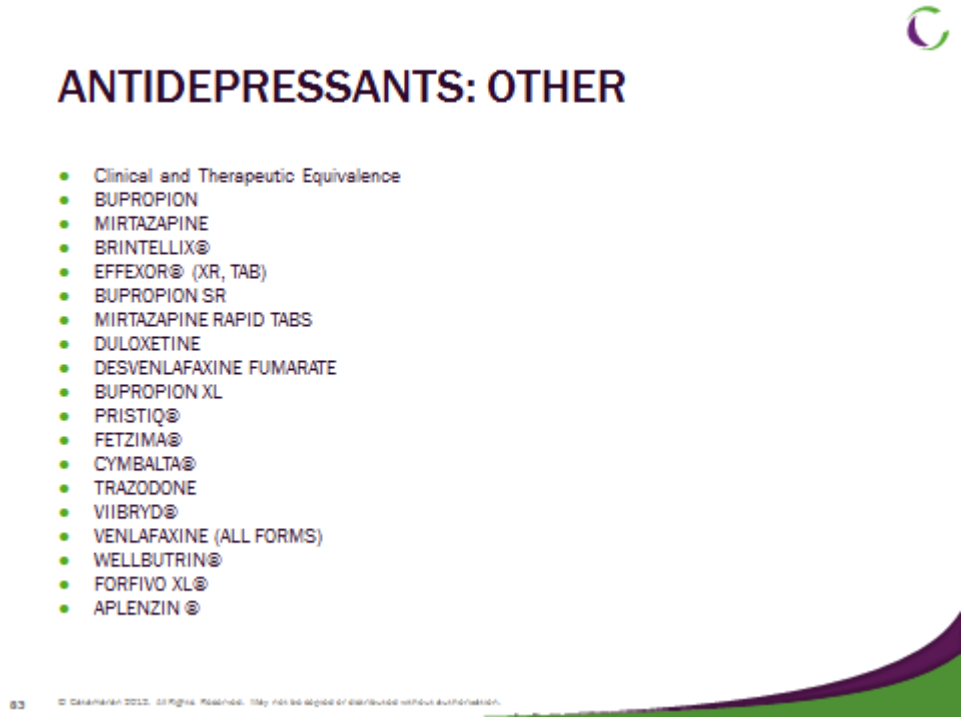
Antidepressants - Other

Public Comment: None.

Carl Jeffery: We brought this up because we had, a couple of meetings ago, we erroneously added the Savella to the preferred side. Technically Savella is in the same class as the other SNRIs, but it's only indicated for fibromyalgia, so the biggest thing we wanted to accomplish today is to get this pulled off there and listed only in the fibromyalgia class, which it still is. But the other agents, there's been some introduction, and we also realized that Effexor wasn't even being addressed on our PDL. We wanted to do the Effexor and the generic, venlafaxine. There are some other agents on here that I'll call out. The Forfivo and Aplenzin are both branded generics of Wellbutrin and the bupropion. And this Khedezla is actually a branded generic of the desvenlafaxine, which is a slightly different salt than the Pristiq, the generic Pristiq. You can see here the breakdown of the indications for the different products. Really Cymbalta is really taking in the most of these agents with the bulk of the indications, whereas the Effexor and its generic have a lot of indications as well. Similar to the SSRIs, it's hard to pin down exactly if there is one product that is better than another one. There have been lots of studies that show that they are all effective in their own right. Catamaran makes the recommendation that these be considered clinically and therapeutically equivalent.

David Fluitt: Move to accept the recommendations.

Bill Evans: Seconded.



Voted: Ayes across the board.

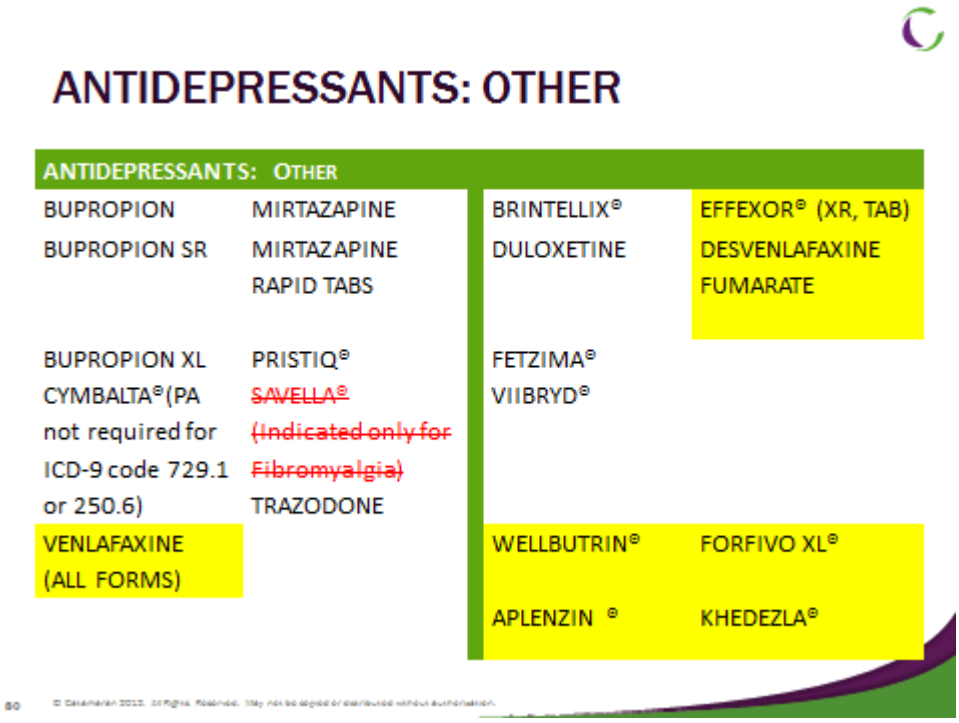
Motion carries.

Carl Jeffery: The move of Savella is probably one the biggest changes out there. So Savella will no longer be listed as preferred on here. It will still be listed as preferred under the Fibromyalgia agents. I want to make sure that is understood. We're not changing that with anything that is non-preferred. The venlafaxine, we want to include all forms of the generics. This includes the XR and the regular release tablets. But then for the non-preferred, we would include these other brands of generics in the brand, like Wellbutrin, and also the brand Effexor both XR and the tabs as non-preferred. There's also a different salt of the generic Pristiq, the desvenlafaxine fumarate. So we would consider those non-preferred.

Chairperson Nagy: Any comments? No comments. Then I need a motion.

Joseph Adashek: Move to accept the recommendations.

Bill Evans: Seconded.



Voted: Ayes across the board.

Motion carries.

Analgesics: Long Acting Narcotics

Public Comment: Good afternoon everyone. My name is Carey Harron. I'm Senior Director for Medical Affairs for Zogenix and a licensed veterinarian by background. Thank you for the opportunity to speak today. Zogenix would like to respectfully request the following action. We are requesting removal of the current 5-dose per month quantity limit for Zohydro ER. We propose non-preferred formulary status for Zohydro, with the institution of a quantity limit of 60 capsules per month, for the lowest Zohydro dosage strength of 10, 15, 20, and 30 mg. We propose that the two highest dosage strengths, 40 and 50 mg, not be covered. This is an acknowledgement of the Committee's concern regarding these dosages. Once the new formulation of Zohydro ER, designed to be an abuse deterrent, has been approved by the FDA, the 40 and 50 mg strengths could then be made available so that providers will have the ability to titrate patients appropriately for such doses. The FDA has set the PDUFA date for the new abuse deterrent formulation of Zohydro for this coming January 2015, 2 months. Zohydro ER was developed and is marketed to fulfill a single critical and previously unmet medical need. Currently in the United States, approximately 5% of the more than 130 million prescriptions dispensed yearly for immediate release, Hydrocodone, acetaminophen, combination products, are being taken chronically by patients suffering from long standing, chronic pain conditions, placing these patients at risk for the development of acetaminophen induced hepatotoxicity and the potential for acute liver failure due to unintentional acetaminophen overdose.

In fact a review published this year reported that 63% of all cases of acute liver failure due to unintentional acetaminophen overdose seen in tertiary care centers in the US were due to exposure to opioid-APAP combination products. Zohydro is designed to be a better alternative to immediate release hydrocodone APAP, for such patients suffering with severe chronic pain by eliminating the concerns regarding hepatotoxicity. Also by decreasing pill counts and dosing frequency and by providing steadier blood levels and more consistent pain relief. All without the need to take these patients off of the hydrocodone that had been working for them and the additional burden of converting them to a different and potentially less efficacious opioid molecule.

Much has been said and frankly misrepresented by the lay media and a few politicians regarding the potency and the strength of Zohydro ER. There has been a particular focus on the highest Zohydro dosage strength of 50 mg with reports suggesting that Zohydro is somehow a super potent opioid, or heroin in a capsule. With another report stating that Zohydro is 5-10 times more potent than Vicodin. In fact, regarding potency, when comparing the highest strength of Zohydro to the highest strengths of other extended release opioids, you must convert all to their morphine equivalent doses. After doing so, it becomes readily apparent that 50mg Zohydro is in fact the least potent of the extended release opioids at their highest dosage strengths. Additionally I can assure you that Zohydro ER is not 5-10 times more potent than Vicodin, because as you all know both contain exactly the same hydrocodone molecule, which of course means they are of equal potency. When it comes to comparing strengths, it has been stated correctly that Zohydro at its highest strength of 50mg contains 10 times the amount of hydrocodone when compared with the lowest strength of immediate release hydrocodone. However when this same comparison is made for the highest strengths of other extended release opioids, such as oxycodone, hydromorphone, and morphine, it is found that they contain from 16-40 times the amount of opioid in comparison to the lowest strengths of their immediate release counterparts. In the end of course these comparisons are meaningless as the extended release forms of all of these products are designed to be administered much less frequently throughout the day than their immediate release versions. The bottom line is Zohydro ER is neither the most potent, nor the highest strength extended release opioid product available. And lastly, regarding abuse deterrent technology, Zogenix fully supports the development of abuse deterrent versions of all opioids extended release, long acting, and immediate release. In fact Zogenix initiated the development of 2 abuse deterrent formulations of Zohydro immediately upon receiving FDA approval for the current formulation at the end of 2013. However, it must be noted that abuse deterrent technology alone is not a panacea for the public health crisis of opioid abuse, misuse, and diversion. Some seem to think that by simply making all formulations abuse deterrent, abuse will be stopped in its tracks. I assure you that nothing could be further from the truth. While abuse deterrent technology absolutely is one component of the solution, in helping to reduce hardcore abuse via injection and snorting, these methods of abuse actually make up less than 25% of the routes by which opioids are actually abused. As the FDA has pointed out multiple times, it is simple oral ingestion that is responsible for fully 70-90% of the abuse of opioids and unfortunately, current technologies do nothing to limit the simple oral abuse of these products. Zogenix firmly believes that by taking a multifaceted and comprehensive approach, including responsible commercialization, strict control of availability, and effective safe use initiatives that go above and beyond the current ER/LA

opioid REMS, we are helping to prevent abuse long before the medication ever even gets into the hands of the individual intending to abuse.

Coleen: Thanks for your time. Just for clarification also, the Pharmacy and Therapeutic Committee will be reviewing the preferred and the non-preferred status of each of the drug classes. Our Drug Use Review Board is our Board that is responsible for the clinical criteria. So they review the quantity limitations and what's covered and not covered. Ok? So today what we're reviewing is what is on the preferred and the non-preferred status. OK?

Public Comment: My name is David Malicki and I'm a Medical Science Liaison Director for Global Medical Affairs for Mallinckrodt Pharmaceuticals and I'm here to provide some information regarding Xartemis XR. As you can see in the slides, Xartemis XR is categorized as a long acting narcotic, but actually the FDA does not categorize it as long acting opioid. It is actually indicated only for acute pain, for a short duration. It has a unique quality, as the only product currently on the market as a combination that has both an immediate release and an extended release component. So again, it does not follow the normal long acting opioid guidelines. We do not need to use the REMS monitoring program for this product. Again it falls into a unique category. It's not immediate release, it's not short acting, and it's not long acting. It sort of falls in between. One of the reasons that Mallinckrodt developed the product was to meet the unmet need of opioids that are seen now that are immediate release that will frequently have high peaks and lower trough values. Sometimes because of the immediate release qualities, we'll not have coverage and will have frequent end of dose failure. Xartemis meets that need in that it has an immediate release component which, at onset, patients can get relief within 45 minutes, but it has a prolonged duration that will last for 12 hours. The product is a combination of oxycodone and acetaminophen. The oxycodone and the acetaminophen in the immediate release component releases 25% of the oxycodone and 50% of the acetaminophen immediately. And then in the extended release component, releases 75% of the remaining oxycodone and 50% of the acetaminophen over the next 11 hours for a 12 hour dosing period. The tablet is one tablet, which is 7.5mg of oxycodone and 325 mg acetaminophen. It's dosed as two tablets, twice a day. It's a fixed dose, very simple, no ramp up, no ramp down.

One of the reasons that Mallinckrodt has developed the product is to fit the unmet need in patients that have acute, especially post-operative, pain. Currently we are working with a focus on surgeons and only acute pain, again, post-operatively, for short duration. It's not indicated for chronic pain. It's not indicated for chronic use.

One of things I do support and recognize is that at this time Xartemis does not have abuse deterrent formulation designation as labeled, but Mallinckrodt has been working closely with the FDA. We've already submitted data that is both manipulation and extraction data for the FDA to review. We also have submitted human abuse and liability data and we're currently working with FDA on 2 additional studies which we believe will increase the likelihood of us getting abuse deterrent formulation in the label. Based on the unique immediate release and extended release formulation, and pharmacokinetic parameters, which are again unique to this product. There's no other combination product for acute pain on the market like this. We would like the Committee to add Xartemis to the Medicaid formulary on Preferred Drug List and if restrictions are necessary, to surgeons only. Any questions?

Committee: No questions.

Public Comment: My name is Rebecca Bischa. I'm Medical Science Liaison with Purdue Pharma. I signed up this afternoon to provide public testimony on Butrans and Oxycontin. Based on the directions provided I'm going to give back time to the Committee, but I'm happy to answer any questions you have.

Committee: Thank you. Any other public comments? No public comments.

Carl Jeffery: As you've heard, we've got two new products - the Zohydro and the Xartemis XR, which is why we are reviewing this class again. Also, some of the other ones, this is a similar to the ADHD class. We had some confusion about which exactly extended...well I guess we wanted to expand the extended release morphine sulfate that's available, so that more of the generics are available. Just a quick overview on what is out there and available currently. You can see all of the brand names over here. Some of these are not available anymore, so there's one up here, the Oramorph, and we'll get to it in a minute, but the Oramorph is no longer available at market, so that's why it's crossed out. I wouldn't mind some discussion from the Committee. I waffled about this because the methadone is considered in some circles to be long acting, in others not, and so depending upon how the Committee feels, I could see that going either way. So if we wanted to remove this as being listed as a long acting, but we can have that discussion in a minute. Some of the long acting narcotics - we've got the Oxycontin, the Opana ER, and the Embeda, which is supposed to be (it was pulled of the market in 2013) rereleased here, if it hasn't already, it's supposed to be soon. They were having some difficulties with it. But they are all built with some abuse deterrent properties. At head-to-head trials, similar to all the other agents, they have similar efficacy across the lines, but fewer showing that one is much better than the other in a significant and routine consistent manner.

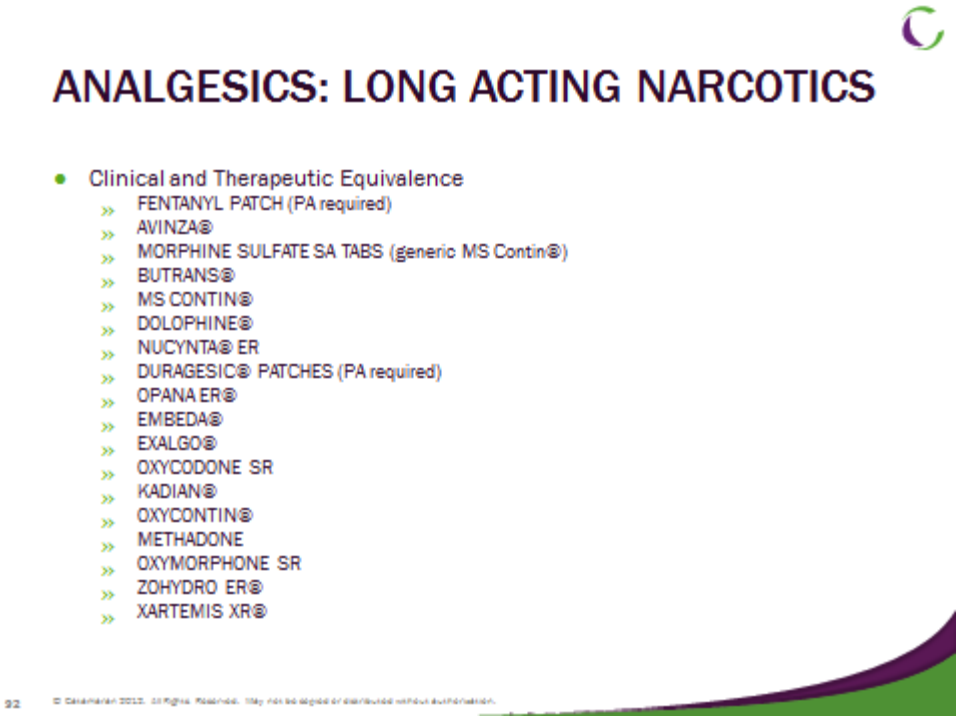
Just talking a little bit about the Xartemis, we learned a little bit about this already. It's a combination of the Oxycodone and acetaminophen extended release. As we heard, it's really only for a short period of time for treating post-operative pain. Now I will say that it is planned to take this to the DUR Board for their evaluation, so maybe we can add some restrictions on there, but again that is up to the DUR Board on that one.

Going with the Zohydro is a hydrocodone. It was approved October of 2013. Treatment of severe pain which requires daily treatment. The DUR Board did put a quantity limit on this, as 5 tablets per month. So they were very aggressive with the quantity limits on these. And I think that was kind of a reaction based on some of the other information we are looking at, some potential abuse of the opioids. This one was one that the FDA advisory panel voted against approving this one 11 to 2, but still the FDA approved it anyway. They provided some rationale as to why they are doing it. Most of it is to provide more medication, more options to the patients.

Catamaran would like to make the recommendation that these products in this class be considered therapeutically and clinically equivalent.

Weldon Havins: Move to accept the recommendations.

Joseph Adashek: Seconded.



Voted: Ayes across the board.

Motion carries.

Carl Jeffery: Our recommendation to update the Preferred Drug List is to add, instead of only covering the generic MS-Contin, but to approve all morphine sulfate extended release products, regardless of what their AB rated brand is. They would all be considered preferred. We're going to remove the Oramorph from the list because it's no longer available on the market, and then include the Zohydro and the Xartemis XR. When we talked about this before, we talked about maybe taking the Xartemis XR to the DUR Board first and then bringing it back here once we have some restrictions from the DUR Board, and then we can reevaluate it after the DUR Committee takes a look at it. For now, we want to include both those as XR.

We had two letters from the community for Butrans. So we'll let the Committee members view the letters that we've received. The Butrans - we've got some support to make that one of our recommendations.

Committee member: I wonder if anyone has any comments on the Zohydro controversy as opioid abuse.

Evelyn Chu: We don't use it in the hospital setting.

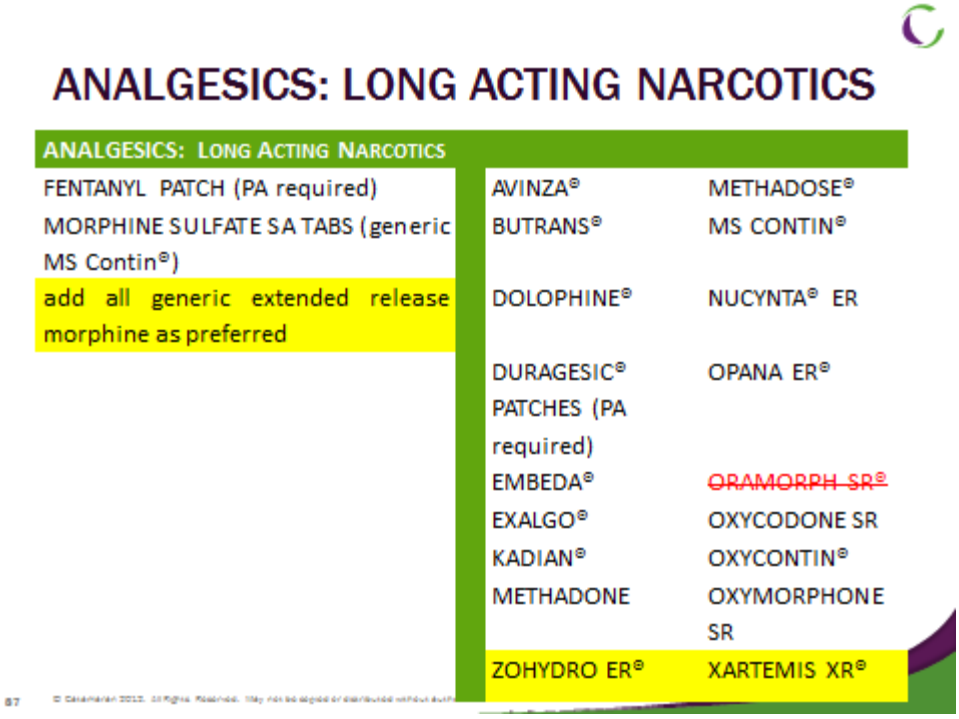
David Fluitt: It hasn't really caused much problem in the retail setting.

Committee member: I do agree with the comments of the prior speaker in terms of some of the sensationalism in terms of the equal potency and equivalency. There has been a lot of falsifying in the media. When you look at converting oral morphine equivalence which is the standard for these products.

Chairperson Nagy: Any other comments?

Weldon Havins: Move to accept the recommendations.

Joseph Adashek: Seconded.



Voted: Ayes across the board.

Motion carries.

SGLT2 Inhibitors

Public Comment: Hi good afternoon. My name is Bill O'Neill and I'm a Pharmacist with Boehringer Ingelheim in their Health Economics and Outcome Research Group and I'm going to speak today on Jardiance. You had a very nice clinical review of the SGLT2 class, but I want to talk a little bit about some of the differences. Even though I think the efficacy in this class are very similar, there are some slight differences that I want to highlight very quickly. We did study Jardiance in mono therapy and in combination with Metformin and pioglitazone. We did get a chance to study it in patients who were renally impaired, so mild to moderately renally impaired patients. In our package we were able to get dosing guidelines

that patients above a EGFR 45 mL per min, which is significant in that if you look at a dataset like the NHANES Dataset, which is a pretty good surrogate for an at risk population, 90% of those patients had an EGFR of 45 or higher. However, if you look at about what percentage of those patients had and EGFR between 45 and 60, which is where the other guidelines are in dosing, about 20% of those patients fall within there, so you have about a 1/5 patient that could still benefit from Jardiance, even if they have some renal impairment. The other thing that was clear in some of our safety data was that we did not see a signal for bladder cancer. We did not see a signal for hyperkalemia. We do have the convenience of dosing with or without food, once daily dose. We were to suggest that if you're going to narrow this class, we think that your Medicaid population could benefit by the dosing options associated with Jardiance and we would respectfully ask that you would add that in there as we let this class play out, particularly from the safety standpoint as well. If there are any questions, I will take them at this time.

Committee: No questions. Thank you.

Public Comment: Good afternoon, ladies and gentlemen. My name is Chuck Cannon and I'm an endocrinologist practicing here in Las Vegas. I'm here to support your decision in having Invokana, or canagliflozin, as the preferred SGLT-2 inhibitor. When I was here the previous time, and this was recommended, now we have almost 18 months of data in the real life setting and I just wanted to point out that in the last 20 months or so there has been tremendous acceptance of this class. This class of SGLT-2 inhibitors has pretty much become the game changer and I'm here to answer any questions you might have in terms of Invokana and humbly request that you retain it as the preferred SGLT-2. It's a growing class and the more this class grows, I think our diabetes patients will improve because of the nature of this disease. Thank you very much for your patience.

Committee: Do you use the current preferred?

Cannon: Yes. The current preferred, if my understanding is correct, is Invokana. That is the first FDA approved drug in this particular class. Now there are 3. Invokana, Farxiga, and then there is Jardiance. They all are similar in terms of their action. They are SGLT-2 inhibitors. What they do is they take blood sugar out of the blood and dump it out through the kidneys, so you're using the kidneys as a flushing mechanism and when you give these drugs, the kidney sees it and the kidney pees it.

Committee: Are you advocating Invokamet?

Cannon: I do not want Invokamet at all. I'm talking about Invokana. Invokamet is a combination of Metformin and Invokana. It's like 2 drugs in one. But the SGLT-2s are Invokana, Farxiga, and Jardiance. They are the three. And the first one that the FDA approved was Invokana, which is what this Committee also did to recommend. Now that it's been around for so long, there is more data, more safety signals, and no bad signals. So, if there are any questions, I would be delighted to answer.

Committee member: So you're advocating what?

Cannon: Invokana as the preferred SGLT-2 inhibitor.

Committee: Thank you.

Public Comment: Good afternoon. My name is Mary Kay Queener. I'm a Principle Liaison with Health Economics & Outcomes Research group with Janssen. I'm also here to support the recommendation to maintain Invokana on the Preferred Drug List, but I came up today to ask you to consider the addition of Invokamet on the PDL. As you have gathered, it is a fixed dose combination of Invokana plus Metformin. It is an immediate release, so it's a twice a day dose, versus the once a day Invokana, but for patients who are already on both medications, it would decrease the pill burden. There are no clinical studies for this fixed dose combination, but there are multiple studies with the development program for Invokana adding Invokana to Metformin. And this approval was based on pharmacokinetic equivalence of the two drugs given independently verses the fixed dose combination. I would ask you to consider that for those patients who are already on these medications and to reduce their pill burden. I'm happy to answer any questions.

Committee: Thank you.

Chairperson Nagy: Any other comments? No comments.

Carl Jeffery: As we heard, we're talking about the new Farxiga and the Jardiance. It's in a slide toward the end of my presentation too, but there's actually a new combination that is on the market with the Farxiga and the Metformin. It's call Xigduo. Probably for the next meeting, we'll have this up again. As we heard the SGLT-2 inhibitors help excrete the glucose into the urine. We've got three of them now on the market. We've got one combination and one that just hit the market maybe a week or two ago. We talked about the Jardiance and the approval process here. We've got it compared with the sitagliptin. It was shown to significantly decrease the A1C compared to placebo. It did bring it down by .7 or .8, depending on the dose. Again another one, another big study, this one has the two different doses compared against the placebo. This one is with the ASRDs, like Bill was talking about. The other ones do have some restrictions. The biggest drawback, and what makes me nervous as a pharmacist is the matter of time that these have been on the market. I think the short amount of time they've been on the market they've shown themselves to be excellent products and safe. So we've got limited experience. There are several favorable side effects with these. We've got weight loss and some of them controlled blood pressure a little bit. The Metformin is still the number one therapy in the cornerstone, but second and third are still up in the air, so this could be considered there.

Right now, Catamaran would like to make the recommendation that these be considered therapeutically and clinically equivalent.

Chairperson Nagy: No comments?

Need a motion to move forward.

Evelyn Chu: Move to accept the recommendations.

Weldon Havins: Seconded.

Voted: Ayes across the board.

Motion carries.

Carl Jeffery: Catamaran makes the recommendation to make Farxiga as preferred, but include the Invokamet and the Jardiance as non-preferred.

Mark Decerbo: I have a question. Seeing as Invokana is currently on our PDL, it's been the past direction of the Committee that when there's a fixed dose product, along with Metformin, that it's generally followed on the PDL as well. Were there any concerns from Catamaran's standpoint in terms of why Invokamet would not be on the PDL as well following other fixed dose combinations?

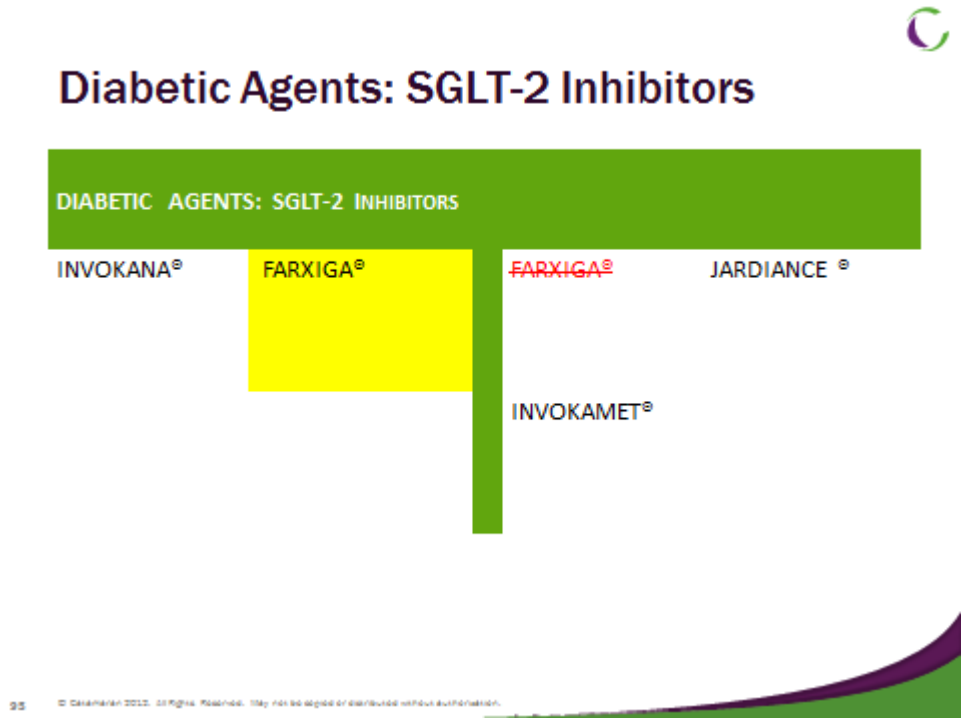
Carl Jeffery: It's hard to compare those because we've got some restrictions as far as the diabetes medications with the June 30th, 2010 date. So if it's available before then, we have to cover it. As far as this one goes, I don't know that there's necessarily a huge concern. I think our thought with this one is that they would probably be, they should be stabilized on both medications individually first, before they were moved to a combination product. Once they are started on the Invokana and they're also on Metformin, once they are stabilized, I don't think it would be an issue to move those over to the preferred agent, to get the Invokamet. So I don't think it's a big hurdle. It's a phone call to the call center to get that approved.

Chairperson Nagy: No comments?

Need a motion to forward.

Evelyn Chu: Move to accept the recommendations.

Weldon Havins: Seconded.



Voted: Ayes across the board.

Motion carries.

Diabetic Agents: GLP1

Public Comment: None.

Carl Jeffery: We've got a new product, the Tanzeum, it is in this class. What really separates this is how often they are given. So the Victoza, which is by far, probably the most popular here in Nevada, is a daily injection. We do have a couple weekly injections, but the Tanzeum is the newest one. It's a weekly dose. Again this is another where Lilly has just released a product in this class, so we'll be seeing this one again in March. Unfortunately it wasn't out in time to get into the clinical review, so we'll see this one again as another weekly injection. We've got the Bydureon, which is weekly and the Byetta, which is a BID injection, sub-Q. With the Tanzeum here, there was just one study on here, but it was pretty good size - 841. It showed some decrease compared to liraglutide. It did show similar results to liraglutide. I will point out, in their defense that it was just one study, but it was broken into 4 phases and it was an extended study. But with the addition of the Tanzeum, Catamaran makes the recommendation that these are clinically and therapeutically equivalent.

Chairperson Nagy: No comments?

Need a motion to forward.

Weldon Havins: Move to accept the recommendations.

Evelyn Chu: Seconded.

Voted: Ayes across the board.

Motion carries.

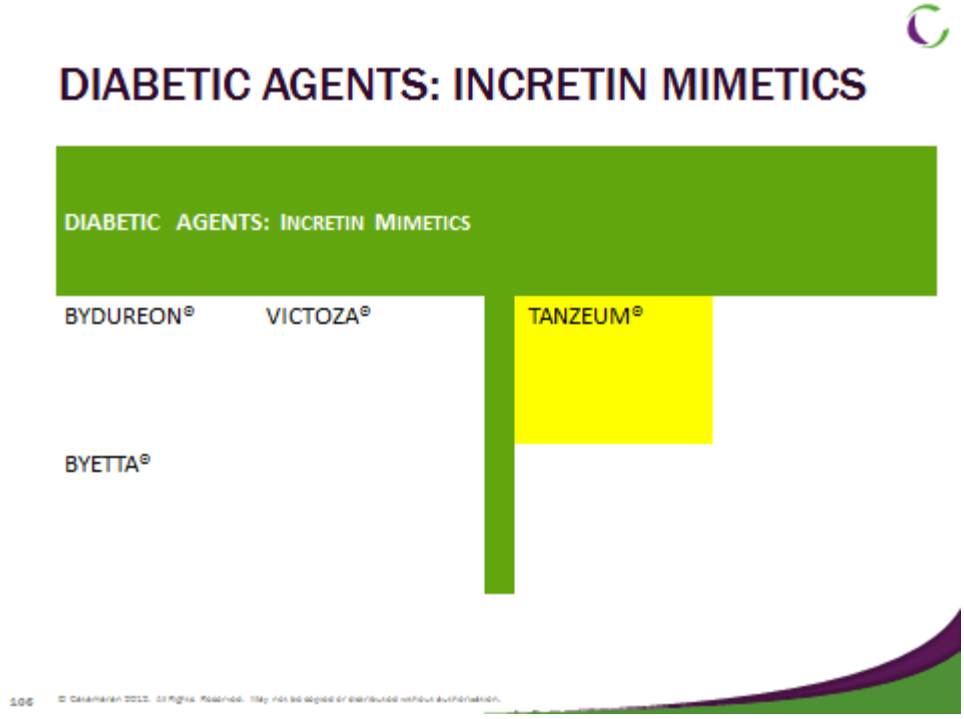
Carl Jeffery: Catamaran makes the recommendation that the new medication, Tanzeum, be considered non-preferred.

Chairperson Nagy: No comments?

Need a motion to forward.

Weldon Havins: Move to accept the recommendations.

Evelyn Chu: Seconded.



Voted: Ayes across the board.

Motion carries.

Nicotinic acid, vitamin B3

Public Comment: None

Carl Jeffery: We don't really have any new products in this one, but we have several new generics. Niaspan ER and the Niacin is generic. We still have, a quick clinical overview, the statins are still considered first lane. These are still recommended if your triglycerides are over 500. Right now there's just the three big, main products. We've got the Niacor, Niaspan ER, and Niaspan that are on here. We'd like to consider those clinically and therapeutically equivalent.

Chairperson Nagy: No comments?

Need a motion to forward.

Bill Evans: Move to accept the recommendations.

Weldon Havins: Seconded.

Voted: Ayes across the board.

Motion carries.

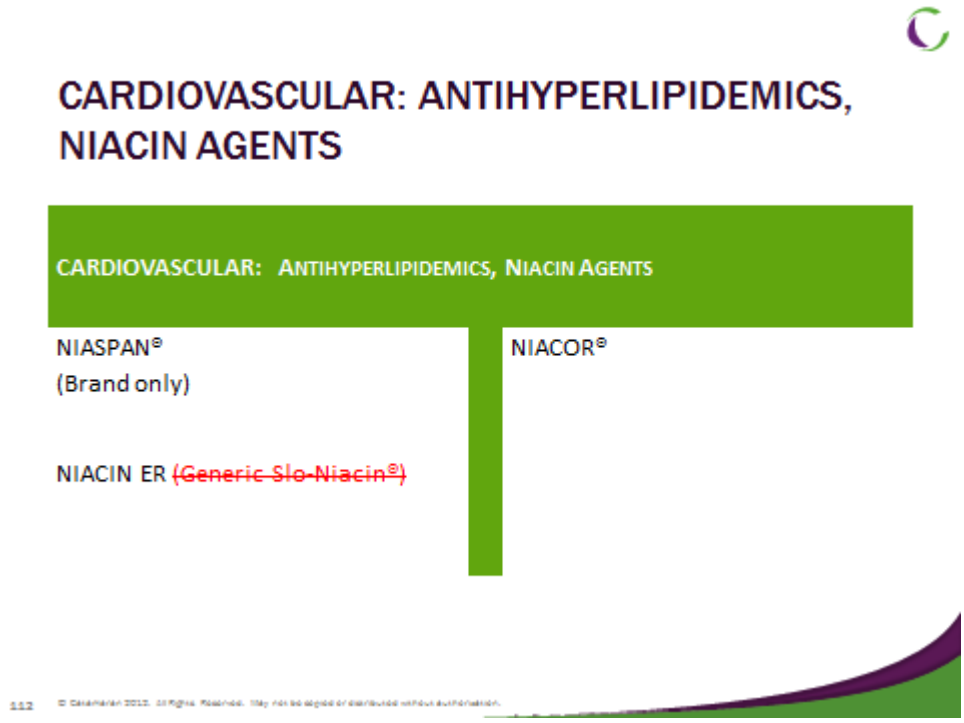
Carl Jeffery: Our only update here is to include all generic extended release Niacin. Before we just had the slow Niacin as considered preferred to the generic, but this would apply to all generics. That's our only changes.

Chairperson Nagy: No comments?

Need a motion to forward.

Mark Decerbo: Move to accept the recommendations.

David Fluitt: Seconded.



Voted: Ayes across the board.

Motion carries.

Central Nervous System: Oral Anticonvulsants, Misc.

Public Comment: Good afternoon. My name is Sammy Verius. I am the Medical Science Liaison at Upsher-Smith. Thank you for the opportunity to provide testimony for Qudexy XR which is extended release topiramate. This is also available as an authorized generic in an extended release capsule. It is rationally designed for once a day, daily dosing and is bioequivalent to the topiramate immediate release as demonstrated in a published switch study. It has a similar pharmacokinetic profile with a lower peak plasma concentration for improved tolerability while maintaining efficacy and plasma concentration for efficacy. It is already administered as a whole capsule and can also be opened and sprinkled on soft food. This method is important for children, the elderly, and patients with swallowing issues. The indication for it is 3. The initial monothereapy in patients 10 years old, as well as adjunctive therapy in patients 2 years old and older with partial onset and primary generalized tonic-clonic seizure. The third indication is adjunctive therapy in patients 2 years and older with seizures connected with Lennox–Gastaut syndrome. Qudexy are the most effective in randomized placebo controlled phase 3 trials in adults patients with refractory epilepsy taking multiple anti-epileptic drugs including the two most commonly prescribed in the United States these days. Many of these drugs were not available at the time of the original launch studies of the topiramate immediate release studies. Qudexy significantly reduces the frequency and partial onset seizure in adjunctive therapy verses placebo. The Qudexy XR trial seizure reduction occurred in week one and was sustained throughout the 11 week trial. These results are consistent with the efficacy seen in pivotal trial for topiramate immediate

release. Overall, patients tolerated Qudexy XR well with a favorable safety profile compared to placebo. Qudexy XR exhibited a low instance of cognitive and neuropsychotic adverse events most often associated with immediate release topiramate. In summary the Qudexy XR contains a single uniform XR bead. It is approved as a whole capsule, whole or sprinkled. It can be taken with our without food. It has established efficacy, steady pharmacokinetic profile in overall tolerability combined with the once daily dosing as demonstrated in the phase 3 trial. It offers an important new option for patients with epilepsy. I would ask the State of Nevada Medicaid to allow unrestricted access to probably all the anti-epileptic drugs and place the Qudexy XR with its authorized generic formulation on the Preferred Drug List.

Chairperson Nagy: Thank you. Any questions?

Public Comment: Good Afternoon. I'm Marilyn Simonchuck. I'm a Pharm-D and I work as a Medical Science Liaison with Azid Network for three and a half years. I have testified previously, in front of the Committees, specific to Fycompa so I will not review any of the clinical efficacy and safety data because you have that information currently. What I will share with you is some new information specific to Fycompa. Fycompa is currently available now in over 40 countries and has been utilized by over 25,000 patients globally. Based on a positive study in primary generalized tonic-clonic seizures, we have submitted for a new indication for primary generalized tonic-clonic seizures to the FDA. We anticipate that we will receive approval in the second to third quarter of 2015. Fycompa does offer many advantages to patients with uncontrolled epilepsy specifically this once daily. It has a long half-life of 105 hours. It is a small tablet which is easily swallowed by patients who have difficulty swallowing. It's indicated in patients 12 years of age and older. It does have a unique mechanism of action so it can be prescribed with other anti-epileptic drugs. I will address any questions the Committee might have.

Chairperson Nagy: Thank you. Any other public comments?

Carl Jeffery: As you just heard, we are talking about the topiramate and the Trokendi XR, the new one on the market, which made us bring this class up for review again. Trokendi XR and the Qudexy are both extended release Topiramate. The Trokendi XR does not have an AB rated generic, but the Qudexy does as we've heard. There's an authorized AB rated generic that can be substituted. We're not going to go through all of that. It's the same as the topiramate, the Topamax. Previously there was not an extended release Topamax. I think these are good products to have available on the market for a lot of the people who are on the Topamax. Now they have an extended release version. Our recommendation is to consider these products clinically and therapeutically equivalent.

Chairperson Nagy: No comments?

Need a motion to forward.

Bill Evans: Move to accept the recommendations.

Weldon Havins: Seconded.

Voted: Ayes across the board.

Motion carries.

Carl Jeffery: Our recommendation is to consider the Trokendi and the Qudexy XR both non-preferred, but to elaborate on the topiramate and to include the immediate release and the extended release versions, so the generic, the authorized generic will be also considered preferred.

Chairperson Nagy: Fycompa remains non-preferred?

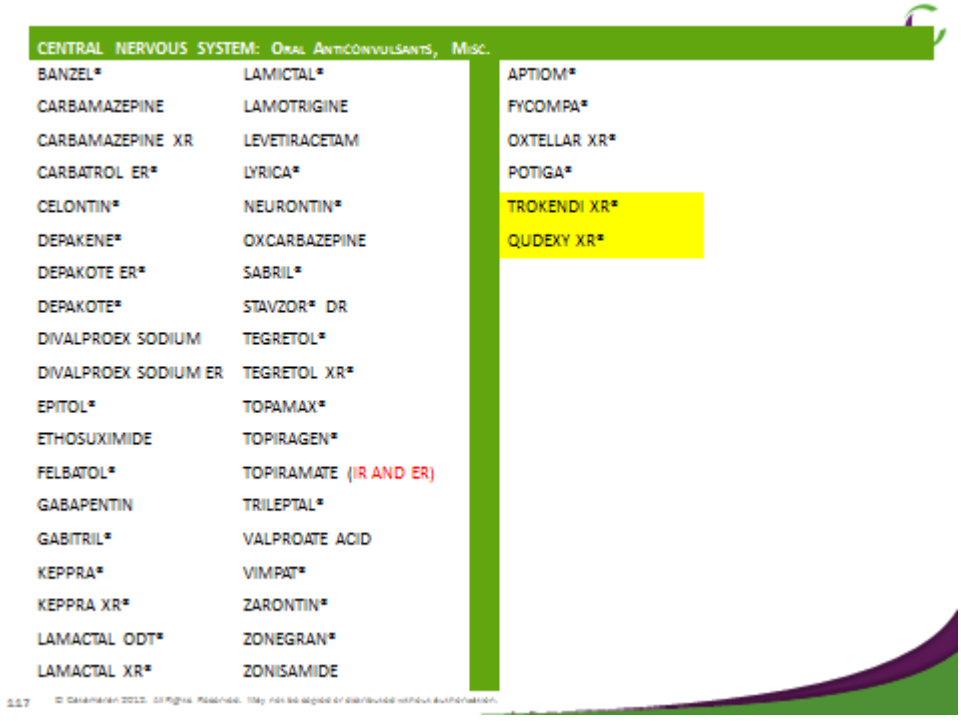
Carl Jeffery: Yes. Fycompa remains non-preferred.

Chairperson Nagy: No comments?

Need a motion to forward.

Weldon Havins: Move to accept the recommendations.

Bill Evans: Seconded.



Voted: Ayes across the board.

Motion carries.

Androgenic Agents topical

Public Comment: None.

Carl Jeffery: We've got a new medication, Vogelxo. It's a new topical testosterone on the market. The difference between this new one and the others is the formulation inside the administration. This new one available, the advantage that they are advertising is that it comes in three different strengths, so it's easier to customize the dose. In head-to-head studies, Testim and the Androgel are showing a slightly higher testosterone but how this ends up clinically is kind of unknown still. One study suggests that patients with a suboptimal response to Androgel may experience dramatic improvements in libido erectile dysfunction and energy following the switch to Testim. There's always the study crafting to get the results you are looking for. Catamaran would like to make the recommendation that these be considered therapeutically and clinically equivalent.

Chairperson Nagy: No comments?

Need a motion to forward.

Joseph Adashek: Move to accept the recommendations.

Weldon Havins: Seconded.

Voted: Ayes across the board.

Motion carries.

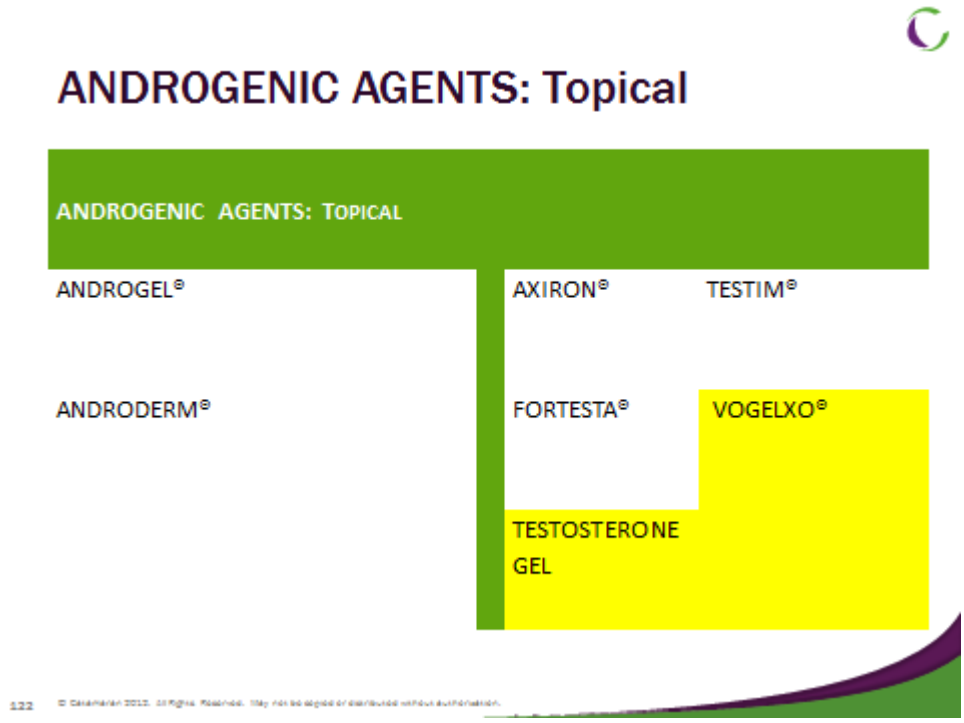
Carl Jeffery: So our recommendation is to consider not only the new agent, this Vogelxo, but there's also a new generic, the Androgel, that's also available as a testosterone gel. It always takes a while for its marketing to catch up for it to become a benefit to the state for this one, so right now we're recommending this as non-preferred.

Chairperson Nagy: No comments?

Need a motion to forward.

Weldon Havins: Move to accept the recommendations.

Joseph Adashek: Seconded.



Voted: Ayes across the board.

Motion carries.

Immunomodulators: Injectable

Public Comment: None.

Carl Jeffery: There's a new product - Actemra - that we have not reviewed previously, so we wanted to include that one on here. Quick overview of the injectable immunomodulators. We do have now 2. The second oral immunomodulator hit the market recently. These will be brought up probably in the March meeting. We'll have the oral agents separated out from the injectable immunomodulators. But they are included in the clinical review. We've got the Xeljanz and the Entyvio. You can see the different medication classes that these are in right here. Lots of indications. Most of them are for rheumatoid arthritis, or ulcerative colitis, or anklyosing spinalitis. The key points with this class is that the immunomodulators inhibit the pro-inflammatory response. They really do have a huge benefit with rheumatoid arthritis and other inflammatory diseases. There's been a few head-to-head studies, but again, like some of the other studies, they don't consistently show superiority over some of the other ones. The current guidelines do not make a recommendation of one over another. Catamaran would like to make the recommendation that the injectable products be considered clinically and therapeutically equivalent.

Chairperson Nagy: No comments?

Need a motion to forward.

David Fluitt: Move to accept the recommendations.

Joseph Adashek: Seconded.

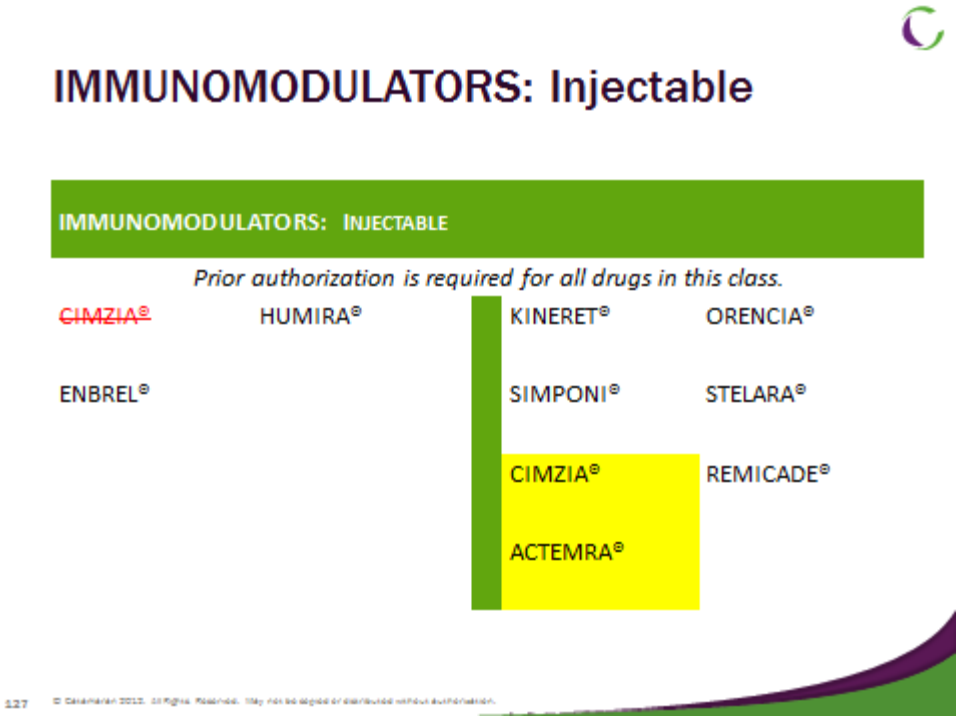
Voted: Ayes across the board.

Motion carries.

Carl Jeffery: Catamaran would like to make the recommendation that Cimzia, which we made preferred about a year ago, to be considered non-preferred. We thought the market share would be driven by the Cimzia, and drive people over to this class, but after a year, it hasn't shown this to be the case. We're not seeing the market share that was promised to us. So we would like to move the Cimzia over to the non-preferred side. I want to guarantee the Committee that we will grandfather anyone who is currently on the Cimzia, so that they don't have to switch over to another agent. We will give everyone who is currently on it the ability to stay on it. Right now there is such a small market share on the Cimzia that I don't think it's going to be a big impact.

Joseph Adashek: Move to accept the recommendations.

David Fluitt: Seconded.



Committee member: I have a question. You know there's one oral agent in that class. Does it get a separate category?

Carl Jeffery: Yeah I think we'll bring that back up in March. Because there's actually a second agent that was just introduced. I don't think it's on the clinical review yet, but I think there was a second agent that was just introduced and we'll bring it back up and it will be in its own class, but we'll bring it back up in March.

Voted: Ayes across the board.

Motion carries.

Platelet Aggregation Inhibitors

Public Comment: None

Carl Jeffery: We have a new drug in this class, Zontivity. It is introduced and it prompted us to bring it up here. We've got all of the other ones on here. We have a couple that have generics available including, probably one of the mainstays, the Plavix clopidogrel. Some of the studies compare against placebo. It does show a slight reduction. Granted these are huge studies -26,000 people in the study - long term, up to 4 years average of 2 and a half years on these. They show a reduction in some of the events in here, but I think there were some problems with causing some intracranial bleeding in a certain subset of patients. There is that warning with this medication. We've got another study of 17,000 people showing similar results. We see a reduction from 12.1% down to 10.5%, so it's got some reduction in the long-term events. It's indicated to reduce the risk of thrombosis cardiac events in patients with myocardial infarction, or with peripheral arterial disease. Based alone on the multifaceted TIMI 50 trial. It was effective at reducing the composite cardiovascular death, in-line stroke and urgent coronary revascularization. It did have significant relative risk reduction over the 3 years. We'll put that in with all of the other medications that are currently on the market and have been out long enough that we have some good experience with, but Catamaran would like to make the recommendation that these be considered clinically and therapeutically equivalent.

David Fluitt: Move to accept the recommendations.

Weldon Havins: Seconded.

Voted: Ayes across the board.

Motion carries.

Carl Jeffery: Our recommendation...the Zontivity was also studied, it was always given with aspirin, or clopidogrel, so we want to make the recommendation, not only because of that, but because I think there are some other agents out there that probably should be tried first, but we'll make it non-preferred as our recommendation.

Committee member: I have a couple of questions that may be housekeeping - First seeing Cilostazol up there is pentoxifylline or Trental. Do we have that listed elsewhere?

Carl Jeffery: We don't have it listed. We can. Do you think we should include it on here?

Committee member: Just didn't know if it was an error of omission or if you had it somewhere else. Just a comment too...back to the comment about market share, do we routinely look into some of these for overall usage for consideration when moving drugs to the non-preferred side?

Carl Jeffery: The Committee can definitely drive market share. If there's an agent you feel is really not worthy of, or if there are other agents that should be tried first, clinically speaking, then absolutely that is a discussion worth having. That's one of the scenarios we use to assess whether or not something, switching over to preferred, has been working, if we are getting the results we are looking for.

David Fluitt: Can you give me some reasons why we are keeping Effient non-preferred? Because from what I'm looking at, some of the studies that I'm seeing, I'm going out on a limb, and what I reviewed recently in Pharmacist Letter is there was less incidence of GI bleed with this product. It seems that there might be some advantages to keep this preferred agent. So what's the reason for Catamaran's recommendation for non-preferred?

Carl Jeffery: I agree. I think there is some good evidence to show that the Effient is probably a good agent. I think it's something worthwhile. I don't know if you have the numbers available.

Mark Decerbo: Maybe on that last comment there, maybe the DUR can take a look at the ticlodipine and the stand alone dipyridamole, there is very little utility for those two products.

Weldon Havins: I move that we accept the drugs on the left as preferred with the exception of ticlodipine and dipyridamole since they have such low utilization.

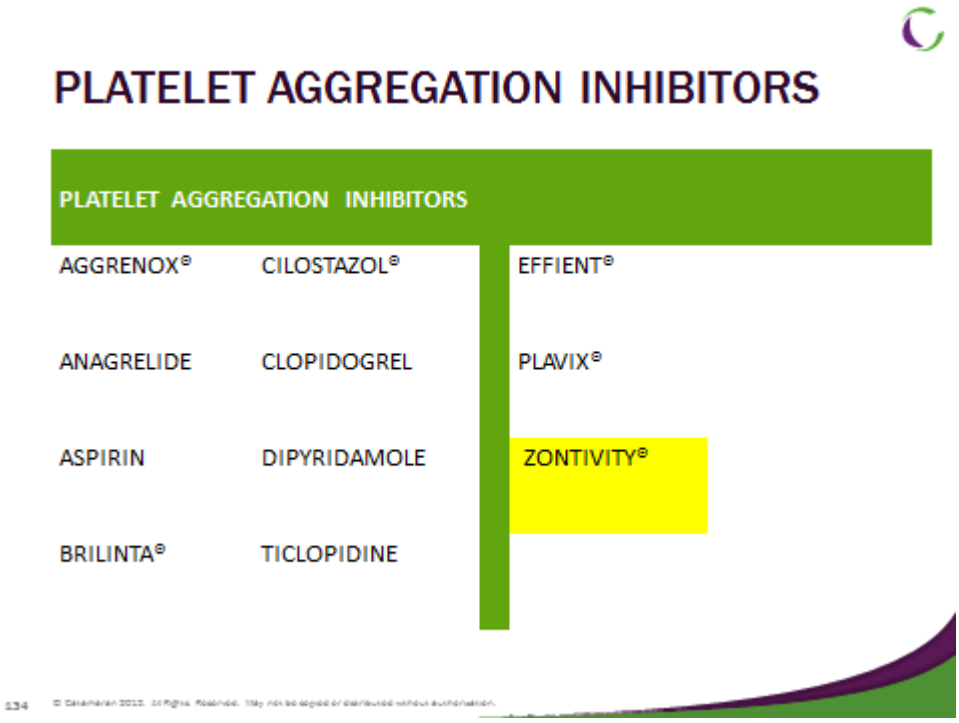
Carl Jeffery: So you want to make those non-preferred?

Committee member: The question is that these may be hardly ever used, but there may be some doctors who prefer to use it as it has no more side effects than the others, I guess, why take it off now when there's doctors going to ask why it is non-preferred now. I guess what's the harm in leaving it on?

Committee discussion

Weldon Havins: I move that we accept those 8 drugs on the preferred list.

Joseph Adashek: Seconded.



Voted: Ayes across the board.

Motion carries.

Respiratory: Inhaled Anticholinergic Agents

Public Comment: Bill O'Neill from BI again. Thank you. We do see a great deal of patients who still really benefit from a short acting LAMA and a short acting beta agonist. I did want to talk real quickly about the Spiriva Respimat. As you know the Respimat in the hand inhaler has been used for quite a long time. Really it's about the device and the utilization of the device. I think that what we've learned with combi - Respimat there's been a great deal of patient satisfaction with the actual slow mist inhaler. Even with the dry powders, there's a certain amount of minimum volume you have to be able to inhale. You basically only have to be able to inhale for 1.5 seconds to receive the dose. We often get questions as to whether this is going to prolong the patent life on Spiriva. It's just, we have a patent on the device, but certainly not the molecule. It's really based on given our patients alternatives. As a transition from the short acting Combivent, it's nice to have a similar device that they go in with the long acting Respimat. So our recommendation and suggestion is that you would also include the Spiriva Respimat because of the utilization and the comfort with that drug. Thank you.

Chairperson Nagy: Any other comments? No comments.

Carl Jeffery: We do have a new agent in the class that we want to review, the Anoro Ellipta. This Spiriva Respimat was a last minute sneak in. It was available on the market about 2 or 3 weeks ago. The reason it's over on this side now, is that we didn't feel they had enough opportunity to get out and put a bid back to the state for us. So that's why it is over there. So

no offense Bill, but we like the Spiriva hand inhaler, so it's looking good. So we've got the new one, which is a combination of the Anoro, which is two new molecules on here, the microdinium and the Vilanterol. It's a combination of the anticholinergic and the beta-agonist. It's a little bit different than what we've seen. It's only once a day dosing. It's got some advantages, plus the delivery method with the Ellipta inhaler is pretty cool little tool. So we have some quick studies here. It's a combination compared to the individual products, showing that the combination is superior to the individual products. We've got an indication for long term, once daily treatment, for maintenance. It's only indicated for COPD right now. It does have some significant lung improvements with FEV-1 when compared to the placebo, or compared to the individual ingredients. Right now, the way the market is, we would like to consider these as therapeutically and clinical equivalent, recognizing that the Anoro is a once a day, while some of them are immediate release. But for the most part, they're molecules and mechanisms are clinically and therapeutically equivalent.

Chairperson Nagy: Need a motion to forward.

Joseph Adashek: Move to accept the recommendations.

Weldon Havins: Seconded.

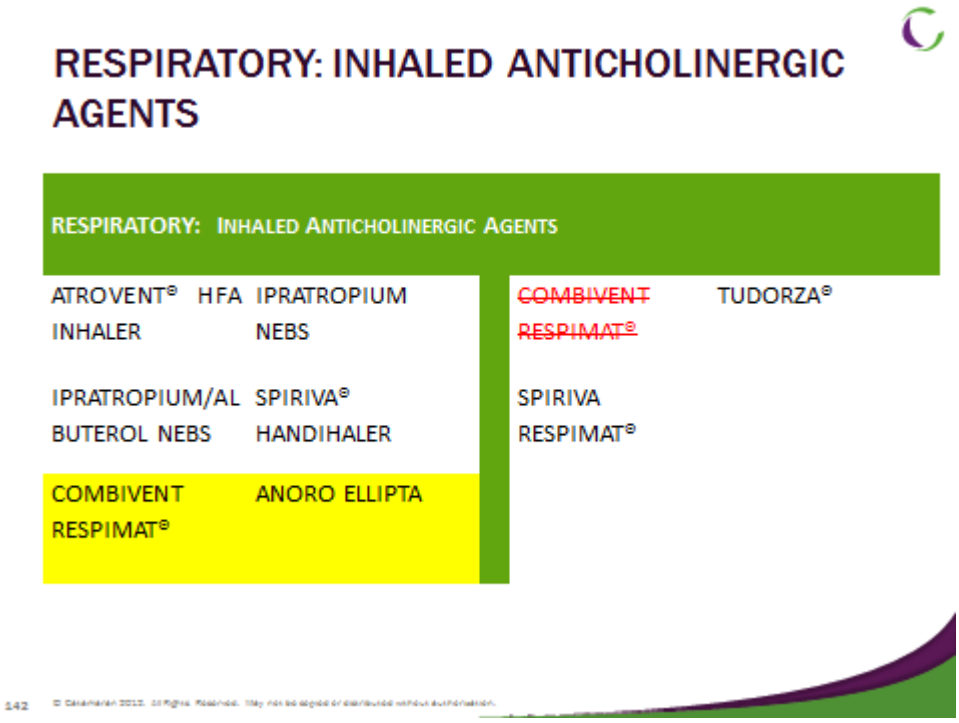
Voted: Ayes across the board.

Motion carries.

Carl Jeffery: So our recommendation is to not only include the Anoro as preferred, but to move the Combivent Respimat. There was a Combivent metered dose inhaler that was pulled off of the market because it had the CFCs in it. It had to be discontinued. We would like to get the Combivent, which had some good benefits, to the patients. It's a combination of albuterol and Ipratropium into the preferred side. This will likely come up in March again. We'll discuss, at that time, the Spiriva Respimat after we've had time to do a write up of that medication.

Joseph Adashek: Move to accept the recommendations.

Weldon Havins: Seconded.



Voted: Ayes across the board.

Motion carries.

Respiratory: Long Acting Beta Adrenergics

Public Comment: No Public Comment.

Carl Jeffery: We thought that there was going to be a new product that would have made it into the clinical review. It didn't make it into the clinical review, so there's actually no recommended changes. It will come back in March because there is a new product on the market, estraveridine, it's a new long acting betantaganist.

No changes. No motion needed.

Anti-viral Hepatitis C Ribavirins

Public Comment: No public comment.

Carl Jeffery: We've got a couple of new Rebetron and the Rebetol that are relatively new on the market. I'm sure you guys have all heard of some of the new Hep-C agents on the market, which are kind of making the Ribavirins go the way of the dinosaur, so I don't think that these are going to be hot topic very much longer. The biggest difference between the different brands on there is, not so much the indication, because they all have pretty much the same indication, but is the doses available. You've got anywhere from a 200 capsule to a tablet, all the way to a little preset dosing tab. These are convenient, but that's pretty much all they are

providing is a convenience. Since they're all ribavirins, Catamaran believes these are clinically and therapeutically equivalent.

Chairperson Nagy: No comments?

Need a motion to forward.

Committee member: Move to accept the recommendations.

2nd Committee member: Seconded.

Voted: Ayes across the board.

Motion carries.

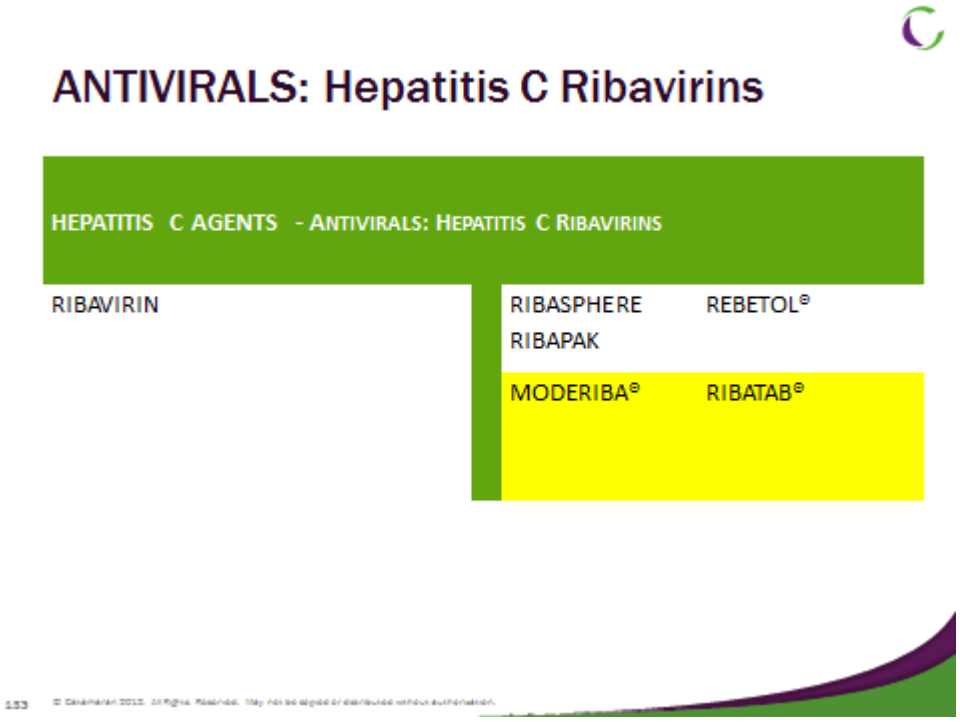
Carl Jeffery: Catamaran's recommendation is to make the two new Moderiba and the Riba-Tab as non-preferred and keep the rest of the class the same.

Chairperson Nagy: No comments?

Need a motion to forward.

Committee member: Move to accept the recommendations.

2nd Committee member: Seconded.



Voted: Ayes across the board.

Motion carries.

Annual Review – Drug Classes without Proposed Changes

Public Comment: Kurt Claim from United Therapeutics. I'm a MSL. We have a new drug out in the pulmonary arterial hypertension space. The oral version of our prostacyclin. It's a treprostinil. Its name is Orenitram. You guys don't have any information on it. I assume you'll look at it in March and I'll be back to talk about it then. Thank you.

Chairperson Nagy: Thank you.

Public Comment: I'm an MSL with Sellex Pharmaceuticals. We'd like to share 3 different medications with you. The first one would be Uceris. It is an extended release tablet containing budesonide. It's a synthetic corticoid steroid. It is indicated for reduction in patients with active mild to moderate ulcerative colitis. The recommended dose is one 9mg tablet taken once a day with or without food, for up to 8 weeks. Uceris is a novel formulation of the budesonide that uses multimatrix system, or MMX technology to target the release of the budesonide throughout the entire colon. The safety of that and efficacy of Uceris tablets were established in two 8-week similarly designed, double blind, placebo controlled trials involving 970 adult patients with active mild to moderate ulcerative colitis. The primary end point was remission at 8 weeks defined as combined clinical and endoscopic remission with an ulcerative colitis disease activity index, or UCDI, score one or less, with sub scores of 0 for rectal bleeding, stool frequency and mucosal appearance and with equal to 1 or more point reduction in endoscopy only score. The baseline median UCDI score in patients was 7, which was considered to be moderate. Uceris achieved both clinical and statistical significance versus placebo in this particular trial. The safety was evaluated in over 1,000 patients. Adverse events occurred in more than 5% of budesonide treated patients included headache, pyrexia, insomnia, back pain, nausea, abdominal pain, diarrhea, and ulcerative colitis. That was no different than placebo. An important point to look it, of course, is the glucocorticoid safety with HAS axis suppression that was found not to be different than placebo, with 10.2% of the patients on Uceris 9mg reporting corticoid steroid related effects versus placebo of 10.5. In summary Uceris' formulation of budesonide, which is designed to release the drug throughout the entire colon, Uceris trials have demonstrated safety and efficacy and remission in patients with active mild to moderate ulcerative colitis. We'd also like to bring to your attention the availability of a new product that was recently approved. It's called Uceris foam. This particular product is approved for ulcerative proctosimotitis and ulcerative proctitis. Unfortunate I don't have any data to share with you at this time but would ask you to consider this product for future review. The third product that we would like to share with you is called Cycloset. It is bromocriptine quick release tablets. It's indicated as an adjunct treatment with diet and exercise to help glycemic control adult patients with type-2 diabetes. There are three important limitations to Cycloset. Cycloset should not be used to treat Type-1 diabetes or diabetic ketoacidosis. There is limited efficacy data with regards to Cycloset with TCDs. An efficacy of Cycloset has not been confirmed in combination with insulin. Cycloset contains bromocriptine solute an (inaudible) derivative, which acts as a dopamine receptor agent while the Cycloset improves glycemic control, we don't know exactly what that mechanism is. Morning administration of Cycloset improves 24-hour

glycemic control in type-2 diabetes patients without increasing plasma insulin. Over 3,700 patients with type-2 diabetes were randomized across 4 double blind studies. In those clinical trials, those patients assigned to Cycloset treatment received an initial dose of 0.8mg which was increased by 0.8mg weekly for 6 weeks. The maximum dose in those particular trials was 4.8mg a day. In patients with type-2 diabetes treatment with Cycloset produced clinically significant improvements in hemoglobin A1C and postprandial glucose. The decrease in A1C with Cycloset group was 0.5 as compared to placebo in the intent to treat population 0.8 in the protocol population. The product was found to be safe and there was also a large clinical trial conducted to find out whether or not there was a cardiovascular safety with this product. In fact, looking at a composite endpoint, cardiovascular endpoint, side effects were 1.5% with Cycloset and 3% with placebo with hazard ratio of 0.58, which is different than most other medications in this class. Across all 4 trials, the most common adverse effects reported by 5% or more of subjects were nausea, fatigue, vomiting, headache, and dizziness. I please ask you to review this product for inclusion.

Coleen: As a reminder, when they are on the end of this list, it's a new product, we will review it. It will probably just be at the next quarter and then it will be reviewed during that drug class, so you might want to save your public comment for when that drug class is being reviewed because we're going to tell you next quarter you've already presented your public comment because these guys have a phenomenal memory and they are going to say that only new information can be presented. If we're in this drug class and you have a new drug that has just been released like coming out in December, or today November, we will review it, I promise. It will just be at the next quarterly meeting. It's not off the charts and it will not take us another year to review it. Any other public comment within this block? If it's a new drug coming out in the next month, we just haven’t' see the data yet that's all.

Committee discussion

Mark Decerbo: On the pancreatic enzymes, there was a PA in place for Viocase, being the only coated enzyme, knowing it is preferred for some patients, just wondering if you’re on a PPI or H2, Viocase would be preferred.

Carl Jeffery: We can certainly take that. I'm not sure if that would be a DUR kind of edit. It would almost be preferred if it's based on a PPI or not. I think we can bring that up in March and discuss that class.

Committee member: So we'll bring that class back up in March.

Carl Jeffery: We can also take that to the DUR Committee and see if that's a requirement and maybe get that put in place.

Public Comment: My name is Barbra Glover. I'm the Nurse Coordinator for the Cystic fibrosis Center of Southern Nevada. I just came to talk about the pancreatic enzymes. Selecting one enzyme as a preferred product disregards that there are clinical responses in CF patient’s pancreatic enzymes therapies. It ignores the lack of published comparative clinical trial data supporting substitution and jeopardizes patient health by requiring individuals to fail on one therapy prior to using another. Nutritional failure of any type for CF patients is

unacceptable as it places them at risk for long-term health consequences. 85-90% of CF patients have pancreatic insufficiency requiring them to take pancreatic enzyme replacement therapy with every meal and snack for the duration of their lives to prevent abdominal distress and malabsorbtion of calories and nutrients. Nutritional status is closely linked to failure of pancreatic enzymes therapy can have significant short term consequences as well as implications for patient survival. The dissolution properties for the pancreatic enzymes are not identical. Individual patients can have a variable response that cannot be predicted. Because pancreatic amylase is destroyed in an acidic environment, all products have a pH dependent polymer coating which is intended to release the product in the more pH neutral environment of the intestine. The coating for each of the FDA approved is different. The degrees of acidification of the GI tract in each CF patient varies, which may be why some patients have better clinical response to one product over another. In addition, the coating process differs among products. Some are micro tablets, some are microspheres, but the size of these micro capsules also varies. The size determines when gastric emptying occurs and how well it is dispersed throughout the meal. Demanding failure on one medication before prescribing another places CF patients at risk for nutritional failure and potential hospitalization. For people with this chronic and progressive disease, step therapy poses an unjustifiable risk. So in a nutshell, optimal nutrition means better PFTs which increases survival. Currently there are 2 enzymes on the Preferred Drug List. There are 5 on the non-preferred. We respectfully request that all the enzymes are on the Preferred Drug List.

Chairperson Nagy: Thank you.

Weldon Havins: The motion is to adopt the 77 classes as is without changes.

Joseph Adashek: Seconded.

Voted: Ayes across the board.

Motion carries.

Carl Jeffery: Just a quick outlook on what's coming down to the market place. We wanted to put all of the binders into an electronic version rather than printing them out. I don't know how people feel about that. It just means that I would email you the binder. Chances are it would contain more information because we're not filling up a whole binder. It's easy to navigate. I'll put it in a pdf. Everything is in one document. I don't know how people feel about that. If there is anybody that is so opposed to it, they like to have the paper document in front of them, I can always run to Kinkos and make a copy of it really quick.

Committee discussion: (Inaudible)

Carl Jeffery: Depending upon the size, sometimes, this electronic version was about 4 MB. That didn't include all of the other information I want to put in the full review. There's also, if you look on the internet, just a quick, brief overview. It's about 4 pages long, there's a full review that includes all of the study information. That's where I get a lot of my information for these. So if you download those, but the electronic binders will also have that

information, or at least links to that information. I think that will be small enough to email, but I know a lot of the systems have limits on how big of a file they can accept.

Coleen Lawrence: I know some other states are doing that and I think we will post all of the information on the website. We'll put it on the portal. That way you can follow along in the meeting and we'll figure out how to do that. I know some states are already doing that.

Chairperson Nagy: How soon will the public get the information?

Carl Jeffery: They will get it about the same time that you do. I want to cover these real quick. We talked about the Embeda. I think it's coming back, if it's not on the market. If you haven't heard of Harvoni. You're going to hear a lot about it. It's the new combination of the Sovaldi with a new agent on here. We'll talk about that in March. It's a big topic. The Xigduo, which we kind of briefly mentioned is a combination of metformin. Again Purdue has a new abuse deterrent hydrocodone product that doesn't have a trade name yet, but it should be coming out. Pending patent expiration dates that will affect us is the Nexium, the Actonel, Invega, which I think is going to be pretty good, and the Asacol.

Public Comment: None.

Date and Location of next meeting

March 26th 2015 is the next meeting.

Public Comment? None.

Adjournment

Meeting adjourned 3:14PM