SILVER STATE SCRIPTS BOARD

MEETING MINUTES

Date and Time of Meeting: Thursday, September 26, 2019 at 1:00 PM

Name of Organization: The State of Nevada, Department of Health and Human Services (DHHS), Division of Health Care Financing and Policy (DHCFP)

Place of Meeting: Springs Preserve
333 S Valley View Blvd
Las Vegas, NV 89107

ATTENDEES

Board Members (Present)
Mark Decerbo, Pharm.D., Chair
Joseph Adashek, MD
Evelyn Chu, Pharm.D.
Mark Crumby, Pharm.D.
Michael Hautekeet, RPh
Sapandeep Khurana, MD
Brian Passalacqua, MD
Aditi Singh, MD
Kate Ward, Pharm.D.

Board Members (Absent)
None

DHCFP:
Holly Long, Social Services Program Specialist III
Gabriel Lither, DAG
Beth Slamowitz, Pharm.D., DHHS Senior Advisor on Pharmacy

DXC:
KayLynn Wight, Pharm.D.

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

Public:

Lee Hochner, Amneal
David Freilich, Amneal
Justin Barnes, Ironshore Pharmaceuticals
Deb Profanty, Jazz Pharmaceuticals
Christa Cooper, Lilly
George Yasutake, Actelion
Jeana Colabianchi, Sunovian
Carol Ricciotti, Aimmune
Alen Dezia, Chiesi
Ryan Bitton, Health Plan of NV
Cynthia Albert, Merck
Erin Russell, United Health Group
Karen Meier, Novo Nordisk
Pauline Whelan, Orexo
Joe Cirrinciore, Otsuka
Joel Moerer, Alkermes
Wilson Liu, Sunovion
Jennifer Lauper, BMS
Gary Okamo, BMS
Stephanie Yamamoto, J&J
Scott Burns, J&J
Michael Walker, J&J
Trey Delay, NAMI-South NV
Don Moran, Teva
Melissa Sommers, Novartis
Amy Heidenveich, UT
Nik Seitter, Sunovion
Laura Hill, Abbvie
Bethany Boyd, Pfizer
David Gross, Pfizer
Amy Rodenburg, Allergan
Suzette Figueroa, Lilly
Marcus Conklin, S360
Sucharita Somkuoan, Otsuka

1:00 PM – 2:00 PM – Closed Executive Session

Attendance:

Mark Crumby
Kate Ward
Brian Passalacqua
Aditi Singh
Mark Decerbo
Michael Hautekeet
Joseph Adashek
Sapandeep Khurana
Evelyn Chu
Holly Long, DHCFP
Beth Slamowitz, DHCFP
Gabriel Lither, DHCFP
KayLynn Wight, DXC
Kevin Whittington, OptumRx
Carl Jeffery, OptumRx
Susan McCreight, OptumRx
Robert Earnest, OptumRx

2:00 PM – 5:00 PM – Public Meeting (Open Session)

AGENDA

1. Call to Order and Roll Call

Meeting called to order at 2:25 PM

Mark Decerbo, Chair: Good afternoon. We have a quorum so I'm calling the meeting to order. We are now the Silver State Scripts Board. Most of the committee members are the same with one new member who Holly will introduce. I will start with a roll call.

Michael Hautekeet: Community Pharmacy in Carson City, Nevada.

Brian Passalacqua: Family physician at URN School of Medicine.

Mark Crumby: Pharm.D., Pharmacy Director at Northern Nevada Hopes.

Kate Ward: Pharmacy Clinical Manager at Renown Medical Center in Reno.

Joseph Adashek: Maternal fetal medicine clinical associate professor at University of Nevada School of Medicine and co-owner of Desert Perinatal Associates.

Evelyn Chu: Pharmacy Director of Henderson Hospital.

Gabriel Lither: Senior Deputy Attorney General, counsel to the Board.

Mark Decerbo, Chair: Faculty to the University and School of Medicine.

Sapandeep Khurana: Associate faculty at University School of Medicine

Aditi Singh: Internal Medicine, UNLV School of Medicine, Associate program director for the residency.

Beth Slamowitz: Senior Policy Advisor for Pharmacy with the Department of Health and Human Services.

Holly Long: Policy Specialists for DHCFP Pharmacy Services

Kevin Whittington: Pharmacist with OptumRx

Carl Jeffery: Pharmacist with OptumRx

2. Public Comment

Mark Decerbo, Chair: Do we have any public comment on any class?

Suzette Figueroa, Eli Lilly: I am here as part of an education from the Department of Health and Human Services and Director Whitley. Following a meeting that we had with him a few weeks ago, I would like to share some information with you about our affordability programs for insulins. Over the past several years, our team has had a goal of improving affordability for patients who are on our insulins. We have done that through several programs. One milestone is known today as the Diabetes Solution Center and we opened that helpline about a year ago. The intent is that we want to make sure people could reach Lilly in case they had any questions about how they could better afford their medications. The helpline is putting real people in front of real people. We have the goal of individualizing solutions. We are helping about eight out of ten people on average since opening the help line. We are asking policy makers in the medical field to help spread the word and share this information with their patients.

Trey Delay, Group Six Partners: I'm here on behalf of the National Alliance of Mental Illness (NAMI) of Southern Nevada. Our objective is to work with the State to assure access to medication to treat mental illness. Individuals, families and the public benefit from the proper treatment of serious mental illness both in increased recovery and reduced

public expense. Prior authorization and formulary restrictions to medications are barriers to effective treatment of mental illness. Long acting medications improve patient outcomes, support recovery and reduce expensive admissions and other costs. The Federal Assistance Abuse Mental Health Services Administration has reported that prior authorizations and formulary restrictions are a barrier to treatment. We support increasing access to these medications for Medicaid recipients and is part of the general support for the Governor's desire to increase the number of community center behavioral health clinics which include medical management services.

3. Old Business

a. **For Possible Action**: Review and Approve Meeting Minutes from June 27, 2019.

Mark Decerbo, Chair: Reviewing the meeting minutes from the past meeting, do we have anyone with additions, corrections or divisions to the minutes? Seeing none, this will stand as approved with unanimous consent.

4. New Business

Mark Decerbo, Chair: We move to new business. Holly will give a status update from DHCFP.

a. Status Update by DHCFP

Holly Long: I first want to introduce Dr. Aditi Singh. She received her Doctor of Medicine from UNLV and is currently the associate program director for the internal medicine residency program at UNLV. I wanted to announce that in recognition that the international overdose awareness day Governor Steve Sisolak proclaimed that Saturday August 31 is the overdose awareness day for Nevada. The proclamation is posted on the Governor's website. On September 2, 2019, the Drug Use Review Board proposed changes from the April 25, 2019 meeting became effective. These changes include revisions to the existing policy on agents for the treatment of attention deficit hyperactivity disorder. Most of the criteria for that prior authorization has been removed. What remains is the requirement of the diagnosis. A revision was made to the existing policy on transdermal fentanyl, buprenorphine/naloxone and naltrexone and new prior authorization criteria for Lucemyra and Xyosted have been added.

b. **For Possible Action:** Board Discussion and Approval of Existing Preferred Drug List as Established by the Nevada Medicaid Pharmacy and Therapeutics Committee.

Mark Decerbo, Chair: We need to vote to accept the existing PDL. We need a motion and a second to accept the PDL as it currently exists.

Motion and second to accept the current PDL.

Voting: Ayes are unanimous, the motion carries.

c. **Annual Review - Established Drug Classes Being Reviewed Due to the Release of New Drugs**

i. Cardiovascular Agents: Antihypertensive Agents (Calcium-Channel Blockers), Antilipemics (HMG-CoA Reductase Inhibitors [Statins])

Mark Decerbo, Chair: Do we have any public comment on the calcium channel blockers?

Carl Jeffery: The new medication is Katerzia, it is a liquid amlodipine, it is an easy ready to use medication for the treatment of hypertension in ages six years and older. Nothing special other than it is a pre-mixed amlodipine. The other products are shown on the list here. We have some new generics now. Optum recommends the board consider these clinically and therapeutically equivalent.

Motion and second to accept the class as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Optum recommends Katerzia be made non-preferred and then remove a couple products that are no longer on the market, Dynacirc CR, Nifediac CC and Nifedical XL, so they would be removed.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: The next class is the HMG-CoA reductase inhibitors or Statins. Do we have public comment?

Carl Jeffery: Ezallor is the new agent in this class. It is similar to Crestor, rosuvastatin except it comes in a capsule. Same indication as Crestor. Here is the list of all the products in this class. Optum recommends the board consider this class clinically and therapeutically equivalent.

Motion and second to accept as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: The new medication, Ezallor, Optum recommends be made non-preferred. Advicor is no longer made, so that should be removed and then move the fluvastatin products both extended release and regular release to non-preferred and then more cleanup, Lescol, Liptruzet, Mevacor and Simcor are no longer available, so those will be removed.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

ii. Psychotropic Agents: ADHD Agents, Psychostimulants (Narcolepsy Agents)

Mark Decerbo, Chair: We move to ADHD agents, do we have any public comment?

Justin Barnes, Senior Medical Liaison with Ironshore Pharmaceuticals. Jornay PM just came to market, it was approved in August 2018. It came to market about three months ago in the middle of June. The important things to note about Jornay PM. Jornay PM is the first and only ADHD medication dosed at night. The importance of that comes with the DELEXIS delivery system. DELEXIS delays release and absorption of methylphenidate for about eight hours post dose which coincides nicely for when most wake up. Then it ramps up to get therapeutic levels after waking. It carries a black box warning for dependence. Jouney PM was originally created because we know parents

reported difficult mornings with kids with ADHD. DELEXIS is a bead with methylphenidate layers and takes 8-10 hours for the whole process. Clinical efficacy trials reviewed demonstrating improvement in the morning and evening. Adverse events are in line with other methylphenidate products.

Carl Jeffery: A few new products, Evekeo ODT. We have Evekeo already, this is an orally disintegrating tablet. Same medication and starting dose, similar to the other products. Mydayis is a little different. It is approved for 13 years of age and older, but it is supposed to last up to 16 hours. We heard about Jornay PM that is dosed in the evening. I have all the available products on the slide here with the new ones. Optum recommends the board consider these clinically and therapeutically equivalent.

Motion and second to accept as clinically and therapeutically equivalent.

Voting: Ayes are unanimous. The motion carries.

Carl Jeffery: Optum recommends swapping brand name Adderall XR to non-preferred but make the generic preferred. Removing Dextrostat and Methylin ER as they are no longer on the market. The new medications, Evekeo ODT, Mydayis and Jornay PM added as non-preferred. There is a product Relexxi and Methylphenidate tab ER, it seems to be a generic Concerta, but we recommend adding it as non-preferred.

Sapandeep Khurana: What about Kapvay?

Carl Jeffery: It is no longer rebatable, so they are not available to Medicaid.

Sapandeep Khurana: The Concerta and the generics, we talked about these before. There are some differences, the generic is preferred, but the brand is non-preferred. And Daytrana, the only non-oral product is non-preferred. The Brand Concerta has a more reliable profile. The Daytrana has a smoother action profile. There is nothing else like it.

Mark Decerbo, Chair: Are there any other restrictions on Daytrana?

Carl Jeffery: There is nothing specific for Daytrana, there is general criteria for the ADHD class.

Mark Decerbo, Chair: We have some discussion for the different delivery.

Sapandeep Khurana: I would like to make a motion to move Daytrana to preferred.

Seconded.

Voting: Ayes are unanimous, the motion carries.

Sapandeep Khurana: I would make a motion to make Concerta brand name preferred along with the generic methylphenidate ER. There are no head-to-head studies comparing the brand to the generic, but the brand is more reliable profile.

Seconded.

Voting: Ayes are unanimous, the motion carries.

Motion to accept the remaining recommendations as presented.

Seconded.

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: Our next topic is Narcolepsy agents, do we have public comment?

Deb Profant, Jazz Pharmaceuticals: Provides information on Sunosi including indication, dosage forms, dosage, DEA Schedule, clinical studies demonstrating effectiveness, adverse events and safety. Requests adding Sunosi as preferred.

Mark Decerbo, Chair: Any questions for the speaker? Any other commentary?

Carl Jeffery: We heard about Sunosi already. Discusses different indications for products, dosing for different products. The generics available are Nuvigil and Provigil. Optum recommends the Board consider these clinically and therapeutically equivalent.

Motion and second to accept as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Optum recommends make brand Nuvigil preferred and the generic armodafinil and Sunosi as non-preferred.

Mark Decerbo, Chair: We have the PDL as presented. Any discussion?

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

d. **Annual Review – Established Drug Classes**

i. Analgesics: Opiate Agonists (Opiate Agonists - Abuse Deterrent)

Mark Decerbo, Chair: Is there any public comment?

Carl Jeffery: This is a challenging class. We have discussed the FDA process for abuse deterrent. We only include products approved by the FDA in this class. This slide shows the different abuse deterrent properties. Most are physical barriers to reduce crushing. None have generics approved. The company that makes Arymo ER is stopping production. Optum recommends the board consider these clinically and therapeutically equivalent.

Motion and second to accept as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Embeda has been preferred for a long time. Optum recommends moving Xtampza ER to preferred and Hysingla ER and Morphabond to non-preferred.

Motion and second to accept the PDL list as presented.

Mark Decerbo, Chair: I will add comment, Morphabond has been well accepted by the community, I think Morphabond may have a place on the preferred list.

Evelyn Chu: Is Morphabond better than Embeda?

Carl Jeffery: There are not any studies comparing them, they both have morphine that is shown equivalent. They have different abuse deterrent properties.

Kate Ward: I withdraw my initial motion.

Brian Passalacqua: I make a motion to include Morphabond as preferred and accept the remaining recommendations.

Second

Voting: Ayes: 5, Nays: 2, the motion carries.

ii. Anti-infective Agents: Aminoglycosides (Inhaled Aminoglycosides), Antivirals, Anti-hepatitis Agents (Polymerase Inhibitors/Combination Products), Antivirals (Influenza Agents), Macrolides

Mark Decerbo, Chair: Any public comment on inhaled aminoglycosides?

Carl Jeffery: This is the aminoglycoside class. All the same active ingredient, same indication. The Tobi Podhaler is the only one that is a little different in that it is administered through a unique device rather than a nebulizer. Optum recommends the board consider these clinically and therapeutically equivalent.

Motion and second to accept the class is clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Optum recommends moving Tobi Podhaler to non-preferred and keep the rest of the class the same.

Mark Decerbo, Chair: Do we have any discussion?

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: Hepatitis C agents. Any public comment?

Carl Jeffery: We have seen this class several times before. The current medications have been effective at getting rid of Hep C in Nevada. Optum recommends the board consider the class as clinically and therapeutically equivalent.

Motion and second to accept the class as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: We are moving some products that are not used as much or do not have the wide indication as the other to non-preferred, moving Sovaldi and Zepatier to non-preferred.

Mark Decerbo, Chair: I think Optum is doing a good job at managing this class.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: Do we have public comment for the Influenza Antivirals?

Carl Jeffery: The only head-to-head study was the Capstone trial comparing Tamiflu to Xofluza. They had similar outcomes. It comes down to taking one dose vs. taking five doses. Optum recommends the board consider this class clinically and therapeutically equivalent.

Motion and second to accept the class as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Optum recommends a few changes. Moving generic Tamiflu, Oseltamivir capsules and Suspension to preferred, the brand Tamiflu to non-preferred and moving Xofluza to non-preferred.

Mark Decerbo, Chair: We have the recommendation from Optum. We heard the Xofluza is similar to Tamiflu in efficacy, it is just the different dosing.

Sapandeep Khurana: I think there is some benefit to taking one dose verses the multiple doses.

Mark Decerbo, Chair: Any other comments, I think the one dose Xofluza is worth discussing.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: Next is Macrolides, do we have any public comment?

Carl Jeffery: When we brought this up, we thought there would be some changes. I heard there were some challenges in getting erythromycin in the pharmacies, but I have not heard that lately. Optum recommends the board consider the class clinically and therapeutically equivalent.

Motion and second to accept the class as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Optum does not have any recommended changes to the class.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

iii. Biologic Response Modifiers: Immunomodulators (Targeted Immunomodulators)

Mark Decerbo, Chair: Next is Targeted Immunomodulators. Do we have public comment?

Laura Hill: My name is Laura Hill, I'm with medical affairs with Abbvie. We have two products that are both new, Rinvoq and Skyrizie. Rinvoq was just approved about a month ago. Discusses indication, safety, clinical trials demonstrating superiority to Humira and methotrexate, remission rates, black box warnings, common adverse events. Covers Skyrizi indication, dosing, clinical trials, superiority to Stelara and Humira, no black box warning. Asks for questions and asks the board to make the products preferred since they are shown superior.

Mark Decerbo, Chair: Any other comment?

Carl Jeffery: Laura gave us a good overview. I have on the slide a brief overview of the two products and the studies. I am showing a graph of the different indications for the different products. The preferred products are highlighted showing we do have all the indications covered. Our exemption criteria does allow a non-preferred product if it has a unique indication. Optum recommends the board consider this class clinically and therapeutically equivalent.

Motion and second to accept the class as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: This is where it gets challenging. Dupixent really should be with the monoclonal antibodies for asthma. Therefore, we will remove it from this class. Optum recommends moving Entyvio, Ilumya, Reflexis and Siliq to preferred and Inflectra to non-preferred and add the two new products Rinvoq and Skyrizi as non-preferred.

Mark Decerbo, Chair: We have the proposed PDL. We have discussed this group and trying to fit them into a single group.

Kate Ward: I would like to have the board make a strong statement about bio-similars being part of the preferred drugs list and make Inflectra staying preferred. I would like to make that motion.

Mark Decerbo, Chair: We have a motion on the floor to keep Inflectra as preferred.

Second.

Joseph Adashek: Can you let me know why you are making that recommendation?

Kate Ward: Inflectra and Renflexis are bio-similars for Remicade and used for multiple indications. I feel they are equivalent and should be used interchangeably and be able to have patients go to where they can get these administered.

Mark Decerbo, Chair: The board really has not addressed the bio-similar.

Kate Ward: It is a balance of not having to infuse one over the other because the patient has Medicaid. The infusion suite may only have one of those products available.

Mark Decerbo, Chair: Is it more of an access or interchangeability?

Kate Ward: It would be both, we would be supporting the use of biosimilars that we should be promoting and the stance that they could receive either. The FDA does not recognize them as interchangeable, but clinically they are. The infusion centers may not have both available. So, the Medicaid population may be limited depending on the infusion location.

Evelyn Chu: The list does support the use of biosimilars, we do have them listed.

Kate Ward: It does not call them out as biosimilars.
Mark Decerbo, Chair: I guess that is the question to the board. We have a motion to move Inflectra to preferred.

Voting: Ayes: 5 Nays: 2, the motion carries.

Mark Decerbo, Chair: We now have the PDL as presented. Any further discussion?

Motion and second to accept the recommendation with the change with Inflectra as preferred.

Voting: Ayes: 5, Nays:2, the motion carries.

iv. Cardiovascular Agents: Antihypertensive Agents (Angiotensin II Receptor Antagonists), Vasodilators (Oral), Antilipemics (Omega-3 Fatty Acids)

Mark Decerbo, Chair: The next class is angiotensin II receptor antagonists. Do we have any public comment?

Carl Jeffery: The list does show the combination products as well as the single-entity agents. Optum recommends the board consider the class clinically and therapeutically equivalent.

Motion and second to accept the class as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Optum recommends moving the brand Diovan and Diovan HCTZ to non-preferred and no other changes to the class.

Mark Decerbo, Chair: I think losartan is the most widely used. But what are the boards thought about just having a single agent as preferred.

Kate Ward: I am concerned about a single agent. We could move valsartan to preferred to give another option.

Evelyn Chu: We have had some drug shortages with both of these. What happens if these are not available.

Carl Jeffery: That is part of our policy, if there is a drug shortage, we could allow alternatives in the system if it was an extended shortage.

Kate Ward: I make a motion to add Valsartan and valsartan HCTZ as preferred and accept the remaining list.

Second

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: The next class is the oral vasodilators. Do we have any public commentary?

George Yasutake, Actelion Pharmaceuticals: Speaks on Opsumit and Uptravi. Discusses indications, progression of disease, patient management, treatment options and benefits, the need for early access to different therapies. Provides benefits of Uptravi on monotherapy and combination. Provides information for Opsumit, disease benefits with treatment, reduces hospitalization and long-term benefits, safety concerns, black box warnings. Summarizes agents and their benefits and indications. Asks the board to add Opsumit and Uptravi as preferred.

Mark Decerbo, Chair: Any other comment?

Carl Jeffery: Ambrisentan, a new generic for Letairis. Nothing really special. There are other generics available for some classes. Optum recommends the board consider this class clinically and therapeutically equivalent.

Motion and second to accept the class as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Optum recommends the class remain the same with the new generic ambrisentan added as non-preferred.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: The next class is Omega-3 Fatty Acids. Any public commentary?

Carl Jeffery: We had more utilization for these than I anticipated. Omtryg is no longer on the market, so we will remove that one. Optum recommends the board consider the class clinically and therapeutically equivalent.

Motion and second to accept as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Optum recommends making the generic omega-3 acid as preferred and the brands Lovaza and Vascepa as non-preferred.

Motion to have Vascepa remain as preferred on the PDL.

Second

Mark Decerbo, Chair: I support that motion, we have had some failures of other products, but Vascepa has been shown to be more effective.

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: Now to vote on the remaing class. We would have now Vascepa and omega-3 as preferred.

Motion and seconded to accept the PDL as presented with Vascepa as preferred.

Voting: Ayes are unanimous, the motion carries.

v. Dermatological Agents: Topical Anti-infectives (Topical Antivirals, Topical Scabicides), Topical Anti-inflammatory Agents (Immunomodulators: Topical)

Mark Decerbo, Chair: The next class is Topical antivirals. Do we have any public commentary?

Carl Jeffery: There is a new generic cream for Zovirax cream. Optum recommends the board consider these clinically and therapeutically equivalent.

Motion and second to accept the class as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Optum recommends moving Denavir to non-preferred and the new generic cream would be included with the acyclovir as non-preferred.

Motion and second to accept the recommendation as presented.

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: Topical scabicides, any public comment?

Carl Jeffery: There are a couple changes here. Vanalice is an OTC that is relatively new, so we want to include that one. What really prompted this review was the limited availability of Sklice. The manufacturer doesn't think it will be

available until late 2020, so the options are pretty limited. Optum recommends the board consider this class clinically and therapeutically equivalent.

Motion and second to accept the class as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Optum recommends moving Lindane and Natroba to preferred and because of Sklice's limited availability, moving it to non-preferred. The new agent, Vanalice, as non-preferred.

Mark Decerbo, Chair: We have a number of different products available. Any discussion?

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: The next class Topical Immunomodulators, any public commentary?

Dave Gross, Pfizer Medical Affairs: Provides information on Eucrisa. Discusses classification, indication, application, contraindications, safety and efficacy studies, clinical studies demonstrating improvement in patients with atopic dermatitis vs control vehicle. Speaks to benefits of Eucrisa and long-term safety. Provides information on pruritus treatment. Asks the board to retain Eucrisa on the PDL.

Mark Decerbo, Chair: Any other public commentary?

Holly Long: We have an email that has been provided to the board members and will be available on line. I have also received 11 other emails from providers speaking in support of Eucrisa.

Carl Jeffery: There is a new generic for Elidel. The indications are shown on the screen, they are very similar with Eucrisa having the first-line indication. Optum recommends the board consider this class clinically and therapeutically equivalent.

Motion and second to accept the class as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Optum recommends moving Eucrisa to non-preferred and the new generic pimecroliums to non-preferred.

Michael Hautekeet: There is a PA requirement for this whole class. Can the prescriber request the Eucrisa at the same time for non-preferred when submitting the PA request?

Carl Jeffery: If the board accepts our recommendation, they need to get a PA and step through Elidel and Protopic.

Joseph Adashek: I make a motion to keep Eucrisa as preferred. I appreciate the doctors have taken the time to write letters, that carries a lot of weight with me.

Second

Mark Decerbo, Chair: We have a motion to accept the PDL as presented except to keep the Eucrisa as preferred. I echo your comments. You look at the label and indication and prescribing, I think that is a good idea.

Voting: Ayes are unanimous, the motion carries.

vi. Gastrointestinal Agents: Antiemetics (Miscellaneous), Antiulcer Agents (Proton Pump Inhibitors [PPIs]), Gastrointestinal Anti-inflammatory Agents

Mark Decerbo, Chair: Miscellaneous antiemetics, any public commentary?

Carl Jeffery: There is a generic for Diclegis available now. Optum recommends the board consider this class clinically and therapeutically equivalent.

Joseph Adashek: I would like to make a motion, I don't know of any other indication for these products to name the class to antiemetics in pregnancy instead of miscellaneous.

Gabriel Lither: This isn't something that is on the agenda, but how are the names of the classes established?

Carl Jeffery: I try to stick with standard names using Clinical Pharmacology therapeutic classes.

Gabriel Lither: So, it is Optum that comes up with the classes. I think you can make the change without a motion.

Motion and second to accept the class as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Optum recommends the new generic doxylamine/pyridoxine tab be added as non-preferred and the rest of the class remain the same.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: Proton Pump Inhibitors, any public commentary?

Carl Jeffery: This is a little busy, there are a lot of similar products available in this class. Optum recommends the board consider the class clinically and therapeutically equivalent.

Motion and second to accept the class as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: I tried to highlight the changes. Optum recommends changing Dexilant to preferred and generic omeprazole to preferred and Nexium to non-preferred and the new generic rabeprazole as non-preferred.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: GI Anti-inflammatory agents, any public comment?

Carl Jeffery: The only new one here is a generic for Canasa. Optum recommends the board accept the class as clinically and therapeutically equivalent.

Motion and second to accept the class as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: This looks like a big change, but all the products recommended to move to non-preferred are similar agents. Giazo is no longer available so that would be removed. Then moving Balsalazide, Delzicol, Lialda and mesalamine enema to non-preferred.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

vii. Hematological Agents: Erythropoiesis-Stimulating Agents

Mark Decerbo, Chair: Erythropoiesis-Stimulating agents. Any public comment?

Carl Jeffery: This class has not been reviewed for a while. Retacrit is a biosimilar to Procrit. Optum recommends the board consider this class clinically and therapeutically equivalent.

Motion and second to accept the class as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Optum recommends Retacrit be made preferred and Procrit as non-preferred.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

viii. Hormones and Hormone Modifiers: Antidiabetic Agents (Biguanides, Dipeptidyl Peptidase-4 Inhibitors, Incretin Mimetics, Insulins [Vials, Pens and Inhaled], Meglitinides, Sodium-Glucose Co-Transporter 2 [SGLT2] Inhibitors, Sulfonylureas, Thiazolidinediones)

Mark Decerbo, Chair: Biguanides, any public comments.

Carl Jeffery: This was a class we were limited in discussing, but now we have a little more freedom to discuss. There are not a lot of differences within the class. Optum recommends the board consider this class clinically and therapeutically equivalent.

Motion and second to accept the class as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: We have an opportunity to narrow this class down. Optum recommends moving Glucophage, Glucophage XR and Glumetza to non-preferred and Metformin ER, the generic for Glumetza, as preferred and keep the rest of the class the same.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: The dipeptidyl peptidase-4 inhibitors, there are no recommended changes, I think we can move past if there is no public comment. Unanimous consent as voted at the beginning of the meeting.

Mark Decerbo, Chair: Incretin mimetics, one thing that jumps out to me is Ozempic has some superiority outcomes including weight loss, we are starting to see more movement.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: Insulin agents, any public comment?

Carl Jeffery: There is an authorized generic for Humalog, Insulin Lispro, made by a Lilly subsidiary. The breakdown is shown on the screen for your reference. Optum recommends the board consider this class clinically and therapeutically equivalent.

Motion and second to accept the class as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Optum recommends the new insulin product, insulin lispro, be added as non-preferred and keep the rest of the class the same.

Michael Hautekeet: Humalog 100 units are preferred, people on an insulin pump use 200 because you use half as much. Could we make an exception for the 200 if it is being used for an insulin pump?

Beth Slamowitz: Pumps are covered on the DME benefit.

Michael Hautekeet: It would be just the insulin for the pump.

Beth Slamowitz: We don't have many people on a pump.

Carl Jeffery: I think it would qualify for the unique indication if it was indicated.

Mark Decerbo, Chair: So, pumps are never covered?

Beth Slamowitz: They are covered for kids.

Kate Ward: We have Toujeo and Basaglar, I wonder if we put one of them on the preferred list if that would increase the usage over Basaglar. If we made one preferred, then patients who don't want to inject every day would have an option. My proposal is to move Toujeo to the preferred list to have a long-acting insulin option.

Second.

Kate Ward: And also accept the rest of the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: Meglitinides, any comment?

Carl Jeffery: Optum recommends the drugs in this class be considered clinically and therapeutically equivalent.

Motion and second to accept as therapeutically and clinically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Now that we can make some changes, Optum recommends repaglidide be the only preferred agent and move nateglinide, Prandin and Starlix to non-preferred.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: SGLT-2 inhibitors, public comment?

Stephanie Yamamoto, Pharmacist at Janssen Pharmaceuticals: Highlights Invokana changes. Provides indication, and reduction in risk of cardiovascular disease. Discusses clinical trials demonstrating hospitalization reduction.

Holly Long: Is there other information you would like to share outside of the information for Invokana?

Stephanie Yamamoto: No, I'll give my time back to the board, thank you.

Gabriel Lither: We will invite you to speak if the Board has questions.

Carl Jeffery: Similar review as we have seen before. We have some more cardiovascular studies available now. Optum recommends the board consider these clinically and therapeutically equivalent.

Motion and second to accept as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: I think we have a favorable recommendation to move Invokamet and Xigduo XR to preferred and keep the rest of the class the same.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: Next is Sulfonylureas, public comment?

Carl Jeffery: I have the different agents broken down by generation. Optum recommends the board consider the medications in this class clinically and therapeutically equivalent.

Motion and second to accept the class as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: We have a lot of changes here, Optum recommends moving Amaryl, Chlorpropamide, Glynase, Glucotrol, Glucotrol XL, Glyburide/metformin, Glucovance, Glipizide/metformin, tolazamide and tolbutamide to non-preferred and keep the rest of the class the same.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: The Thiazolidinediones, any public comment?

Carl Jeffery: The list of products is here, Optum recommends the board consider this class clinically and therapeutically equivalent.

Motion and second to accept as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Optum recommends having the Pioglitazone as the sole preferred product and the rest of the agents be moved to non-preferred.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

ix. Neurological Agents: Anti-Migraine Agents (Calcitonin Gene-Related Peptide [CGRP] Receptor Antagonists, Serotonin-Receptor Agonists)

Mark Decerbo, Chair: Next is the CGRP class, public commentary?

Don Moran, Teva Pharmaceuticals: At the March meeting, the board elected to make Ajovy preferred. In the monograph, there is a piece of information missing to keep in mind before you make a decision. The monograph was updated as of July 1, there have been critical data that has been updated since then. There was a news release out of the National Health Service, they made a comment on the CGRP. There is paragraph, consider the data and consider keeping Ajovy as preferred. In the paragraph it states there is limited analysis about the CGRP class and trials examining the efficacy and patients who failed two or more prior preventive therapy. However, available data suggests these patients may achieve greater reductions in migraine headaches and frequency further research is warranted. The National Health Service today agreed. They decided to not add one CGRP to their national formulary because patient study in the phase three trials are not reflective of the population in the UK. In addition, Teva, the European Medicines Association agrees with Optum's statement that more research is needed. For that reason, we conducted additional phase three research. That data is published in Lancet on August 16, 2019. It looks at the results of a subset of patients that failed between two and four therapeutic classes of preventive agents and tracked over a 12-week period their response to therapy. Patients were randomized to monthly or quarterly Ajovy or placebo. At the end of that time frame the analysis revealed that those patients who had failed higher coursed including Botox, they had about a 35% reduction in symptoms thereby fulfilling the hypothesis that patients with recalcitrant disease did indeed respond. That was successful enough for us to secure approval for a product in Europe. The last thing, the monograph states that caution should always be exercised for the use of these agents due to the lack of long-term safety data. We have now published and made available 18 months of experience with about 1500 patients revealing there are no signals of liver toxicity, anaphylaxis, severe hypersensitivity and very low rates of drug antibody. I agree with Optum authors. Ajovy is the only agent in the class that can be administered quarterly which may fulfill the niche for patients non-adherent to treatment.

Mark Decerbo, Chair: With the new information, what are the thoughts from the Committee to bring this back at the next meeting? Should we deliberate and vote or have it brought back?

Motion to keep the PDL as previously with two agents preferred and bring back in December. Seconded.

Voting: Ayes are unanimous, the motion carries.

Mark Decerbo, Chair: Triptans, public comment?

David Freilich, Medical Department with Amneal Pharmaceuticals: I'm here to talk to you about Zomig nasal spray. Triptans are the gold standard for treating migraine. Different people respond well to different triptans. It is important to maintain access to multiple options. Papers report between 50 and 90% of patients have nausea and or vomiting and about 30% have nausea. Gastric Stasis and nausea and vomiting are key features in migraine. It is important to have non-oral routes. I would like to request Zomig and sumatriptan as preferred agents in the nasal spray.

Lee Hochner, National Account Manger with Amneal Pharmaceuticals: When the Board reviewed this class last year, I believe the recommendation was to add Zomig nasal spray to non-preferred, but I don't see it listed there. If you want to add a nasal spray as a preferred agent, I ask you add Zomig nasal spray.

Mark Decerbo, Chair: Are you suggesting there might be an error of omission?

Lee Hochner, National Account Manger with Amneal Pharmaceuticals: I believe so.

Mark Decerbo, Chair: I remember having a discussion of alternate sites of administration.

Kate Ward: We did have a discussion of having a nasal spray on the preferred drug list.

Holly Long: We will go back and check on that.

Carl Jeffery: There are two new products, Tosymra and Migranow Kit. Tosymyra is another sumatriptan nasal kit. The Migranow is not actually approved by the FDA, so it will not be included in further discussion. Optum recommend the board consider this class clinically and therapeutically equivalent.

Motion and second to accept as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Optum recommends adding Relpax and the new product Tosymra as non-preferred.

Mark Decerbo, Chair: We will go back and look at the minutes, I remember talking about a nasal spray and if there is any doubt, we can bring this back for December.

Carl Jeffery: There is another new product coming out, so we will likely see this again at the next meeting anyway.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

x. Psychotropic Agents: Antipsychotics (Atypical Antipsychotics – Oral)

Mark Decerbo, Chair: Atypical Antipsychotics, public comment?

Sucharita Somkuren, Managed Market Liaison with Otsuka: I'm here to provide information on Abilify Mycite to the Board. The suboptimal response to treatment of patients with serious mental illness and may be due to several factors or alone in combination of under dosing and limited medication effectiveness despite adherence. Covers approval and indication of Abilify Mycite, to track drug ingestion. Covers Mycite app and provider access to data. Provides information on clinical data and offers reasons for use. Indicates how the product will be introduced to providers and patients. Speaks to the Black Box warning for Abilify. Abilify Mycite is a drug and device combination that communicates with a patch and a medical software application.

Carl Jeffery: The new product we have is Abilify Mycite, we just heard about it. Nothing really new or changed otherwise. Optum recommends the board consider the class clinically and therapeutically equivalent.

Sapandeep Khurana: Where do the injectables fall in this list?

Carl Jeffery: We talked about adding the injectable antipsychotics and the board decided not to add it as a class. That is something we can bring back if the board is interested in adding now. If there is no class on the PDL, it is not managed, and everything essentially goes through as preferred.

Motion and second to accept as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Optum recommends the new Abilify Mycite be added as non-preferred and the rest of the class remain the same.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous. The motion carries.

xi. Respiratory Agents: Long-Acting/Maintenance Therapy

Mark Decerbo, Chair: Respiratory agents, long acting/maintenance therapy, any public comment?

Wilson Liu, Medical Science Liaison, Sunovian Pharmaceuticals: Presenting a clinical overview of Utibron Neohaler for COPD. There is a medical need for medical treatment of COPD. About 30% of patients report nighttime symptoms three times per week. Errors in device handling can impact delivery and overtime reduce the clinical benefit. Covers Utibron indication, device and description and instruction for use. Clinical studies discussed and benefit compared to placebo. Please consider adding Utibron Neohaler as preferred.

Carl Jeffery: We just heard about one of the new agents, the other is Wixela is a branded generic for Advair Diskus. There are too many products to fit on a single slide, I have them all listed here. Optum recommends the board consider these clinically and therapeutically equivalent.

Motion and second to accept as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: The biggest change is swapping the generic budesonide nebulizer solution for the brand Pulmicort nebulizers, we will make the budesonide generic preferred and the brand Pulmicort non-preferred and then make the two new products, Utibron and Wixela as non-preferred.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

xii. Toxicology Agents: Substance Abuse Agents

Mark Decerbo, Chair: Substance abuse agents, public comment?

Carl Jeffery: We don't have anything new in this class. Optum recommends the board consider the class clinically and therapeutically equivalent.

Motion and second to accept as clinically and therapeutically equivalent.

Voting: Ayes are unanimous, the motion carries.

Carl Jeffery: Optum recommends moving Bunavail and Zubsolv to non-preferred and leave the rest of the class the same.

Motion and second to accept the PDL as presented.

Voting: Ayes are unanimous, the motion carries.

e. **Annual Review – Drug Classes Without Proposed Changes, For Possible Action**

Carl Jeffery: This meeting is our annual review. The Board is required to review the PDL once per year. The classes listed in the agenda are classes Optum is not making any recommended changes to the current preferred drug list. Unless the Board has any classes they want to call out for discussion, the Board can approve to accept the remaining classes as one motion.

Mark Decerbo, Chair: Do we have any public comment?

Motion and second to accept the remaining classes on the PDL as-is.

Voting: Ayes are unanimous, the motion carries.

f. **Presentation, Discussion and Possible Adoption of Updated Silver State Script Board Bylaws for Possible Action**

Mark Decerbo, Chair: We are a new Board, so we have new bylaws. Can we get a brief overview of changes?

Holly Long: The last page is the most important. These have been approved by the director. We tried to make them look nicer with a table of contents. The main reason behind the change is Senate Bill 378, the changes that impact the name change from P&T to Silver State Scripts Board has been updated throughout the document. There is a change to the terms that I've taken the opportunity to update here which is separate from the Senate Bill. The terms are every two years, that is going to stay the same, we put a limit of three consecutive two-year terms, so a total of six years.

Kate Ward: Does that start from the previous committee?

Holly Long: It is going to start today once these are updated and approved since they will be approved today. Even though your appointment started before today, I won't take that into consideration until today's date. If you have already served two two-year terms, I wouldn't take that into consideration. Some language in green has been reorganized, anything red with a line through it has been removed, red type is new. We do have the cost discussion information included now as well. I did update some of the language related to the open meeting law, I removed public comment requirements. The last part is the disclosure agreement that need to be signed, you don't have to return them to me today, but for the future we ask that you have them completed at every appointment and reappointment. It is pretty basic that other boards have, especially now with our cost discussions and proprietary information shared in the meeting. I need the board to vote to approve it.

Mark Decerbo, Chair: I was looking over some stuff, section 6each of the members constituting a quorum shall vote. So, I guess going forward as the chair, since I am part of the quorum I would vote.

Gabriel Lither: I think the chair can certainly vote. People get caught up with what the chair can and cannot do, but there are not any rules that says the chair cannot vote. Sometimes we need the chair's vote depending on how many members show up to the meeting.

Holly Long: Yes, we would need your vote depending on how many we have for a quorum. I have never heard of this being a problem with other boards.

Mark Decerbo, Chair: Any other comments or questions from the Board?

Motion and second to approve the bylaws as presented.

Voting: Ayes are unanimous, the motion carries.

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

Carl Jeffery: I will be quick here. We talked about the oral CGRP for migraine coming, a new insomnia medication and something for schizophrenia all coming soon. Those are the highlights.

h. **Closing Discussion**

Mark Decerbo, Chair: Do we have any public comment on any topic?

Carl Jeffery: Our next meeting will be back here, December 5th.

Meeting adjourned.