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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 March 24, 2016 beginning at **1:00 p.m.** at the following location:

Spring Preserve
Desert Living Center
333 S. Valley View Blvd
Las Vegas, NV 89107
702-822-7700

Committee Members Present:
Mark Decerbo, Pharm.D.; Shamim Nagy, MD; Weldon Havins, MD; Adam Zold, Pharm.D.; Evelyn Chu, Pharm.D.; David Fluitt, RPh; Mike Hautekeet, Pharm.D.

Committee Members Absent:
Bill Evans, MD; Joseph Adashek, MD

Others Present:
DHCFP:
Mary Griffith, RN, Pharmacy Services Specialist; Susanne M. Sliwa, Deputy Attorney General;

HPES:
Beth Slamowitz, Pharm.D.

Optum:
Carl Jeffery, Pharm.D., Kevin Whittington, RPh; Daniel Medina (via teleconference)

Others:
Jeff Buel, J&J; Sergio Gonzalez, Takeda; Dr. Robert Lynn Hornee; Krystal Joy, Otsuka; Samantha Min, Otsuka; Yurri Yamamoto, Alkermes; Melissa Walsh, Novartis; Kriby Consier, Novartis; Jennifer Lauper,

MBS; Charissa Anne, J&J; Mary Kay Queener, J&J; Gregg A Gittus, Akermes; Colin Carey, Eli Lilly; Mark Shaw, Allergan; Sean M, Allergan; Kathy Moore, Otsuka; Cynthia Kouske, Otsuka; Kerry Kostman Bonilla, AstraZeneca; Gin Yun, AstraZeneca; Ann Nelson, Vertex; James Kotusky, Gilead; Deron Grothe, Teva; Bob G, Lundbeck; Sandy Sierawski, Pfizer; Contessa Fincher, Teva

Others via teleconference:
Laurie Kelly, Optum; Rob Bigham, Shire; Ann Nelson, Vertex; Lovell Robinson, Abbvie; John Pruett; Philip Walsh, Sunovion; Dr. Charles Costas; Kim Brown; Ken Ley; Deborah Campanella

AGENDA

1. Call to Order and Roll Call

Meeting called to order at 1:15 PM.

Roll Call:

Kevin Whittington, OptumRx

Carl Jeffery,

Mary Griffith

Mike Hautekeet

Evelyn Chu

Mark Decerbo

Adam Zold

Weldon Havins

Shamin Nagy

Susanne M. Sliwa

Beth Slamowitz

David Fluitt

Public Comment

Shamim Nagy, Chair: Calls for public comment.

2. Administrative

A. **For Possible Action:** Review and approve meeting Minutes from December 3, 2015

Shamim Nagy, Chair: We need a motion for approval of the minutes from the last meeting.

Weldon Havins: So moved.

Adam Zold: Second.

Voting: Ayes across the board, the motion carries.

B. Status Update by DHCFP

1. Public Comment

Mary Griffith: Coleen Lawrence is working in the Director's office for the Director of Health and Human Services. Interim CPT chief is Marti Cote. We have a permanent person starting soon, Shannon Sprout. She has been with the State for a long time.

From CMS on covered outpatient drugs as a result of the ACA, the biggest change is how we reimburse 340b providers. We are prohibited from exceeding the ceiling price, even though we don't know what it is. That is one of the things we are working through.

We do have the WebEx up, so please talk clearly if you are going to give public comment.

Weldon Havins: What is a 340b provider?

Mary Griffith: A 340b provider is a federal program where certain clinics in Nevada get drug discounts from the manufacture. We don't collect rebates on these claims. It started to expand with ACA. It doesn't impact this group, but it does impact DHCFP.

Shamim Nagy, Chair: Public comment? None.

3. Established Drug Classes

A. Respiratory Long-Acting Anti-muscarinic/Long-Acting Beta-Agonist Combinations

Shamim Nagy, Chair: Moving to the established class of drugs. The respiratory long-acting anti-muscarinic/long-acting beta-agonist combinations.

Carl Jeffery: We anticipated a new product on the market by the time of the meeting, but it is not yet available. We ask the chair to bypass this agenda topic.

B. Acne Agents: Topical, Benzoyl Peroxide, Antibiotics and Combination Products

Shamim Nagy, Chair: acne agents. Any public comment? No.

Carl Jeffery: We have a new product on the market in this class, generic dapsone, or Aczone is the trade name for it. The Duac CS is no longer on the market. We wanted to review this class with the Committee. I am not going to spend a lot of time on the clinical side with this class. Most of these have been on the market for a long time and are well known. The anti-infectives are well established in the guidelines in the treatment of acne, and it is not different with the dapsone. These are all categorized as anti-infectives. The guidelines recommend adding benzoyl peroxide with the clindamycin and erythromycin so there is not as much drug resistance. The safety and efficacy is well known and are shown to be more effective than placebo. Sulfacetamide of note was available on the market before the 1962 FDA classification and was never shown to be safe and effective. It is widely used, but it is not approved. Aczone was approved based on two studies. Shown to be safe and more effective over vehicle alone. Another study looked at adolescent females vs. adult females and it was shown it was more effective in the adults, but the researches were not sure why. There are several dosage forms available. Optum recommends the Committee consider these clinically and therapeutically equivalent.

Adam Zold: I motion that they are therapeutically equivalent.

Weldon Havins: Second.

Voting: Ayes across the board, the motion carries.

Carl Jeffery: We want to shuffle this around a little. Aczone we recommend be non-preferred, and move sulfacetamide to non-preferred since it is not FDA approved. There are some new products, Onexton and Acanya are newer combination products to be preferred. A couple new aerosol products on the market. They shouldn't be first line, so we are recommending these be non-preferred.

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

Michael Hautekeet: Second.

Voting: Ayes across the board, the motion carries.

4. Proposed New Drug Classes

A. Ophthalmic Anti-infective/Anti-inflammatory Combinations

Shamim Nagy, Chair: The next class, ophthalmic anti-infective/anti-inflammatory combinations.

Public comment? None.

Carl Jeffery: This is a new class we would like to propose adding to the PDL. We have the individual products on the list now, but would like to add the combinations. A couple newer products, Pred G, Zylet, they are all combinations of well-known products that have been out for years. Most are available generically, just the Pred-G and the Zylet do not have generics. The Zylet has tobramycin and a newer steroid that is in Alrex. Optum recommends these be considered clinically and therapeutically equivalent.

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

Michael Hautekeet: Second.

Voting: Ayes across the board, the motion carries.

Carl Jeffery: Our recommendation is shown on the screen. The Pred-G and Zylet are the two brand names available as preferred. The Tobradex ointment, sulfa/prednisone and the Neo/Poly/Dexamethasone are all widely used. But the one that might get some pushback is the Tobradex suspension as it is widely used and this may not be a popular decision. Having Zylet which is the same ingredient, we are hoping to push some utilization to that medication.

Weldon Havins: The Tobradex suspension is also available as a generic.

Carl Jeffery: Right, we have the generic listed as non-preferred as well.

Weldon Havins: I think this is a commonly used medication, I hate to see it not available. I move that we move the generic Tobramycin dexamethasone be move to preferred. And that the preferred drug list be accepted.

Adam Zold: Second.

Voting: Ayes across the board, the motion carries.

B. Injectable Long-Acting Atypical Antipsychotics

Shamim Nagy, Chair: The next class is long-acting injectable atypical antipsychotics. Optum wanted to make a comment before we open to public comment?

Carl Jeffery: Thank you. I know there will be public comment for this class, to make sure everyone is on the same field. We have to cover them, but there are some limitations, on or before June 30, 2010. I understand the way this is interpreted is that if the product was on the market before June 30, 2010, the Committee cannot make them non-preferred. If the product came on the market after that date, the Committee has the option to make it non-preferred. Also, the exception criteria, recipients discharged from an acute mental health facility have up to 90 day to see a provider. They will be given an approval for 90 regardless if preferred or non-preferred. That is across the board and is how the oral atypical antipsychotics are being handled.

Mary Griffith: As of April, we will have a public hearing on some other changes, that 90 days will be increased to 6 months.

Carl Jeffery: The other exclusion criteria, in order for a member to get a non-preferred medication, they only need to try one preferred. The other classes require two trials. I would like to make sure we keep the comments in line with our objective here and not get sidetracked with PA process or what the call center does.

Shamim Nagy, Chair: Public comment?

Samantha Min: My name is Samantha Min, I am a Pharm.D. with the Medical Affairs Department with Otsuka and I want to talk today about Abilify Maintena. I want to first review our position on open access. Reviews studies showing different medications work differently for different patients. Formulary restrictions more likely to be hospitalized and have higher costs. Otsuka supports open access to all medication. She presented indications and trials of Abilify Maintena, adverse events and black boxed warning. I ask for Abilify Maintena to be available unrestricted.

MaryKay Queener: My name is MaryKay Queener, I'm a Pharm.D. with Johnson and Johnson. I also support open access and support Invega Trinza and Consta on the preferred drug list.

Weldon Havins: So you are in favor of having these on the preferred drug list?

Mary Kay Queener: I am.

Robert Horne: I am Dr. Robert Horne. I was previously on the P&T. I'm asking today this class not be removed from the excluded list. He presented on two studies involving, fewer hospitalizations and readmissions with long-acting injectable antipsychotics. The problem is if you put all of these on, next year they don't have to be all preferred. If they continue to be excluded, then we don't have to worry about it becoming non-preferred at some point. We don't want to be in a position of having to use Haldol or Prolixin like some MCOs. I think it would be best for psychiatrists to use what is best for the individual patient, we know our patient's better. Please allow us to continue to use the best medication at the time for that patient by excluding these medications from the preferred drug list.

Weldon Havins: Dr. Horne, is it your impression that all these drugs are on the excluded drug list.

Robert Horne: I know there is some controversy about what is excluded, but I think these are all excluded. I don't think they should all be excluded.

Weldon Havins: Do you think they should be moved to the excluded list?

Robert Horne: Yes.

Weldon Havins: Is it your understanding that if they are on the preferred drug list they have to fail on some other drug to use these?

Robert Horne: For the patient for one of the two MCO's, they have to fail Prolixin or Haldol.

Mary Griffith: This criteria is for fee for service only, this will not affect MCO coverage.

Robert Horne: I understand that, if it comes off the excluded list and added to the preferred drug list, it can be moved to non-preferred the following year. I don't want to see that happen and the only way I know to make sure it doesn't happen is if they all stay on the excluded list.

Weldon Havins: But you are aware if they were on the preferred drug that psychiatrists could use these without any drug failure.

Robert Horne: Right, for the next year, but what I'm saying is I have seen many times something that is preferred on the list and be non-preferred the next year.

Weldon Havins: But to do that it would have to come before this Committee.

Robert Horne: Yes, but it comes up every year.

Weldon Havins: Potentially.

Robert Horne: So I would just like to see it not to be able to happen for the benefit of my patients. Thank you.

Dr. Gellifen: I'm the Director of Mental Health. We sent a letter yesterday for the Committee, I just wanted to make sure the Committee saw the letter and ask for any questions.

Carl Jeffery: He is referring to the letter from Dr. Gellifin, you should have a copy. Dr. Gellifin, I do not see any questions from the Committee at this time.

Dr. Gellifen: Thank you. I just want to request to not have any restriction to this class of medications as expressed in the letter.

Shamim Nagy, Chair: Any other public comment?

Carl Jeffery: We talked about the exclusion criteria and the Committee I think understands the ramification. We have the injectable atypical antipsychotics, they are all available orally as well and you can see the indications for each listed on the screen. What really separates these products is the half-life. On the screen lists the number of days for the half-life. There have been a lot of trials showing they are safe and effective, they are used quite a bit. They are established in numerous trials. The clinical guidelines do not have a preference for one single agent. The Zyprexa is part of a limited distribution due to some special administration requirements and a black box warning. When looking at practice guidelines, they have not been updated for a while, they say these agents are good for patients having a hard time with compliance. That is really where they fall into therapy according to these guidelines. This slide shows the brand and generic names of each of the injectable product. Optum recommends these products be considered clinically and therapeutically equivalent.

Weldon Havins: The list you presented highlighted in yellow, are those currently part of the excluded list?

Carl Jeffery: The initial screen showed that we wanted to make all the products preferred.

Weldon Havins: That wasn't my questions, currently are these on the list of excluded?

Carl Jeffery: I don't know that excluded is the right word, they are not included in any category, so there is no PA restriction for preferred or non-preferred right now.

Weldon Havins: So a psychiatrist writing for one of these currently does not have any restrictions?

Carl Jeffery: Right, the only limitation is the DUR board added criteria for the Invega Trinza. It follows the approved labeling.

Weldon Havins: Since we have had testimony for them to remain excluded, is there a compelling reason to move them to the preferred drug list?

Carl Jeffery: It gives the Committee the ability down the road to evaluate new products and if there are some products that come on the market that are subpar or have some limitations in use then the Committee can drive utilization to other agents. As the Committee, your first priority is to make sure everything on the preferred side is clinically appropriate and is the best therapy. If there is a product released in the future that is substandard, the Committee can drive the utilization to the better agents.

Weldon Havins: But we are not considering those drugs now, we are considering these currently available. Several clinical psychiatrists believe they should remain in the current status as they are now. Is there a compelling need to move them to the preferred drug?

Carl Jeffery: It is in the interest of the state to have these on the PDL and down the road we can drive utilization.

Weldon Havins: Couldn't we address that down the road.

Carl Jeffery: Yes, for any changes we propose to the PDL needs to come to this Committee first.

Mark Decerbo: For the exclusion criteria, is it the dosage form or the molecule? They don't appear like they meet the excluded list. Is this a unique example or are there other examples around?

Carl Jeffery: My understanding is it is by dosage form, so it would be the long-acting injectable agents. There are only three that were introduced after the date, the Invega Trinza, Aristada and Abilify Maintena.

Mary Griffith: To clarify, there is not a list of drugs that are excluded. If there is a category that is not listed on the PDL, then they are not subject to the same criteria as a listed class. If we are adding the class to the PDL, there is going to be more scrutiny, and if listed as non-preferred it

will require a PA. So it isn't a list, it is just when something is added to the PDL. It is the Committee's responsibility to decide what is preferred and non-preferred.

Weldon Havins: I understand, as I read the screen, I don't see where it lists the oral antipsychotic medications. I see "antipsychotic medications".

Mary Griffith: We do have the drug class.

Carl Jeffery: I don't have the orals listed.

Weldon Havins: This is from the legislature, they did not distinguish between the injectables and oral agents. I move we keep them in the same class as they are now until there is a compelling reason to change their status.

Mark Decerbo: Second. I work with USP along with CMS that works with the Part D formularies, there are six protected classes which antipsychotics are one. This is one category where I would endorse a protected status, while I do not have any issue with putting them all on the PDL, thinking for the future and different compositions of the Committee and what changes may come from that. That is my main hesitation.

Mary Griffith: Did we do the therapeutic equivalency vote for this yet?

Weldon Havins: No, but we don't have to go there if we are voting this way. We don't want them on the list at all.

Beth Slamowitz: For clarification, is it still possible that if these are added as a class, that the DUR Board can make decisions for criteria to be placed on those products for safety reasons. The DUR Board can still add restrictions, so just by not adding this class, there could still be PA requirements from the DUR Board added.

Weldon Havins: That is out of the scope of this Committee.

Beth Slamowitz: Correct, I want to make sure that is understood by the public as well.

Voting: Ayes across the board, the motion carries.

C. Oral Non-steroidal Anti-inflammatory Drugs (NSAIDs)

Shamim Nagy, Chair: Next is Oral Non-steroidal anti-inflammatory drugs. Any public comment?

Carl Jeffery: This is our last class. This is a new class of medications. This is the NSAIDS, these have been out for years. We are seeing manufacturers bringing new forms out after tweaking old formulations a little. We would like to push utilization to the more well-known, established medications in this class. Looking at the list, there really are not any new molecules. The literature available is old and there isn't really studies showing one is better than the other.

A few of the new agents compare to Celebrex and they are shown to be non-inferior. The advantage of the newer agents is it works just a little faster. The three new products are ground down to a very fine powder in theory absorbing a little faster. The other two I will point out is Duexis and Vimovo, they are combination products where the DUR Board has placed criteria on them. All the NSAIDS have a black-box warning. There is supposed to be a big study coming out later this year showing the results of cardiovascular effects. Optum recommends the products listed be considered clinically and therapeutically equivalent.

Mark Decerbo: I move this list be accepted as clinically and therapeutically equivalent.

Adam Zold: Second.

Voting: Ayes across the board.

Carl Jeffery: We came up with the preferred list by drawing a line between the brands and generics. We included the highly used medications. This gives the availability of the higher used products.

Mark Decerbo: We didn't have this as a class before?

Carl Jeffery: No, up until recently all the products were generic.

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

Weldon Havins: Second.

Voting: Ayes across the board, the motion carries.

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

Carl Jeffery: Your binders have some new drug information. Hepatitis C agents are coming. Please let us know if there are other classes you think should be included in the future.

Weldon Havins: Is there a list of HIV medications?

Carl Jeffery: For prophylaxis? We are excluded from having HIV medications as a class on the PDL.

6. **Closing Discussion**

Shamim Nagy, Chair: Any public comment? Date and location of the next meeting?

Carl Jeffery: June 23rd, does this location work?

Shamim Nagy, Chair: Meeting adjourned.

Meeting adjourned at 2:20 pm.