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Nevada Medicaid
Pharmacy and Therapeutics
Draft Meeting Minutes

The Division of Health Care Financing and Policy (DHCFP) Pharmacy and Therapeutics Committee held a public meeting on **September 24, 2015**, beginning at **1:00 p.m.** at the following location:

JW Marriott – Las Vegas
Marbella Room
221 N Rampart Blvd
Las Vegas, NV 89145
702-869-7777

Board Members Present:
Mark Decerbo, Pharm.D.; Shamim Nagy, MD; Weldon Havins, MD; Joseph Adashek, MD; Adam Zold, Pharm.D. Evelyn Chu, Pharm.D.

Board Members Absent:
David Fluitt, RPh; Bill Evans, MD; Mike Hautekeet, RPh

Others Present:
DHCFP:
Coleen Lawrence, Chief, Program Services; Mary Griffith, RN, Pharmacy Services Specialist; Shannon Richards, Deputy Attorney General;

HPES:
Beth Slamowitz, Pharm.D.

OptumRx:
Carl Jeffery, Pharm.D., Kevin Whittington, RPh, Robert Earnest, Pharm.D, JD

Others:
Cynthia Patterson, BioDelivery; Jennifer Lauper, BMS; Lee Stout, Chiesi; Nick Casale, Indivior; Mark Edwards, Mylan; Elizabeth Ariano, Indivior; Melissa Walsh, Novartis; Rupa Shah, Purdue; Sergio

Gonzalez, Takeda; Amy Everitt, Sunovion; Robert Jaramillo, Sunovion; Phil Walsh, Sunovian; Jon Bloomfiled, Jazz; James McAdams, Orexo; Mike Strong, Novo Noardisk; Bret Ferguson, Pfizer; Rob Bigham, Shire; Frank Ragone, Genzyme; Mark Schwartz, GSK; Lauren Nelson, Genzyme; Tyson Park; Teva; Deron Grothe, Teva; Kara Sperandeo, Astra Zenaca; Efrain Alton, Merck; Tom O'Connor, Novartis; Markus Laughlin, BI; Lovell Robinson, Abbvie; M. Kelly Bafield, NNI; Julie McDavitt, BI; Samantha Muir, Otsuka; Krystal Joy, Otsuka; Sarica Cohen, Mylan; Todd Schuidec, BIPI; Don Nopper, United Therapeutics; Kirk Lane, United Therapeutics; Corinne Copeland, Eisai; Soheyla Azizi, Eisai; Charissa Anne, J&J; Marykay Queener, J&J; James Kutasky, Gilead; Roy Palmer, Pfizer; David Post, Actelion; Sal Lofaso, Horizon; Gina Sota, Alkermes; Yumi Yamamoto, Alkermes; Ben Skoog, Biogen; Dana Conell, NNF; Sandy Sierawsky, Pfizer; Theresa Benkert, Eisai; Shane Hall, Purdue; Susan Lawrence, Amgen; James Tate, IHC; Chi Kohlhoff, Kadman; Kim Jacoby, Lundbeck

I. CALL TO ORDER AND ROLL CALL

Meeting called to order at 1:04 PM

Coleen Lawrence – DHCFP
Mary Griffith – DHCFP
Beth Slamowitz – HPES
Mark Decerbo
Adam Zold
Evelyn Chu
Joseph Adashek
Weldon Havins
Shamim Nagy, Chairperson
Shannon Richards – DAG
Kevin Whittington – OptumRx
Carl Jeffery – OptumRx

II. PUBLIC COMMENT

Shamim Nagy, Chairperson: Public comment?

None.

III. **FOR POSSIBLE ACTION**: Review and Approval of the March 26, 2015 Meeting Minutes

Shamim Nagy, Chairperson: We need a motion to approve the minutes from the last meeting.
Joseph Adashek: I move to approve.
Weldon Havins: Second.
Voting: Aye's across the board – motion carries.

IV. STATUS UPDATE BY DHCFP

Coleen Lawrence: We have a couple updates from our last legislative session. With SB459, Naloxone is going to continuously be a preferred agent, it moved automatically October 1, 2015. It did not require any action by the Committee members due to statutory requirements. Also, we have a new interim administrator, Ms. Marta Jensen. She was previously with the Division as Compliance Chief. Effective October 1, 2015, ICD-10 is here. We count on field reps to assist us. The pharmacies will be impacted with lots of coding that allow claims to bypass PA when the correct ICD code is submitted. With Nevada Medicaid and Nevada Checkup, we will not be running parallel systems, we will not be accepting ICD-9 and ICD-10. Please work with your field reps to help educate prescribers. Also coming November 1, 2015, we are moving to NADAC, an actual acquisition cost. With the NADAC, the dispensing fee will be increasing to one fee across the board to $10 and some change. CMS required the dispensing fee survey.

We have some ground rules to run an effective and efficient meeting. The NRS requires that Nevada Medicaid reviews the preferred drug list every year. There are some other states don't review their PDL on a regular basis. We don't wait until the year review to review the classes. A class may not be reviewed if there are not any changes in that class. We break this down to two sections, the drugs that we are going to review today, the Second. section is one motion that we say there are not any changes to these drug classes. We recommend to the Committee to approve classes in one motion. The first section is broken down further to new drugs to be reviewed, and then classes that are requested to be reviewed by Committee members or the community. Please keep your speaking to 5 minutes per entity. We are very transparent in our recommendations, they will be listed on the screen before public comment is opened. Testimony should be limited to new information only. The P&T Committee role is to decide preferred and non-preferred only, the clinical criteria is decided by the DUR board. Please do not discuss cost. This Committee is prohibited of listening or deliberating products related to cost.

Shamim Nagy, Chairperson: Any comments from the public?

None.

V. ANNUAL REVIEW - NEW DRUG CLASSES

A. ANTI-EMETIC – MISCELLANEOUS

Shamim Nagy, Chairperson: Public Comment?

None.

Carl Jeffery: There are two new products in this antiemetic, miscellaneous class. The more popular one is Diclegis. This is indicated for treatment of nausea in pregnancy. The other product is Emend, which does not fall into any other class. It is indicated for chemotherapy induced nausea. Optum recommends these two products be considered clinically and therapeutically equivalent.

Joseph Adashek: Move.
Weldon Havins: Second.
Vote: Ayes across the board.

Carl Jeffery: OptumRx recommends these two agents be considered preferred.

Joseph Adashek: Move.
Adam Zold: Second.
Votes: Ayes across the board.

B. PSYCHOSTIMULANTS - NARCOLEPSY AGENTS

Shamim Nagy, Chairperson: Public comment?

None.

Carl Jeffery: This is a new class, they are currently in the ADD/ADHD class. We don't feel this is quite appropriate. It makes sense to break them out to their own class. The DUR Board did just update the clinical criteria, including the Xyrem which is really only used for cataplexy and narcolepsy. The others have similar indications. The clinical guidelines recommend modafinil as first line, but the guidelines have not been updated since Nuvigil was released. Optum recommends these products be considered clinically and therapeutically equivalent.

Mark Decerbo: Thank you for breaking the class out, we have seen some products being shoehorned into classes that may not fit.

Adam Zold: I move these be considered clinically and therapeutically equivalent.
Mark Decerbo: Second.
Votes: Ayes across the board.

Carl Jeffery: Optum recommends brand Provigil preferred, the others non-preferred

Adam Zold: Motion.
Chu: Second.
Votes: Ayes across the board, the motion carries.

C. LONG-ACTING ABUSE DETERRENT OPIOIDS

Carl Jeffery: A quick overview of the class before the public comment for the long-acting abuse deterrent opioids. We brought this up at the request of the Committee at the last meeting. This is an option of the Committee to add this as a new class. We can consider pulling out these products into their own class, it is fully up to the Committee.

Weldon Havins: By the way, the bill that was proposed did not pass, the legislature did not pass it. I don't know if that will make a difference if you feel this should be a separate category.

Shamim Nagy, Chairperson: Public Comment?

Rupa Shaw, clinical pharmacist and clinical liaison with Purdue: Provided an overview of abuse deterrent opioids. The FDA is in support of the development of opioids with abuse deterrent properties. The FDA released guidance with suggested studies, how they will be evaluated and what labeling claims will be included. Section 9.2 is where the data will be listed. In Section 9.2 in the PI, each product lists how it will deter abuse. Some opiate products may have some abuse deterrent properties, but not all have been recognized by the FDA. Three products are available on the market now. OxyContin and Hysingla have been approved for labeling with abuse deterrent properties. Purdue is pursuing epidemiological studies. Please consider products recognized by the FDA.

Roy Palma, Pfizer: The previous speaker did a great job covering the FDA's stance. Studies are robust to get the labeling claims. Embeda has done abuse studies for the FDA labeling. We encourage making this a separate class. These products will have a significant impact in the treatment of pain management.

Carl Jeffery: There are three letters handed out from physicians in the area talking about abuse deterrent opioids. The FDA has changed how they evaluate the abuse deterrent opioids. There are just Embeda, OxyContin and Hysingla that have the FDA abuse deterrent labeling. There are some others in the works, they claim they have abuse deterrent properties, but have not been given the ok from the FDA. Most have a physical barrier, the Embeda is little different in that it is combined with naloxone. We have some options, we can combine with the current class of opioids, or make it its own class or not do anything. Within this class, we consider these clinically and therapeutically equivalent.

Mark Decerbo: This makes sense to separate these out. I have no problem separating out the abuse deterrent agents. My concern is what are our criteria in how we determine what agents are in this class, with two of the agents working toward the labeling, but not having it yet. I don't want to box us in going forward. The oxymorphone and hydromorphone not having the label yet, is there a reason we should include or exclude these two from the new class?

Adam Zold: I agree it should be a separate class and it should be limited to products approved by the FDA.

Evelyn Chu: I agree as well, but they all have abuse potential. Do we wait until the FDA approves all of them? Do we know when they will approve these?

Carl Jeffery: We don't know the exact timeline of when these will be approved. For example, Zohydro told me they have the properties, but they don't have the label ok from the FDA. We struggle with this class just for this reason as Dr. Zold said, should we limit to FDA approved products?

Coleen Lawrence: When we are looking at therapeutic alternative, we are not looking at if they are FDA approved, based on our definition of FDA approved indication to be in the therapeutic class.

Evelyn Chu: So what does this mean for a patient population, when they come in with prescriptions?

Carl Jeffery: All of these are nonpreferred right now, so they will have to try one of our two preferred agents, long-acting morphine or fentanyl patches before getting one of the abuse deterrent agents. Adding this class as we have proposed, they would have access to Embeda first line without having to step through fentanyl or morphine first.

Evelyn Chu: Then I agree it should be its own class.

Shamim Nagy, Chairperson: Then it sounds like it should be its own class. We are in agreement.

Coleen Lawrence: So then we will put them in their own bucket.

Weldon Havins: Could some of these be in two different classes? In both long-acting opioids and abuse deterrent?

Carl Jeffery: They could be if between meetings until they can be reviewed.

Mark Decerbo: I hate having to rely on the FDA as the final arbiter, but if there is another product that was sub-par that did not receive the FDA label, but they stated it because was abuse deterrent, I would hate to be bound to include that product in this class. I think there is some value in the FDA labeling. It is hard to see doing this without the FDA labeling.

Carl Jeffery: So I hear that we would just list the FDA label products, Embeda, OxyContin and Hysingla would be considered clinically and therapeutically equivalent.

Mark Decerbo: Yes, I would support that.

Carl Jeffery: Then to complete the thought, Exalgo and Opana would go back to the regular long-acting opioid class.

Mark Decerbo: Unless we can think of another mechanism or until they receive FDA labeling.

Coleen Lawrence: So you would utilize the FDA label indication?

Mark Decerbo: Yes,

Carl Jeffery: So the motion would be consider Embed, Hysingla and OxyContin clinically and therapeutically equivalent.

Mark Decerbo: Correct.

Adam Zold: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: Embeda would be preferred and OxyContin and Hysingla non-preferred.

Coleen Lawrence: Dr. Jeffery, sorry, you cannot make the motion, it must come from a Committee member.

Mark Decerbo: I move that we strike the oxymorphone and hydromorphone products from the right side as non-preferred.

Adam Zold: Second.

Voting: Aye's across the board – motion carries.

Coleen Lawrence: So we need a therapeutic equivalent motion, and that is based on the Committee that the long acting opioids is based on FDA indication.

Mark Decerbo: I move that the Embeda, Hysingla and OxyContin be considered clinically and therapeutically equivalent.

Evelyn Chu: Second.

Voting: Aye's across the board – motion carries.

D. ANTILIPEMICS – OMEGA-3 FATTY ACIDS

Shamim Nagy, Chairperson: Next class, antilipedemic. Public comment?
None.

Carl Jeffery: We have a new class we are proposing, the omega 3 fatty acids. They have been around for a long time. They lower the triglycerides. There are two brand products and one generic. Optum considers these clinically and therapeutically equivalent.

Weldon Havins: do we need a motion to make this new category?

Shamim Nagy, Chairperson: No, I need a motion for clinical and therapeutic equivalency.

Adam Zold: Motion.

Weldon Havins: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: Optum recommends Lovaza and Vascepa be considered preferred and the generic Omega-3 acid and Omtryg be considered non-preferred.

Shamim Nagy, Chairperson: Any comments?

Adam Zold: Motion to accept recommendation.

Mark Decerbo: Second.

Voting: Aye's across the board – motion carries.

E. RESPIRATORY LONG-ACTING BETA AGONISTS/LONG-ACTING ANTIMUSCARINIC COMBINATIONS

Shamim Nagy, Chairperson: Respiratory Long-acting antimuscarinics/long-acting beta agonists combination. Any public comment?

JM, Pharm.D. with BI: We make Stiolto, a combination of Spiriva and Striverdi. I promise not to go into the safety and efficacy of the drug, but I wanted to show the Committee the delivery device (hands out sample inhalers). The delivery system is Respimat, it is a hand-held pocket device that used mechanical energy, there is a spring in here, to deliver a slow moving aerosol cloud of medication. The effort needed is minimal, the medication is delivered independent of inspiratory capacity. There is a simple pneumonic, TOP, turn, open, press. Turn the base, open the lid, press the button. Are there any questions?

Shamim Nagy, Chairperson: Any question or comments?

None.

Carl Jeffery: This is a proposed new class, the long-acting antimuscarinic and long-acting beta agonist combinations. Anoro has been out for a little, and it was shoehorned into another class. Both are indicated for maintenance of COPD. Stiolta was approved on these studies, about 5,000 patients, showing good results. We have an alternative of having people use two agents that would accomplish the same result, and the screen shows the other products available. Optum recommends these be considered clinically and therapeutically equivalent.

Weldon Havins: Moved these be considered clinically and therapeutically equivalent.

Adam Zold: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: With this being a new class, Optum recommends both products be considered preferred.

Weldon Havins: Moves to accept recommendation.

Adam Zold: Second.

Voting: Aye's across the board – motion carries.

VI. ANNUAL REVIEW - ESTABLISHED DRUG CLASSES

A. NEUROPATHIC PAIN AGENTS

Shamim Nagy, Chairperson: Neuropathic agents, any public comment?

None.

Carl Jeffery: We currently have two classes with some overlap, the Neuropathic agents and the Fibromyalgia agents. The only one that sticks out a little is Savella, it is only indicated for fibromyalgia whereas the others go back and forth. We want to combine these two classes. The reason this is coming up is the generic Cymbalta has been out for some time and the other agents have been out for a long time. Optum recommends these be considered clinically and therapeutically equivalent with the footnote that Savella is for fibromyalgia only.

Shamim Nagy, Chairperson: Comments?

None, we need a motion.

Adam Zold: Moves these products be considered clinically and therapeutically equivalent.

Evelyn Chu: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: By combining these, we keep everything as before except switch the brand Cymbalta to non-preferred and duloxetine to preferred.

Mark Decerbo: This is somewhat off the topic, but is it up to the DUR Board to update the ICD-9 codes?

Coleen Lawrence: The state is working on this to get it taken care of.

Evelyn Chu: Motion to accept the recommendation.

Adam Zold: Second.

Voting: Aye's across the board – motion carries.

B. FIBROMYALGIA AGENTS

C. OPIATE AGONISTS

Shamim Nagy, Chairperson: Next topic is Long-acting opioid agonists. Public comment?

None.

Carl Jeffery: This class was included because we were altering the abuse deterrent opioids. To these slides we will add Opana ER and Exalgo to the list. Optum recommends these be considered clinically and therapeutically equivalent with the addition of Opana ER and Exalgo.

Mark Decerbo: Move that these be considered clinically and therapeutically equivalent with the addition of the Opana and Exalgo.

Adam Zold: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: This slide will need some updating with the addition of Opana ER and Exalgo to non-preferred, keeping morphine sulfate extended release and fentanyl patch as preferred.

Weldon Havins: Move to accept the recommendation.

Joseph Adashek: Second.

Voting: Aye's across the board – motion carries..

Coleen Lawrence: We should have asked before, but are there any practicing providers that would like to speak so they can get back to their practice?

JT: Dr. James Tate, I practice here in town. This is the issue that all prescribers face. Most of these will not fill, the reason is, and insurance companies won't pay for it, including Medicaid. I don't know if you want people to become addicted, because these are abuse deterrent. In two years, we are going to have to pay for it, because drug companies and big pharma is moving away from immediate release. Because of the blood brain barrier. If you take an IR opioid, it crosses the blood brain barrier. If you have one that doesn't cross the blood brain barrier or does so slowly, it loses its street value. Remember when it was called "Hillbilly Heroin"? It's not called that anymore because it is an abuse deterrent medication. Because you can't chop it up, snort it or inject it, so it loses its street value. But nobody wants to pay for it. But a month's supply is $500. What is your rationale for not paying for it, do you want people to become addicted. You need to think about why we are doing it, or why are we not. All I want to do is prescribe medications for my patients without putting them in jeopardy. So I ask you to consider what medications you put on the list. Frankly, it is not my job as a practicing physician to figure out who is doing what. So fix it, thank you.

D. MULTIPLE SCLEROSIS AGENTS - INJECTABLE

Ben Stoag, Pharm.D. with Biogen. I want to talk about Plegridy. Biogen has four drugs for MS, I'm not sure where Tecfidera is since it will be reviewed next, so I can present both now. Avonex, is an IM once weekly injection, Pegridy is a SQ every 14 day injection, Tysabri is Q 4 week IV infusion and Tecfidera is an oral medication. MS is a disease where the body's own immune system is attacking itself. The disease depends on the number of plagues. Most patients will need some assistance in walking within 10 to 20 years. The goal is to slow the progression of the disease. There are three main points in clinical trials. Annualized relapse rate, reduction of disability and reduction of MRI lesions. Plegridy, approved at the end of 2014, SQ pegylated interferon. Developed to reduce the

number of injections, this is 26 injections per year, vs. others with much more. Plegridy shows 36% reduction in annualized relapse rate. It has a 30% reduction and 12 week affirmed disability at one year. And then it is significant for MRI endpoints. The safety profile is similar to other interferon's. Plegridy offers once every 14 day injection, side effects are similar and it has demonstrated efficacy. For Tecfidera, 155,000 patients have been on Tecfidera. Tecfidera has been shown safe and effective as outlined (Study information outlined with safety information).

Shamim Nagy, Chairperson: Thank you. No more comments.

Carl Jeffery: A couple new drugs added. The biosimilars are coming out, Glatopa is the generic version of Copaxone. We heard about Plegridy. We have the class broken down to relapsing remitting multiple sclerosis. Lemtrada has a two phase study. This one has been trying to come out for several years. It has a unique delivery system, given once per year. It sounds convenient and the efficacy is good, but the adverse effects are alittle scary. The injection site reaction is almost everyone. And then two deaths reported during the study. I'm not sure this one should be first-line. We heard about Plegridy, good efficacy and safety profile and dosed conveniently. For the class, we would like to consider these clinically and therapeutically equivalent.

Evelyn Chu: Motion the class be considered clinically and therapeutically equivalent.

Weldon Havins: Second.

Vote: Ayes across the board, motion carries.

Carl Jeffery: Optum recommends we keep the preferred side the same with Avonex, Betaseron, Copaxone, Extavia, Rebif and Tysabri be preferred, leaving Glatopa, Lemtrada and Plegridy as non-preferred.

Mark Decerbo: I move we accept the preferred and non-preferred agents as presented.

Joseph Adashek: Second.

Votes: Ayes across the board, motion carries.

E. MULTIPLE SCLEROSIS AGENTS - ORAL

Shamim Nagy, Chairperson: Oral Agents for MS, any public comment?

None.

Carl Jeffery: This is another carry over from the injectable agents. The fingolimod has some recent cases of cardiac related death. Teriflunomide has two black box warnings regarding hepatotoxicity and the risk of teratogenicity. Dimethyl fumarate, limited post-marketing data shows it likely has the mildest side effects. Optum recommends these three products be considered clinically and therapeutically equivalent.

Mark Decerbo: I move these three agents be considered clinically and therapeutically equivalent.

Adam Zold: Second.

Votes: Ayes. Motion carries.

Carl Jeffery: Optum recommends moving Gilenya to non-preferred and keeping Aubagio and Tecfidera preferred.

Mark Decerbo: What was behind the moving of Gilenya to non-preferred, and what are the ramifications for patients currently stabilized on this medication?

Carl Jeffery: We have the option to grandfather recipients already on this medication when removing agents. The utilization was relatively low. We can grandfather those recipients that are currently on it. The reason behind it is for the interest of the State.

Mark Decerbo: I would support the move as long as people can be grandfathered in, especially with Gilenya that can cause some symptoms with the flares and other issues with withdrawal. I move to accept as presented with the caveat the people currently on Gilenya be grandfathered.

Weldon Havins: Second.

Votes: Ayes . Motion carries.

F. VASODILATORS – ORAL

Shamim Nagy, Chairperson: Vasodilators – Oral. Public comment?

David Post, PharmD. with Activia Pharmaceuticals. I would like to talk about the Opsumit. PAH is a rapidly progressing cardio-pulminary disease that ultimately leads to death. Opsumit is indicated for PAH to delay disease progression, demonstrating a 45% risk reduction vs. placebo. Opsumit reduces risk of hospitalization. The effects of Opsumit was demonstrated in a study (outlines details of study). In summary, the FDA approval is based on the largest placebo controlled trial, it reduces hospitalizations and improves outcomes. For this reason I would like you to consider adding Opsumit to the preferred drug list.

Kirk Lane, MSL United Therapeutics. Provided an overview of PAH disease and an overview of available therapies. Combinations from different classes are often used today. Adcirca, once a day approved for group one for PAH. Adcirca, like other oral PAH agents, may be considered first-line therapy, or as an add-on therapy with other therapies. Adcirca clinical study and adverse events presented. In summary, Adcirca provides once day therapy of PDE-5 for PAH. I ask you consider adding Adcirca to the PDL.

Carl Jeffery: There are basically four different medications in this class. We break out the inhaled forms, and they are not included in this review. Adcirca, which is the same molecule as Cialis, and we want to make sure we have one, and the sildenafil covers. The guidelines talk about recommendations, start with a PDE-5 or endothelin inhibitor and then work your way down. Optum recommends the oral agents in this class be considered clinically and therapeutically equivalent.

Adam Zold: I move these be considered clinically and therapeutically equivalent.

Weldon Havins: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: Optum recommends to move Adcirca to non-preferred to move people to sildenafil, and then add Orenitram to add another option.

Evelyn Chu: I move to accept the list as presented.

Joseph Adashek: Second.

Voting: Aye's across the board – motion carries.

G. PHOSPHATE BINDING AGENTS

Shamim Nagy, Chairperson: Phosphate binding agents, public comment?

None.

Carl Jeffery: There is a new agent in this class, Auryxia. It is a little different because it is ferric Citrate. They all have similar indications to reduce phosphate in renal disease. Ferric citrate has been shown safe and effective in two clinical trials, placebo controlled. What I thought was interesting, because it is a ferric compound, it didn't decrease the iron levels in the body as much and required less erythropoietin. I'm not sure if this is significant. All the other ones are the same. Optum recommends these be considered clinically and therapeutically equivalent.

Adam Zold: I motion they are clinically and therapeutically equivalent.

Evelyn Chu: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: Optum recommends the new agent Auryxia be considered non-preferred and the rest of the class remain the same.

Adam Zold: I move we accept the recommendation.

Evelyn Chu: Second.

Voting: Aye's across the board – motion carries.

H. INCRETIN MIMETICS

Shamim Nagy, Chairperson: diabetic agents, public comment?

None.

Carl Jeffery: We brought this up because we thought there were going to be some changes, but that didn't pan out. We also need to get these new agents to the DUR board. These medications have been reviewed before, but we are not recommending any changes at this time. Optum recommends these be considered clinically and therapeutically equivalent.

Evelyn Chu: I move these be considered clinically and therapeutically equivalent.

Adam Zold: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: Optum recommends keeping everything the same, Bydureon, Byetta and Victoza as preferred and Tanzeum and Trulicity as non-preferred.

Joseph Adashek: move to accept recommendations

Adam Zold: Second.

Voting: Aye's across the board – motion carries.

I. SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS

Joseph Adashek: In the future, could you list the generic name underneath these. In the studies they publish the generic names, that would be great.

Carl Jeffery: Sure, no problem.

Shamim Nagy, Chairperson: SGLT-2 class. Public comment?

CD with BI, We make Jardiance, Glyxambi and Synjardy. Jardiance is an SGLT-2 that you have heard about before. Synjardy is a combination with Jardiance and metformin. The one I want to talk about today is Glyxambi. It is a first-in-class medication that inhibits both the SGLT-2 with the combination of a DPP-4, which is linagliptin or Tradjenta. It is not recommended for type 1 diabetes or those with ketoacidosis. [Study information presented]. I ask the Committee to consider adding Glyxambi as preferred. And since we are the makers of Jardiance and the Synjardy, the SGLT2 class has been in the press a lot lately, I am here for any other questions.

Carl Jeffery: We just heard about some of these new combination products. I won't go over them again. This slide shows the breakdown of what each agent is. Optum recommends these be considered clinically and therapeutically equivalent.

Adam Zold: I move these are clinically and therapeutically equivalent.

Evelyn Chu: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: Optum's recommendation is to move Invokamet to preferred and Xigduo XR to preferred and the two new products Glyxambi and Synjardy non-preferred.

Evelyn Chu: I make a motion that we accept the recommendation.

Weldon Havins: Second.

Voting: Aye's across the board – motion carries.

J. ANTI-MIGRAINE AGENTS - SEROTONIN-RECEPTOR AGONISTS

Shamim Nagy, Chairperson: Antimigraine agents, public comment?

Carl Jeffery: What brought this up is that we have a new drug, Zecuity transdermal. A novel treatment option and delivery mechanism. It moves the sumatriptan transdermally. It has been shown to decrease the symptoms, it doesn't seem to have anything better than the other agents. It sounds like a fancy new toy, but the other products on the list we have all covered before. Optum recommends these be considered clinically and therapeutically equivalent.

Shamim Nagy, Chairperson: Is the pump included in the package?

Carl Jeffery: It's not a pump, it has a battery that...

Rob Earnest: It is on the molecular charge to move the medication. It is only available through specialty pharmacy. It really it is being used for patients who experience nausea and difficulty taking the tablet formulation. It is not being considered first-line therapy.

Mark Decerbo: I move the listed agents be considered clinically and therapeutically equivalent.

Weldon Havins: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: Optum recommends moving the Zomig ZMT non-preferred and Rizatriptan ODT generic preferred and the new Zecuity non-preferred.

Adam Zold: I move we accept the class as presented.

Evelyn Chu: Second.

Voting: Aye's across the board – motion carries.

K. ADHD AGENTS

Shamim Nagy, Chairperson: ADHD agents, public comment?

None.

Carl Jeffery: No new agents in this class, we are just shuffling things around. Displayed is a breakdown of the agents in the class. Xyrem is on this list, but we included that I the narcolepsy agents. Optum recommends these to be considered clinically and therapeutically equivalent.

Adam Zold: I move these be considered clinically and therapeutically equivalent.

Weldon Havins: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: A couple products to shuffle around. A few meetings ago, Adderall XR was moved to non-preferred., we want to move that back so the brand Adderall XR is preferred and the generic amphetamine XR be non-preferred. The Procentra is the brand-name for the dextroamphetamine solution, we want to make the brand preferred and the generic non-preferred.

Adam Zold: I move we accept the recommendations.

Mark Decerbo: Second.

Voting: Aye's across the board – motion carries.

L. RESPIRATORY CORTICOSTEROIDS

Shamim Nagy, Chairperson: Respiratory Corticosteroids, public comment?

None.

Carl Jeffery: Last time we had this class, Aerospan HFA had just been reintroduced and now the Pulmicort Respules have a generic. This slide shows a quick breakdown of the class, they all have the same indication. Optum recommends these be considered clinically and therapeutically equivalent.

Adam Zold: I move these be considered clinically and therapeutically equivalent.

Evelyn Chu: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: Optum proposed the Aerospan HFA be considered preferred and the brand Pulmicort Respules be non-preferred, this still leaves the generic version budesonide nebs as preferred.

Adam Zold: Move to accept the recommendations.

Evelyn Chu: Second.

Voting: Aye's across the board – motion carries.

M. SUBSTANCE ABUSE AGENTS - MIXED OPIATE AGONISTS/ANTAGONISTS

Shamim Nagy, Chairperson: Substance abuse agents – mixed opiate agonists/antagonists. Public comment?

None.

Carl Jeffery: Another class we just discussed not too long ago. I think it was a tough decision from last time. Optum recommends these be considered clinically and therapeutically equivalent.

Adam Zold: I move these be considered clinically and therapeutically equivalent.

Evelyn Chu: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: Optum recommends adding Zubsolv to the preferred list.

Evelyn Chu: Motion to accept the proposed preferred list.

Weldon Havins: Second.

Voting: Aye's across the board – motion carries.

VII. ANNUAL REVIEW - ESTABLISHED DRUG CLASSES BEING REVIEWED DUE TO THE RELEASE OF NEW DRUGS.

A. ANTICOAGULANTS - ORAL

Shamim Nagy, Chairperson: Anticoagulants – Oral. Public comment?

None.

Carl Jeffery: Savaysa is a new product in this class. It is similar to the other agents in this class. It has fewer indications as the others. There are some decent studies, showing non-inferior to warfarin, no difference an annualized bleeding. Outcomes were similar to warfarin. Something a little unique, it actually has a black-box warning if your creatnine clearance is too high. It shouldn't be used if you

are over 95. Just a little unique. It increases risk of ischemic stroke. Optum recommends these be considered clinically and therapeutically equivalent.

Evelyn Chu: I make a motion that these agents be considered clinically and therapeutically equivalent.

Adam Zold: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: Since we have other products on the market already with additional indications, Optum recommends Savaysa be considered non-preferred.

Mark Decerbo: I move to accept the recommendation of the preferred list as presented.

Evelyn Chu: Second.

Voting: Aye's across the board – motion carries.

B. INSULINS (VIALS AND PENS)

Shamim Nagy, Chairperson: Insulins, public comment?

None.

Carl Jeffery: there are three new agents to this class. We haven't seen anything new here for a while. Afrezza is the new inhaled insulin and then a couple new strengths of existing insulins. This slide shows the break out of the fast acting vs. long acting. These are the same agents we have seen for years, just a little different strength. Afrezza to be shown to be non-inferior to insulin for A1c lowering, but it will be a pretty unique population it is intended for. It did not cause as much hypoglycemia and weight gain for Type 1. When they looked at it for Type 2 diabetics, it wasn't much better than placebo. For the purpose of the class review, Optum recommends these products be considered clinically and therapeutically equivalent.

Joseph Adashek: I move we accept the recommendations.

Adam Zold: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: Optum recommends the new agents, Afrezza, Humalog U200 and Toujeo Solo 300 be considered non-preferred and the remaining as preferred.

Adam Zold: I move we accept the recommendations as presented.

Evelyn Chu: Second.

Voting: Aye's across the board – motion carries.

C. ANXIOLYTICS, SEDATIVES, AND HYPNOTICS

Shamim Nagy, Chairperson: Anxiolytics, sedatives and hypnotics, public comment?

None.

Carl Jeffery: There are a few new agents in the class, Belsomra, eszopiclone, which is the generic for Lunesta and another new agent, Hetlioz. These were recently discussed by the DUR Board. Hetlioz is pretty specific to who it is intended to treat. It was studied in people completely blind, to keep their circadian rhythm. It is indicated for the non-24 hour sleep/wake cycle. The DUR Board put some criteria on this medication. Belsomra, it had good hopes for being a good drug, but it is working the same as some of the others that are already on the market. I'm not aware of any benefit of this one over the others. Optum makes the recommendation these be considered clinically and therapeutically equivalent.

Shamim Nagy, Chairperson: Do we have a motion?

Mark Decerbo: Move to accept the medications as shown as clinically and therapeutically equivalent.

Adam Zold: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: Optum recommends the new agents, Belsomra, eszopiclone and Hetlioz be considered as non-preferred and the rest of the class remain the same.

Evelyn Chu: I make the motion we accept the list as presented.

Joseph Adashek: Second.

Voting: Aye's across the board – motion carries.

D. BETA-BLOCKERS

Shamim Nagy, Chairperson: Beta blockers. Public comment?

Carl Jeffery: We have a new agent in this class, Sotylize, a liquid form of sotalol. When I first saw this I thought it would be for pediatric use, but looking at the package insert, it is not studied in kids, it hasn't been shown safe and effective in children. I'm not sure who the target is for this medication. I don't want to see this mis-used in the nursing homes for the ease of the nursing staff. It is the same as the sotalol that has been available for a long time. Optum recommends these be considered clinically and therapeutically equivalent.

Adam Zold: I move these agents be considered clinically and therapeutically equivalent.

Mark Decerbo: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: Without the indication for children, Optum recommends the Sotylize be considered non-preferred. The rest of the class remains the same.

Adam Zold: I move we accept the recommendation.

Joseph Adashek: Second.

Voting: Aye's across the board – motion carries.

E. TOPICAL ANTIFUNGALS (ONYCHOMYCOSIS)

Shamim Nagy, Chairperson: Topical Antifungal Agents, public comment? None.

Carl Jeffery: This is another class that was just discussed by the DUR Board. They updated the criteria to make it a step through for oral agents before moving to a topical agent. It has to do with the efficacy of the oral agents vs. the topical agents. We want to clarify the class name as well since we have topical agents and oral agents, but the class is to treat topical fungal infections. Onychomycosis is really what this class is intended for. We have the class broken out. I didn't include griseofulvin because it has some other indications, so it is not just for Onychomycosis. The studies show terbinafine and itraconazole as far superior to topical agents, and unless they have some contraindication, they should use these agents first. Some of the topical agents, removing the nail bed and using these topically, there is still a high recurrence rate. Jublia and Kerydin have a very low cure rates, about 17%. Optum recommends this class be considered clinically and therapeutically equivalent.

Adam Zold: I move we consider these clinically and therapeutically equivalent.

Weldon Havins: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: We haven't looked at this for a while, we have some new drugs, Jublia, Kerydin, Penlac and Itraconazole, which we realize can be used for other indications, would be considered non-preferred.

Adam Zold: When it says "PA required", does that include the entire class?

Carl Jeffery: Yes, the whole class requires PA. The DUR Board established that criteria.

Mark Decerbo: Move to accept the recommended preferred and non-preferred agents and include the aforementioned name change to the class to include topical fungal infection agents.

Adam Zold: Second.

Voting: Aye's across the board – motion carries.

F. ANTICONVULSANTS

Shamim Nagy, Chairperson: Anticonvulsants, public comment?

Roberta Hobneil, Sanovian – I want to share some updates for Aptiom. Covered indications. Only requires once daily dosing and requires only one week of titration. No blackbox warning as with some others. Over three months, reduced seizure frequency 30-40% compared to other classes. Even with many therapies available, there are still treatment challenges. Sunovian would like the Committee to provide access to Aptiom to provide more options to the community.

Carl Jeffery: We included this class because we thought there was going to be a new agent on the market, but it didn't come out in time to review it. We don't have any changes at this time. Optum recommends this class be considered clinically and therapeutically equivalent.

Adam Zold: I motion they clinically and therapeutically equivalent.

Evelyn Chu: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: There are not changes proposed so Optum recommends the class remain the same.

Joseph Adashek: I move we accept the recommendations.

Adam Zold: Second.

Voting: Aye's across the board – motion carries.

G. ANDROGENS

Shamim Nagy, Chairperson: Androgens, public comment?

None.

Carl Jeffery: Natesto is a new drug in this class, a nasal administration. Studies reviewed. It was effective, but given multiple times a day. Optum recommends this class be considered clinically and therapeutically equivalent.

Adam Zold: I move they be considered clinically and therapeutically equivalent.

Weldon Havins: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: Optum recommends Natesto be considered non preferred.

Adam Zold: I move we accept the recommendation.

Evelyn Chu: Second.

Voting: Aye's across the board – motion carries.

H. DISEASE-MODIFYING ANTIRHEUMATIC AGENTS

Shamim Nagy, Chairperson: Antirheumatic agents, public comment?

Mellissa Walsh, Novartis, MSL for Cosentyx: First, this is under "Disease-Modifying Antirheumatic agents", but we do only have one indication for moderate to severe plaque psoriasis. Covered indications and trials. We request it be added as preferred, but it only has the one indication.

Chris Connor, BMS, Orencia: Covered the indications for Orencia. Data not covered well in the class review. One and two year trials of head-to-head vs. adalimumab in RA who failed methotrexate. The efficacy measures showed no significant measures, but what was missing, the investigators also looked at adverse events, injection site reactions were fewer in abatacept. While this may not be a significant effect, but they looked at discontinuations. Patients on abatacept had fewer discontinuations. In conclusion, consider tolerability along with efficacy and consider adding Orencia to the PDL.

Carl Jeffery: We were just discussing this class, it does get a little muddy. We have several agents in the review that do not fit into the class. We can bring this class back with a proposed class name that makes more sense. Talking about Cosentyx, it was shown to be safe and effective for patients with plaque psoriasis. For the purpose of the review today, Optum recommends the drugs in this class be considered clinically and therapeutically equivalent.

Evelyn Chu: I make a motion these agents be considered clinically and therapeutically equivalent.

Weldon Havins: Second.

Voting: Aye's across the board – motion carries.

Carl Jeffery: Optum recommends making the new agent Cosentyx non-preferred. We will bring this up again at the next meeting.

Adam Zold: Motion to accept the recommendation and also to bring it up at the next meeting.

Weldon Havins: Second.

Voting: Aye's across the board – motion carries.

VIII. ANNUAL REVIEW – DRUG CLASSES WITHOUT PROPOSED CHANGES

Shamim Nagy, Chairperson: Drug classes without proposed changes

Carl Jeffery: We have several pages of the remaining classes that we do not propose any changes to. Optum recommends these drug classes remain without changes.

Coleen Lawrence: During the meeting, we received a comment in our offices regarding one of the classes for Hep C. The comment was not pertinent to P&T, so we will redirect to the DUR board, but did want to acknowledge the comment.

Shannon Richards: It isn't an action item, there is nothing to vote on.

A. TRAMADOL AND RELATED DRUGS
B. NON-SEDATING H1 BLOCKERS
C. INHALED AMINOGLYCOSIDES
D. ANTIVIRALS - ALPHA INTERFERONS
E. ANTI-HEPATITIS AGENTS – POLYMERASE INHIBITORS/COMBINATION PRODUCTS
F. ANTI-HEPATITIS AGENTS – PROTEASE INHIBITORS
G. ANTI-HEPATITIS AGENTS – RIBAVRINS
H. ANTI-HERPETIC AGENTS
I. INFLUENZA AGENTS
J. SECOND.-GENERATION CEPHALOSPORINS
K. THIRD-GENERATION CEPHALOSPORINS
L. MACROLIDES
M. QUINOLONES - 2ND GENERATION
N. QUINOLONES - 3RD GENERATION
O. SELF-INJECTABLE EPINEPHRINE
P. MULTIPLE SCLEROSIS AGENTS - SPECIFIC SYMPTOMATIC TREATMENT
Q. ANGIOTENSIN II RECEPTOR ANTAGONISTS
R. ANGIOTENSIN-CONVERTING ENZYME INHIBITORS (ACE INHIBITORS)
S. CALCIUM-CHANNEL BLOCKERS
T. DIRECT RENIN INHIBITORS
U. VASODILATORS – INHALED
V. BILE ACID SEQUESTRANTS
W. CHOLESTEROL ABSORPTION INHIBITORS
X. FIBRIC ACID DERIVATIVES
Y. HMG-COA REDUCTASE INHIBITORS (STATINS)
Z. NIACIN AGENTS
AA. ANTIPSORIATIC AGENTS - TOPICAL VITAMIN D ANALOGS
BB. TOPICAL ANALGESICS

CC. ACNE AGENTS: TOPICAL, BENZOYL PEROXIDE, ANTIBIOTICS AND COMBINATION PRODUCTS
DD. IMPETIGO AGENTS: TOPICAL
EE. TOPICAL ANTIVIRALS
FF. TOPICAL SCABICIDES
GG. IMMUNOMODULATORS: TOPICAL
HH. TOPICAL RETINOIDS
II. SEROTONIN-RECEPTOR ANTAGONISTS/COMBO
JJ. H2 BLOCKERS
KK. PROTON PUMP INHIBITORS (PPIS)
LL. GASTROINTESTINAL ANTIINFLAMMATORY AGENTS
MM. GASTROINTESTINAL ENZYMES
NN. 5-ALPHA REDUCTASE INHIBITORS
OO. ALPHA-BLOCKERS
PP. BLADDER ANTISPASMODICS
QQ. ANTICOAGULANTS – INJECTABLE
RR. COLONY STIMULATING FACTORS
SS. PLATELET INHIBITORS
TT. ALPHA-GLUCOSIDASE INHIBITORS/AMYLIN ANALOGS/MISC.
UU. BIGUANIDES
VV. DIPEPTIDYL PEPTIDASE-4 INHIBITORS
WW. MEGLITINIDES
XX. SULFONYLUREAS
YY. THIAZOLIDINEDIONES
ZZ. GROWTH HORMONE MODIFIERS
AAA. PROGESTINS FOR CACHEXIA
BBB. ANTIGOUT AGENTS
CCC. BISPHOSPHONATES
DDD. NASAL CALCITONINS
EEE. RESTLESS LEG SYNDROME AGENTS
FFF. SKELETAL MUSCLE RELAXANTS
GGG. ALZHEIMERS AGENTS
HHH. BARBITURATES
III. BENZODIAZEPINES
JJJ. HYDANTOINS
KKK. NON-ERGOT DOPAMINE AGONISTS
LLL. CARBONIC ANHYDRASE INHIBITORS/BETA-BLOCKERS
MMM. OPHTHALMIC PROSTAGLANDINS
NNN. OPHTHALMIC ANTIHISTAMINES
OOO. OPHTHALMIC MACROLIDES
PPP. OPHTHALMIC QUINOLONES
QQQ. OPHTHALMIC CORTICOSTEROIDS

RRR. OPHTHALMIC NONSTEROIDAL ANTIINFLAMMATORY DRUGS (NSAIDS)
SSS. OTIC QUINOLONES
TTT. ANTIDEPRESSANTS – OTHER
UUU. SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRIS)
VVV. ATYPICAL ANTIPSYCHOTICS
WWW. NASAL ANTIHISTAMINES
XXX. LEUKOTRIENE RECEPTOR ANTAGONISTS
YYY. NASAL CORTICOSTEROIDS
ZZZ. PHOSPHODIESTERASE TYPE 4 INHIBITORS
AAAA. RESPIRATORY ANTIMUSCARINICS
BBBB. LONG-ACTING RESPIRATORY BETA-AGONIST
CCCC. SHORT-ACTING RESPIRATORY BETA-AGONIST
DDDD. RESPIRATORY CORTICOSTERIOD/LONG-ACTING BETA-AGONIST COMBINATIONS
EEEE. ANTIDOTES - OPIATE ANTAGONISTS

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

Shamim Nagy, Chairperson: New drugs to market.

Carl Jeffery: There are a lot of drugs in the pipeline in different phases. Many of them are biologics. A few to point out, a new morphine with abuse deterrent properties, an oral testosterone, another biosimilar to Remicade, and a monthly aripiprazole injection. Some patent expirations that will impact the PDL are Ivega, Travatan Z, Nasonex, Renagel, Androderm, Prempro, Epogen, and Neupogen.

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

A. December 3, 2015

Shamim Nagy, Chairperson: Next meeting, when and where?

Carl Jeffery: December 3, 2015 works well for everyone, 1:00 PM. Location to be determined. I like it at the JW Marriott if they will accommodate us.

X. PUBLIC COMMENT

Weldon Havins: Coleen, there was a bill to change the P&T, did that pass and how does it impact us?

Coleen Lawrence: Yes, that did pass, and it changed the composition requirements for the Committee. It was mathematically difficult to meet the requirements. It reduced the requirements and it is now more flexible. It doesn't impact the current members, but it does give us flexibility with the addition of new members. The quorum is still based on the total number of members that are on the board. We are still looking for new members.

Shamim Nagy, Chairperson: Public comment?

None.

Meeting is adjourned.

XI. ADJOURNMENT

Meeting adjourned at 3:15 PM