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Nevada Medicaid

PHARMACY AND THERAPEUTICS COMMITTEE

DRAFT MEETING MINUTES

The Division of Health Care Financing and Policy (DHCFP) Pharmacy and Therapeutics Committee held a public meeting on March 23, 2017 beginning at **1:00 p.m.** at the following location:

North Nevada Location:
Silver State Health Insurance Exchange
2310 S. Carson St
Ste. 3A
Carson City, NV 89701

South Nevada Location:
Silver State Health Insurance Exchange
150 N. Stephanie St
Ste. 100
Henderson, NV 89074

Committee Members Present:
Mark Decerbo, Pharm.D.; Shamim Nagy, MD; Mike Hautekeet, Pharm.D.; Joseph Adashek, MD; Nikki Beck, Pharm.D.; Christopher Highley, MD; Weldon Havins, MD; Adam Zold, Pharm.D.

Committee Members Absent:
Evelyn Chu, Pharm.D.

Others Present:
DHCFP:
Mary Griffith, RN, Pharmacy Services Specialist; Gabriel Lither, Deputy Attorney General; Sherri Eggleston

HPES:
Beth Slamowitz, Pharm.D.

Optum:
Carl Jeffery, Pharm.D., Kevin Whittington, RPh; Daniel Medina

Others:
John Sandstrom, Shire; Rob Bigham, Shire; Nana Numapau, Boehringer Ingelheim; Jennifer Lauper, BMS; Samantha Sweeney, Otsuka; Sane Guo, Otsuka; Melissa Walsh, Novartis; Tom O,Connor, Novartis; Mark Schwartz, GSK; Leon Ravin, DPBH; Joe Schreck, Allergan; Chris Stanfield, Supernus; Addie Meyers, Merck; Coleen Lawrence, Moxy; Phil Walsh, Sunovian; Cynthia Albert, Merck; Dave West, United Therapeutics; Aimee Dorman, United Therapeutics; Mike Strong, Novo Nordisk; Toby Damron, Novo Nordisk

AGENDA

1. Call to Order and Roll Call

The meeting is called to order at 12:58 PM.

Roll Call

North:

Christopher Highley: Here
Michael Hautekeet: Here
Beth Slamowitz: Beth Slamowitz, HPE
Sherri Eggleston: Sherri Eggleston, DHCFP

South:

Weldon Havins: Present
Joseph Adashek: Present
Adam Zold: Present
Shamim Nagy, Chair: Present
Mark Decerbo: Present
Mary Griffith: Mary Griffith, DHCFP
Carl Jeffery: Carl Jeffery, OptumRx
Kevin Whittington: Kevin Whittington, OptumRx
Gabe Lither: Gabe Lither, Senior Deputy Attorney General

2. Public Comment

Shamim Nagy, Chair: Any public comments?

3. Administrative

a. **For Possible Action**: Review and Approve Meeting Minutes from December 8, 2016.

Shamim Nagy, Chair: We need a motion to approve the minutes from the last meeting.

Weldon Havins: So moved.

Joseph Adashek: Second.

Voting: Ayes across the board, the motion carries.

b. Status Update by DHCFP

Shamim Nagy, Chair: Status update from the DHCFP.

Mary Griffith: This is Mary Griffith, the pharmacy specialist for the DHCFP. I want to welcome everyone to our March Pharmacy and Therapeutics Committee meeting. This is our first split meeting. We wanted our members in the north to be able to continue their normal business as much as possible. This is a learning curve for us.

Regarding status updates, we have some personnel changes. Duane Young is the new chief for pharmacy. He comes to us from the Division of Public and Behavior Health. He has a lot of knowledge of the ACA. Shannon Sprout was the Chief and is now the Deputy Administrator, replacing Betsy Aiello who retired last month.

Medicaid Services Manual Chapter 1200 changes are scheduled to go to April 26 public hearing. Included in those changes is the requirement for opioids be a seven day dispense only on initial prescriptions. The policy on dispensing practitioners will be included and be effective April 27, 2017.

The DHCFP has been working with the Legislature.

For housekeeping, for the P&T Committee, Carl Jeffery will display the proposed preferred drug list, if your drug is recommended as preferred, you do not need to testify. Because we have a split committee, the voting will be called out by name so we can record the votes. If there are questions, I encourage you to not all talk at once or make sure we acknowledge that you have a question. That is the end of my update.

Shamim Nagy, Chair: Do we have any public comments?

4. Established Drug Classes

a. Psychotropic Agents: Atypical Antipsychotics – Oral

Shamim Nagy, Chair: We will start with established drug classes, psychotropic agents, atypical antipsychotic, oral agents. Do we have any public comment? None.

Carl, could you give us your update?

Carl Jeffery: I hope this will be a quick review. We are bringing this up because there is a new generic for Seroquel XR. Right now, since there is only one manufacturer of the generic, we are recommending it be non-preferred. I am showing the indications on the screen, the generic has the same indications as the brand. I think it will be available from multiple manufacturers pretty soon. Optum recommends the Committee consider the drugs in this class to be clinically and therapeutically equivalent.

Weldon Havins: I move they be considered clinically and therapeutically equivalent.

Joseph Adashek: Second.

Voting: Ayes across the board, the motion carries.

Carl Jeffery: Optum recommends the quetiapine XR, the generic for the Seroquel XR be considered non-preferred.

Mark Decerbo: I move to approve as presented on the screen.

Adam Zold: Second.

Christopher Highley: I have a question, are there any other approved antipsychotic extended release that are generic at this time?

Carl Jeffery: There are some that are just once a day, not necessarily extended release, like aripiprazole.

Christopher Highley: Ok, that works for me, I agree with the motion.

Weldon Havins: I have a question too. I noticed some material with the NRS422, it says the Medicaid program must make available without prior authorization atypical and typical antipsychotic medications. Are you making this non-preferred?

Mary Griffith: NRS422.4025 allows for oral typical and atypical antipsychotics to be on the PDL as long as they were not on the market before 2010.

Gabe Lither: All of the products on the market at that time were grandfathered in. Since then, we can make new rules going forward.

Weldon Havins: Ok, thank you. I appreciate the clarification.

Voting: Ayes across the board, the motion carries.

b. Respiratory Agents: Short-Acting Respiratory Beta-Agonists

Shamim Nagy, Chair: Respiratory agents, short-acting respiratory beta-agonists. Do we have any public comment? None.

Carl Jeffery: This is another easy one, we have a newly available generic for the Xopenex HFA, levalbuterol HFA. This is straight forward AB rated generic, it really isn't any different than the brand that is available. Optum recommends the Committee consider these to be clinically and therapeutically equivalent.

Weldon Havins: I move that these be considered clinically and therapeutically equivalent.

Joseph Adashek: Second.

Voting: Ayes across the board, the motion carries.

Carl Jeffery: Optum recommends the new generic levalbuterol HFA be considered non-preferred and the rest of the class remain the same.

Joseph Adashek: Will brand name Xopenex remain preferred?

Carl Jeffery: Yes, the brand Xopenex HFA will remain preferred.

Joseph Adashek: I move we accept the recommendations.

Weldon Havins: Second.

Voting: Ayes across the board, the motion carries.

5. Established Drug Classes Being Reviewed Due to the Release of New Drugs

a. Cardiovascular Agents: Antihypertensive Agents: Vasodilators – Oral

Shamim Nagy, Chair: Established drug classes being reviewed due to the release of new drugs. Cardiovascular agents, antihypertensive agents, vasodilators, oral. Do we have any public comment? None.

Carl Jeffery: Uptravi is a relatively new product, it has been available for about a year. We barely missed it the last time we reviewed the class. We are talking about the oral agents today, there are also inhaled and injectable products in this class. I broke out the drugs to see the classes. There are three classes, and you can see the indications. The PDE 5 and sGC Stimulators all work on the prostaglandin pathway. The endothelin receptors, PCA and PRA are all listed. When we talk about pulmonary hypertension, there are three basic pathways that we consider, prostacyclins, endothelins and nitric oxide pathways. I may have misspoke on the previous slide the prostacyclin pathway is the PCA's and the prostacyclin receptor agonist. The active drugs that do affect the prostacyclin is Uptravi and Orenitram. The others are available inhaled, IV or sub q. Speaking of Uptravi specifically, the GRIPHON study had about 1100 patients. It compared to placebo and it had a significant reduction in endpoints of all-cause death and complications. It didn't show any mortality reduction, but it did show a benefit of either reducing hospitalizations or disease progression. There were several meta-analysis studies done. The first here is 18 trials, about 4000 patients. Looking at the therapeutic benefit was done before Uptravi was available, but you can see PDE-5 inhibitors show a significant benefit. The next one was 14 trials with about 2200 patients looking at overall survival. Really only the patients getting the IV formulation showed a benefit, the oral and sub q did not show a significant benefit. Another study with 21 trials and about 5000 patients showed all classes reduce clinical worsening. There were lots of other smaller studies, IV was better, combo is better than monotherapy. One analysis showed prostacyclin was better than some of the other agents. The treatment guidelines have not been updated since the release of Uptravi. But they

do start with monotherapy and then move to parenteral therapy with the more severe disease. The European society has been updated since Uptravi and they recommend any oral agent, no preference for one over another. With this information, Optum recommends the class be considered clinically and therapeutically equivalent.

Joseph Adashek: I move we accept the recommendation that they are therapeutic alternatives.

Weldon Havins: Second.

Voting: Ayes, across the board, the motion carries.

Carl Jeffery: Because Orenitram is a similar agent and uses the same pathway as Uptravi and is preferred, Optum recommends Uptravi be non-preferred.

Adam Zold: I move to accept Optum's recommendation.

Weldon Havins: Second.

Voting: Ayes across the board, the motion carries.

b. Hormones and Hormone Modifiers: Antidiabetic Agents – Insulins (Vials, Pens and Inhaled)

Shamim Nagy, Chair: The next item is hormones and hormone modifiers, antidiabetic agents, insulin. Do we have any public comment? None.

Carl Jeffery: We have another kind of generic, Basaglar is the same molecular entity as Lantus. They used an abbreviated approval process to get it approved through the FDA. This is called a follow-on biologic. This has been available since late last year. Safety and efficacy are similar to Lantus. They did a comparison with Lantus in a non-inferiority study. Really nothing else showing it is superior to Lantus. Optum recommends this class be considered clinically and therapeutically equivalent.

Joseph Adashek: I move we accept the recommendations from Optum.

Weldon Havins: Second.

Voting: Ayes across the board, the motion carries.

Carl Jeffery: Optum recommends Basaglar be non-preferred since the Lantus is preferred and they are similar agents.

Michael Hautekeet: I make a motion to accept Optum's recommendation.

Mark Decerbo: Second.

Voting: Ayes across the board, the motion carries.

c. Hormones and Hormone Modifiers: Antidiabetic Agents – Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors

Carl Jeffery: Dr. Nagy, the SGLT2's the product we had hoped to review at this time is not yet available on the market. We usually wait until the product is on the market until we review it. We request to bypass this review.

6. Proposed New Drug Classes

a. Ophthalmic Agents: Opthalmics for Dry Eye Disease

Shamim Nagy, Chair: Proposed new class, new subclass, ophthalmic agents, ophthalmics for dry eyes.

John Sandstrom: My name is John Sandstrom from Shire Medical Affairs. I want to thank Optum for the thorough review. Xiidra is the first and only FDA approved medication for the treatment of signs and symptoms of dry eye disease. Dry eye disease is a multifactorial disease causing discomfort of the tears and ocular surface that results in symptoms of discomfort, visual disturbance with potential damage to the ocular surfaces. Dry eyes is one of the most common complaints to eye care professionals and is often chronic.

Some highlights, studies, efficacy and safety of Xiidra was presented.

I will leave it open to any questions.

Carl Jeffery: We do have some comments from the web.

Rick Croshella: My name is Rick Croshella, I am an MSL for Allergan. I just wanted to mention a couple things about Restasis. It is approved for dry eyes. It increases tear production in patients related to ocular inflammation associated with KCS. Restasis is believed to be a partial immune modulator and has been well studied for over 13 years. It has been proven to be safe and well tolerated with limited side effects. It has no detectable levels in the blood.

Some studies and the mechanism of action was presented.

Only Restasis has been shown to be more effective than artificial tears. I will take any questions.

Carl Jeffery: I don't see any other public comment. This is a new class we are proposing. There are two drugs in this class. Before we only had Restasis, Xiidra is relatively new. They have similar indications with dry eye disease. I am looking for Dr. Havins to provide some input too. The dry eye disease is a common complaint. Restasis is cyclosporine, it really isn't known how it works but is thought to help with inflammation. With two randomized placebo controlled trials, about 870 patients and open label extension, the treatment group improved over baseline. It works about the same as punctal plugs for efficacy, but the punctal plugs work much faster. With the review of about 18 randomized trials, 100% of the studies improve dry eyes over placebo. Xiidra is a small molecule, not something that is not currently available. It is T-cell mediated inflammation response modifier. The exact mechanism is unknown but probably related to decreasing inflammation. Four 12 week studies with almost 1200 patients. Dry eye scores reduced over placebo, visual related scores are improved, and corneal staining reduced. Guidelines have not been updated to incorporate Xiidra yet, but they do include cyclosporine for

the treatment of severe dry eyes. Optum recommends this class be considered clinically and therapeutically equivalent.

Mark Decerbo: Somewhat off topic, but thank you to you and Optum. We have had a cornucopia of classes before and I don't think this was a class before, but I think it is a new class, but thank you for picking some of these out into more pharmacological categories.

Carl Jeffery: Thanks, and just for clarification, this is a new class.

Weldon Havins: I think the most important statement here is there are no comparative trials of cyclosporine to this new class with Xiidra. Restasis has been around a long time. In my experience Restasis is helpful in those who have an inflammatory component to their dry eyes. In my experience it does not have any superiority over artificial tears or punctal plugs in those that do not have an inflammatory component. It would be interesting to see a head-to-head study with these two drugs. I move that these are clinically and therapeutically equivalent. It is with some degree a movement of ignorance because I don't know that to be an absolute fact, but based on the information that we have.

Adam Zold: Second.

Voting: Ayes across the board, the motion carries.

Carl Jeffery: Optum recommends making Restasis preferred and Xiidra non-preferred.

Weldon Havins: I move we accept the recommendations from Optum that Restasis is preferred and Xiidra is non-preferred.

Michael Hautekeet: Second.

Voting: Ayes across the board, the motion carries.

7. Report by OptumRx on New Drugs to Market, New Generic Drugs to Market, and New Line Extensions

Shamim Nagy, Chair: Report on new drugs to the market by Optum.

Carl Jeffery: We have been talking about these for a few quarters now. A new generic for Pristiq, Emend and Zetia. They will have spots on our PDL and will have an impact. Some new drugs that I think will be more of a discussion are Qtern, a combination of dapagliflozin and saxagliptin. Then Soliqua and Xultophy are combinations of insulins and GLP-1. I think for the discussion on which classes they go into, we have to look at the classes that are similar and should be tried first. It makes sense to put these in the insulin class because someone would be on insulin before getting one of these. Trulance is a new treatment for idiopathic constipation. It was a new class we added at the last meeting. A couple new extended release opioid products, Vantrela ER and Arymo and a few others that are coming out too. These will probably be on our June agenda and there is another one too. A couple new formulations with Vyvance with a new chewable tablet. Synjardy will be coming back again with the label update and the cardiovascular risk reduction studies.

Weldon Havins: If someone has type 2 diabetes and starts on metformin and then moves to add a GLP-1. Is that ok or is there something that needs to be tried before that?

Carl Jeffery: No, they could move to a GLP-1, there are not any restrictions as long as they request a preferred GLP-1. I think they have to have a diagnosis of diabetes now.

Shamim Nagy, Chair: You go with a clinical algorithm?

Carl Jeffery: We don't really go with an algorithm with the P&T, it is just the preferred drug list. We don't have step therapy per se. The DUR Board could add some criteria to have to try some therapies before moving to another.

Mark Decerbo: In general, we as a Committee, we are not following an algorithm, but the algorithms are based on clinical data and then the two comport with one another like the two GLP-1s like Victoza. It has got the cardiovascular data now and it is on the preferred drug list. And I think you raised a good point, what do we do with combo products moving forward? Hopefully, these are hand-in-hand and we don't need too much from the DUR Board. We are following evidence in what is out there with results and treatment guidelines.

Weldon Havins: For the biosimilars, where do those stand?

Carl Jeffery: We have one biosimilar we reviewed last time with the immunomodulators. There are more coming out and we will review them as individual products going forward.

Weldon Havins: Are we only going to review those the FDA has approved?

Carl Jeffery: Right, approved and on the market. We need some market data before we can do a review on those.

8. Closing Discussion

Shamim Nagy, Chair: Moving to closing discussion. Do we have any public comment? No public comment. Date and location of the next meeting.

Carl Jeffery: I have June 22 at 1:00. We have booked this room for the remainder of the year.

Shamim Nagy, Chair: The meeting is adjourned.

Meeting adjourned at 1:45 PM.