

STATE OF NEVADA DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH CARE FINANCING AND POLICY

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Nevada Medicaid P&T Committee. Draft Meeting Minutes

The Division of Health Care Financing and Policy (DHCFP) P&T Committee. conducted a public meeting on March 26, 2015 beginning at 1:00 pm at the following location:

South Point Casino/Hotel 9777 Las Vegas Blvd. S. Las Vegas, NV 89183

Committee. Members Present:

Mark Decerbo, Pharm.D.; David Fluitt, RPh; Shamim Nagy, MD; Weldon Havins, MD; Joseph Adashek, MD; Bill Evans, MD; Mike Hautekeet, RPh; Adam Zold, Pharm.D.

Committee. Members Absent:

Amir Qureshi, MD; Evelyn Chu, Pharm.D.

Others Present:

DHCFP:

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

HPES:

Beth Slamowitz, Pharm.D.

Catamaran:

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

Others:

Pamela Vincent, Indivio; Barbara Glover, CF Center of Southern NV; Julia Harder, AZ; Caroline Nguyen, AZ; Pat Wiseman, AZ; Anne Marie Licos, AZ; Theresa Beukert, Eisai; Charlie Collins, Gilead; Lovell Robinson, Abbvie; Vicky Voss, Salix; Tom O'Connor, Novartis; Becky Gonzales, Viiv Healthcare; Brad Willie, Novartis; Deron Grothe, Teva; Gregg Gittus, Alkerines; Marykay Queener, J&J; Charissa Anne, J&J; Sergio Gonzalez, Takeda; Marcus Laughlin, BI; Kirk B Lane, UT; Cynthia Patterson, BDSI; Bob Gustafson, Lundbeck; David Melikian, Mallinckrodt; Wendy Joles, Mallinckrodt; Lee Marks, Orexo; Rupa Shah, Purdue, Samantha Min, Otsuka; Shelby Foral, Mylan; Lee Stont, Chesi; Chris Holtzer, Abbvie; Rob Bigham, Shire; George Yasutake, Actelion; Scott Larson, BMS; Melissa Walsh, Novartis; Akshaya Patel, Mylan; Betty Chan, Gilead; Phil Walsh, Sunovion; Berlain Aloune, Marck; Sandy Sierawski, Pfizer

I. CALL TO ORDER AND ROLL CALL

Meeting called to order at 1:13PM

Roll Call Joseph Adashek Mike Hautekeet David Fluit Shannon Richards Shamim Nagy Weldon Havins Bill Evans Adam Zold Mark Decerbo Coleen Lawrence - DHCFP Mary Griffith - DHCFP Beth Slamowitz - HP Kevin Whittington - Catamaran Carl Jeffery - Catamaran

II. PUBLIC COMMENT

No Public Comment.

III. <u>FOR POSSIBLE ACTION</u>: Review and approval of the November 13, 2014 meeting minutes.
 Voted – Ayes across the Committee.
 Motion approved.

IV. STATUS UPDATE BY DHCFP – Coleen Lawrence

Update for Preferred Drug List – Yesterday (03/25/15) SV 422, NV Medicaid's budget bill regarding the preferred drug list, was released. The goal was to eliminate the "sunset expiration" on the current NRS 422.4025. That is where the preferred drug list regulation lays for the Division of Healthcare Finance and Policy. The Sunset Bill allows us to manage atypical and typical classes of drugs. If the bill does not go forward, effective 07/01/15, the Division will no longer be able to manage atypical and typical psychotropic medications. The bill that was submitted requests that the sunset be eliminated to allow

the Division to continue to manage this drug list. The Division, along with stakeholders, and the P&T Committee, feels that they have been very transparent since the inception of the PDL in 2003 and implementation in 2004. They have been able to successfully manage the preferred drug list without hampering or impeding access to care for any Medicaid recipients.

There has been discussion that instead of eliminating the sunset timeframe, that it may extended, which happened in the last legislative session. The sunset language was postponed from 2013 to 2015. Due to negotiations, it may be extended again rather than eliminated. With an extension, we would be able to continue to manage the atypical and typical antipsychotic medications on the preferred drug list and the regulation would continue to read as it does today.

The sunset language has nothing to do with the Committee itself, it just allows us to manage the atypical and typical medications on the preferred drug list. If the language remains with no extension, or elimination, it would become a prohibited class that the Division would not be allowed to manage on the preferred drug list. They would still be accessible, but not managed on the preferred drug list. The possible extension length is unknown at this time. Coleen will keep the Committee. members up-to-date as this develops.

PDL Formulary – Overarching goal through the Division to streamline processes and different aspects of the benefit plans between Fee-For-Service and Managed Care. The PDL has received the most feedback from physicians and providers. We cannot have the exact same formulary for both FFS and MC, but we can have the same look and feel between the two. This will result in less effort to look at and review the two because the reviewers will be used to the same look and their eyes will be trained. HP and Catamaran have reworked and created new Fee-For-Service formulary to match the existing Managed Care formulary. Draft formulary was provided to the Committee. Carl Jeffery of Catamaran suggested that the Committee. provide feedback on the formulary and is open to suggestions for any needed changes and recommendations. Beth Slamowitz noted the addition of indicators for quantity limits, age limits, diagnosis codes, PA codes etc. This was a result of changing the formulary to read in a very similar way to the existing Managed Care formularies.

Committee members reappointment – Several members are up for reappointment. Coleen advised that reappointments do not go through her office, but rather the Governor's office. Reappointments will need to be completed before the next Committee. meeting in June 2015.

Discussion / Comment: None

V. **FOR POSSIBLE ACTION**: Discussion of Medicaid Services Manual Chapter 1200 regarding preferred antidepressants

Carl Jeffery – Catamaran – Medicaid Services Manual Chapter 1200 dictates what people need to move to a non-preferred agent. The PDL Exception Criteria was presented and Carl noted that in the list of criteria, #7 is not a good indicator of Continuity of Care due to the possibility that a patient could be taken off their medication after 90 days or be forced to switch to something else.

Carl asked the Committee for their opinions on changing the wording for Criteria #7. Possibly removing the 90 day requirement and saying if the patient comes out of an acute care hospital stabilized on meds, they can continue on those meds indefinitely. These same criteria are true for atypical antipsychotics, anticonvulsants, and antidiabetic medications. The wording is odd that they called out only antidepressants with these criteria.

Coleen added that maybe there should be an institutional clause added to the criteria. Institutional Continuity of Care. She asked the Committee if they want the patients after 90 days to have to change to a PDL drug or do they want them to continue with the regimen they have. For example, one suggestion, for continuity of care from discharge from an institution, the recipient may be grandfathered on that medication. The suggestion is to change the class and the timeframe. In the very beginning, antidepressants were the original to be reviewed. Atypical and typical were not being reviewed. The antidepressant review was deferred over to the DUR Board. The DUR Board made the first review on this. The goal is Continuity of Care from discharge from an institution. Coleen suggested that the wording be changed to eliminate the distinguishing factor of being a specific class of psychotropic medication and the timeframe. Our Senior Deputy Attorney General wants the change to come through the P&T Committee..

MH: A continuity of care clause for psychotropic medications for discharge from an institution, grandfather those patients who have been discharged from an institution by allowing them to remain on their discharge regimen medication even after the initial 90 days.
Motion seconded., JA.
Committee voted: Ayes across the Committee.
Motion approved.

VI. NEW DRUG CLASSES

A. AGENTS USED TO TREAT OPIOID ADDICTION

1. **Public Comment: Dr. Pam Vincent** – Indivior – presented some important changes in the prescribing information that occurred last spring for Suboxone sublingual **No questions from the Committee.**

Public Comment - Lee Marx: State Government Executive with Orexo – Manufacturer of Zubsolv – a drug under a new drug class being considered today. Mr. Marx is asking to include Zubsolv as a preferred drug on the State's PDL. He presented a hand-out to the Committee.

Question from Committee: When Zubsolv is prescribed, does the physician have to have an X number?

Marx: Yes, when it is being used in the treatment of opioid dependency. Committee. member: This can be circumvented when a prescriber adds the amount and "As needed for pain". **Marx:** Yes, a physician can write whatever prescription they want, so they can write for pain.

Question from Committee: As a pharmacist, we are only allowed to dispense the products if the physician has an X number, or if the directions state specifically "As needed for pain." So any physician can write the prescription, and there is no control. We don't know who it is for. We don't know if it's for a dependency, or is it just for pain?

Marx: We would support the motion for any Zubsolv product, for this class of drug, in this category, to be only used for opioid dependency.

Question from Committee.: Could we attach a certain ICD-9 code to allow this drug to be used for dependency rather than for pain?

Marx: I would ask the State of Nevada to add that specification.

Coleen covered the meeting ground rules.

Public Comment - Cynthia Patterson – Medical Science Liaison with
 BioDelivery Sciences International: Speaking to the rationale regarding access of
 Bunavail to the appropriate Nevada Medicaid patients.

No questions from the Committee.

3. **Drug Class Review Presentation** – Catamaran – Carl Jeffery - 4 agents used to treat opioid addiction – Suboxone, Bunavail, Subsolv, and Buprenorphine/Naloxone. Catamaran recommends that these drugs be considered clinically and therapeutically equivalent.

DF, Motion: Approval of all agents in this class being considered clinically and therapeutically equivalent.

Motion seconded.

Committee Voted: Ayes across the Committee. Motion approved.

Catamaran recommends that the Suboxone and the Bunavail be made preferred and then the Buprenorphine/Naloxone and Zubsolv be made non-preferred on the PDL. The reason for this is that the Suboxone has the gross market share at this point. To shift that would be overtly difficult and the Bunavail because it has the abuse deterrent technology in it.

Question from the Committee: Do all of them still require Prior Authorization? **Carl:** Yes, they all still require Prior Authorization.

Question for the Committee: We've seen with some of these drugs that they maybe more tolerant by patients. Is this reflected in the success rate of treatment plans?

Carl: There haven't been any reports of patients dropping out of treatment due to how the medication is administered (holding pill under tongue vs. film).

Question from the Committee: You have to get a Prior Authorization for either preferred or non-preferred, so what is the difference?

Carl: For the non-preferred, you'd have to meet both criteria. You'd have to meet the clinical criteria and the non-preferred criteria. In essence, to get Zubsolv, if this motion were to go through, which is what we recommend, they would have to meet their criteria which is in the chapter 1200 designed by the DUR Board. In addition, they would have to try or have some contraindication as to why they can't take the two preferred agents.

Motion: Approve the drug preferred/non-preferred as presented. Motion seconded. Committee Voted: Ayes Across the Committee. Motion approved.

B. INHALED AMINOGLYCOSIDES FOR THE TREATMENT OF CYSTIC FIBROSIS

1. **Public Comment:** None.

Drug Class Review Presentation – Catamaran – Tobramycin is the only drug currently being reviewed today. There are a couple different dosage forms and that is where they differ. Three agents are nebulized products and then there is the addition of the Tobi Podhaler. Catamaran recommends to consider these all clinically and therapeutically equivalent. No head-to-head trials have seen one agent over the other.

Questions: None. Motion: Consider all drugs in the class clinically and therapeutically equivalent. Motion seconded. Committee. Voted: Ayes Across the Committee. Motion approved.

Catamaran's recommendation is to accept all drugs in this class as preferred. This is simply to provide access to this vulnerable population.

Questions: None. Motion: Approve all drugs in this class as preferred. Motion seconded. Committee Voted: 7 Aye. 1 Nay. Motion approved.

VII. ESTABLISHED DRUG CLASSES

A. GASTROINTESTINAL AGENTS: PANCREATIC ENZYMES

1. **Public Comment – Barbara Glover – Cystic fibrosis Coordinator for the CF Center Southern Nevada:** Committee. was given handout. Presentation about pancreatic enzymes. Asks that ALL enzymes be added to the PDL.

Question from Committee: Have you had trouble getting the non-preferred enzymes? Glover: No trouble, asking as preemptive. Are there any on the non-preferred side that you see being used so much that it would be difficult to get the PA? Glover: The ones that are non-preferred that are written more are Pancreaze and Ultresa.

2. **Drug Class Review Presentation** – Catamaran – The reason we brought this class up is because it was recommended in the last meeting. There are no recommendations from Catamaran to change the preferred list. We recommend that all drugs be considered clinically and therapeutically equivalent.

Questions: None. Motion: Consider all drugs in the class clinically and therapeutically equivalent. Motion seconded. Committee. Voted: Ayes Across the Committee. Motion approved.

VIII. ESTABLISHED DRUG CLASSES BEING REVIEWED DUE TO THE RELEASE OF NEW DRUGS.

A. ANALGESICS: LONG ACTING NARCOTICS

1. Public Comment – Sandy Sierawski – Pharmacist in State of Nevada: – Pfizer in Medical Division – She presented on prescription misuse and abuse of opioids in this drug class. She provided a handout to the Committee. with warnings and indications for Embeda.

Public Comment – Rupa Shaw: Medical Science Liaison Purdue Pharma – presentation on Hysingla ER. She went over warnings and indications, and provided the Committee with a handout.

Public Comment – David Malickian: Director of Global Medical Affairs – Mallinckrodt Pharmaceuticals presented on Xartemis XR . This drug was placed in the category of long acting opioids , but the FDA does not consider it a long acting opioid.

Question from the Committee: Are you suggesting that we remove it from long-acting opioids? Malickian: Yes. 2. Drug Class Review Presentation – Catamaran – presented drugs, makeup, warnings, indications, and tiers.

Questions: None.

Motion: Consider all drugs in the class clinically and therapeutically equivalent. **Motion seconded.**

Committee Voted: Ayes Across the Committee. Motion approved.

Catamaran's recommendation is to make the two new drugs on the market, Embeda and Hysingla ER non-preferred at this time to see what happens with the market.

Questions: None. Motion: Motion to approve drugs that Catamaran recommended as preferred, but bring back the AD drugs for discussion and consideration next time. Motion seconded. Committee Voted: Ayes across the Committee. Motion approved.

B. DIABETIC AGENTS: SGLT-2 INHIBITORS

1. **Public Comment – Bill O'Neill:** Jardiance – He discussed warnings, indications, and study results. He requested that Jardiance be moved to preferred.

Question from the Committee: Do you see an A1C difference between Jardiance and other drugs in the category? **O'Neill:** Similar to Invokana.

Public Comment - Caroline Winn: Pharmacist AstraZenica – Medical Science Liaison. She presented on Xigduo XR. She discussed makeup, warnings, indications, and study results. She requested that Xigduo XR be added to the preferred drug list.

Public Comment – Mary Kay Queener: Medical Science Liaison with Jannssen, Invokana and Invokamet. She gave an update regarding warnings and indications. She encouraged the Committee to add Invokamet to the PDL.

2. **Drug Class Review Presentation** – Catamaran – Reviewing Xigduo XR – Dr. Jeffery discussed studies. Catamaran recommended to the Committee to consider all drugs in the class clinically and therapeutically equivalent.

Questions: None.

Motion: Consider all drugs in the class clinically and therapeutically equivalent. Motion seconded. Committee Voted: Ayes Across the Committee. Motion approved. Catamaran recommended to make the new Xigduo XR non-preferred and keep the rest the same because each product in the combination is available independently.

Questions: None. Motion: Approve Catamaran's recommendation. Motion seconded. Committee Voted: Ayes across the Committee. Motion approved.

- C. DIABETIC AGENTS: INCRETIN MIMETICS
 - 1. **Public Comment:** None.

2. **Drug Class Review Presentation** – Catamaran –The new drug in the class is Trulicity. Dr. Jeffery went over dosage, administration, and clinical information.

Questions: None.

Motion: Consider all drugs in the class clinically and therapeutically equivalent. Motion seconded. Committee Voted: Ayes Across the Committee.

Motion approved.

Catamaran's recommendation is that the new agent Trulicity be considered nonpreferred and keep the rest of the medications the same.

Questions: None. Motion: Approve all drugs in this class as preferred. Motion seconded. Committee Voted: Ayes across the Committee. Motion approved.

D. DIABETIC AGENTS: OTHER AGENTS

1. **Public Comment - Dr. Alex Morray PhD,** for Cycloset. He discussed makeup, warnings, indications, and the study results.

Drug Class Review Presentation – Catamaran – Dr. Jeffery discussed Cycloset, and the study results. Catamaran recommended that these drugs in the class be considered clinically and therapeutically equivalent.

Questions: None. Motion: Consider all drugs in the class clinically and therapeutically equivalent. Motion seconded. Committee Voted: Ayes Across the Committee. Motion approved. Catamaran's recommendation is to make Cycloset non-preferred.

Questions: None. Motion: Make Cycloset non-preferred. Motion seconded. Committee Voted: 6 Ayes. 2 Nays.

Motion approved.

E. RESPIRATORY: INHALED ANTICHOLINERGIC AGENTS

1. **Public Comment – Bill O'Neill:** Spiriva Respimat. He discussed the Respimat device, requesting the Committee consider putting the Respimat device on the PDL.

Question from the Committee: Do you have the studies that show less hospitalizations with the Spiriva medication? **O'Neill**: Yes.

Public Comment - Julia Harder, Pharmacist, AstraZeneca. She discussed Tudorza., giving an overview including clinical data. She provided indications, warnings, and studies, and requested Tudorza be included on the PDL.

2. **Drug Class Review Presentation** – Catamaran – Dr. Jeffery discussed the two new agents, Incruse Ellipta and Spiriva Respimat. He gave an overview of studies, indications, and warnings. Catamaran recommends that the agents in this class be considered clinically and therapeutically equivalent.

Questions: None. Motion: Consider all drugs in the class clinically and therapeutically equivalent. Motion seconded. Committee. Voted: Ayes Across the Committee. Motion approved.

Catamaran's recommendation is the Spiriva Respimat and the Incruse Ellipta be considered non-preferred and the rest stay the same.

Questions: None. Motion: Accept Catamaran's recommendations for the PDL as indicated. Motion seconded. Committee Voted: Ayes across the Committee. Motion approved.

F. RESPIRATORY: LONG ACTING BETA ADRENERGICS

1. Public Comment – Bill O'Neill discussed Striverdi Respimat.

Public Comment – Pharmacist Akshaya Patel for Mylan discussed Performist. It is not listed on the PDL on either the preferred or the non-preferred side. An overview was presented including an overview of the drug, warnings, indications, and study results.

2. Drug Class Review Presentation – Catamaran – Dr. Jeffery discussed drugs in this class. He gave study results, warnings, and indications. Catamaran would like to recommend that all drugs in this class be considered clinically and therapeutically equivalent with the addition of the Performist.

Questions: None.

Motion: Consider all drugs in the class clinically and therapeutically equivalent with the addition of Performist.

Motion seconded.

Committee Voted: Ayes Across the Committee. Motion approved.

Catamaran's recommendation is to include the Striverdi and Performist as nonpreferred and keep the rest of the class the same.

Questions: None. Motion: Accept Catamaran's recommendations for Striverdi and Perfomist as nonpreferred and keep the rest of the class the same. Motion seconded. Committee Voted: Ayes across the Committee. Motion approved.

G. RESPIRATORY: INHALED CORTICOSTEROIDS/NEBS

1. Public Comment - None

2. Drug Class Review Presentation – Catamaran – Dr. Jeffery discussed the old and new products on the market. He presented indications, warnings, and study results. Catamaran recommends that all agents in this class of drugs be considered clinically and therapeutically equivalent.

Questions: None.

Motion: Consider all drugs in the class clinically and therapeutically equivalent.Motion seconded.Committee Voted: Ayes Across the Committee.

Motion approved.

Catamaran's recommendation is to make Arunuty Ellipta and Aerospan HFA nonpreferred and leave all other drugs the same.

Questions: None. Motion: Accept Catamaran recommendations. Motion seconded. Committee voted: Ayes across the Committee. Motion approved.

H. PULMONARY ARTERIAL HYPERTENSION: ORAL AGENTS

1. **Public Comment – Kirk B. Lane,** UT, discussed Orenitram. He provided studies, warnings, indications, and dose information. He requested Orenitram be placed on the PDL.

Public Comment – Dr. George Yasutake, Actelion discussed Opsumit , including studies and outcomes.

2. Drug Class Review Presentation – Catamaran – Dr. Jeffery discussed drugs in this drug class including drug trials. Catamaran recommended that the drugs in this class be considered clinically and therapeutically equivalent.

Questions: None.

Motion: Consider all drugs in the class clinically and therapeutically equivalent. Motion seconded. Committee Voted: Ayes Across the Committee. Motion approved.

Catamaran's recommendation is to consider the new product Orenitram as nonpreferred and keep the rest of the drugs on the list as is.

Questions: None. Motion: Approve Catamaran's recommendation. Motion seconded. Committee voted: Ayes Across the Committee. Motion approved.

I. ANTIEMETICS: ORAL, 5-HT3S

1. **Public Comment – Theresa Beukert**, Eisai Pharmaceuticals, discussed the makeup, dosage, warning, studies, and indications for Akynzeo .

2. Drug Class Review Presentation – Catamaran – Dr Jeffery discussed Akynzeo. Catamaran made the recommendation that the drugs in this class be considered clinically and therapeutically equivalent.

Questions: None.

Motion: Consider all drugs in the class clinically and therapeutically equivalent. **Motion seconded.**

Committee Voted: Ayes Across the Committee. Motion approved.

Catamaran's recommendation is to make Akynzeo non-preferred and leave the other drugs as they are.

Questions: None. Motion: Approve Catamaran's recommendations. Motion seconded. Committee Voted: Ayes Across the Committee. Motion approved.

J. GASTROINTESTINAL AGENTS: ULCERATIVE COLITIS

1. **Public Comment – Ed Himenson,** discussed Apriso, including indications, dosage, makeup, studies, and warnings.

2. Drug Class Review Presentation – Catamaran – Dr. Jeffery discussed Colazal and Giazo, as well as Balsalazide. He discussed studies, the differences between the drugs, and the dosages. Catamaran made the recommendation that the drugs in this class be considered clinically and therapeutically equivalent.

Questions: None.

Motion: Consider all drugs in the class clinically and therapeutically equivalent. Motion seconded. Committee Voted: Ayes Across the Committee.

Motion approved.

Catamaran's recommendation is to consider the generic Balsalazide as preferred and keep Colazal and Giazo as non-preferred.

Questions: None. Motion: Approve Catamaran's recommendation. Motions seconded. Committee Voted: Ayes Across the Committee. Motion approved.

K. ANDROGENIC AGENTS

2. **Public Comment** – None.

Drug Class Review Presentation – Catamaran –Dr. Jeffery discussed Striant, the application, dosage, and efficacy. Catamaran makes the recommendation that the drugs in this class be considered clinically and therapeutically equivalent.

Questions: None. Motion: Consider all drugs in the class clinically and therapeutically equivalent. Motion seconded. Committee Voted: Ayes Across the Committee. Motion approved.

Catamaran's recommendation is to make Striant non-preferred and keep the rest of the list as is.

Questions: None. Motion: Approve Catamaran's recommendation. Motion seconded. Committee Voted: Ayes across the Committee. Motion approved.

L. HEPATITIS C AGENTS - ANTIVIRALS: HEPATITIS C POLYMERASE INHIBITORS/COMBINATIONS

1. **Public Comment –** None.

2. Drug Class Review Presentation – Catamaran – Dr. Jeffery discussed Harvoni and Viekira Pak. He provided an overview of Hep-C. And he discussed indications, dosage, and guidelines of Harvoni and Viekira Pak. Catamaran makes the recommendation that the drugs in this class be considered clinically and therapeutically equivalent.

Questions: None.

Motion: Consider all drugs in the class clinically and therapeutically equivalent.Motion seconded.Committee Voted: Ayes Across the Committee.Motion approved.

Catamaran's recommendation is to make all the drugs in this class preferred.

Questions: None. Motion: Approve Catamaran's recommendation. Motion seconded. Committee Voted: Ayes across the Committee. Motion approved.

VIII. REPORT BY CATAMARAN ON THE NEW DRUGS TO MARKET, NEW GENERIC DRUGS TO MARKET, AND NEW LINE EXTENSIONS – Outlook is in the meeting binder.

- IX. REVIEW OF NEXT MEETING LOCATION, DATE, AND TIME
 - A. June 25, 2015
- X. PUBLIC COMMENT None.
- XI. ADJOURNMENT