North Dakota Medicaid Drug Use Review (DUR) Board
Meeting Minutes
September 7th, 2022

Members Present: Joshua Askvig, Andrea Honeyman, Kathleen Traylor, Amy Werremeyer, Laura Kroetsch, Kevin Martian, Kristen Peterson, Gabrielle Balf

Medicaid Pharmacy Department: Alexi Murphy, Brendan Joyce, LeNeika Roehrich, Jeff Hostetter

Old Business

A. Honeyman called the meeting to order at 1:18 p.m.; however, there were technical issues that arose in the Board meeting room. The microphones were not working, thus the members in the Board room were not heard during the meeting. L. Morgan presented the material, relayed the conversations that took place in the Board meeting room to those who joined virtually. A. Honeyman stood for T. Schmidt as Chair. L. Morgan discussed the meeting minutes from the June meeting with the Board members. There were several moments during the last Board meeting in which the microphones in the Board meeting room did not pick up voices. With this in mind, L. Morgan asked the Board members to state their name and speak up during discussion and voting from now on. The Board members agreed to this request. L. Morgan asked for a motion to approve the minutes of the June 1st, 2022, meeting. J. Askvig moved that the minutes be approved, and A. Honeyman seconded the motion. L. Morgan called for a voice vote to approve the minutes with revisions, and the motion passed with no audible dissent. Lastly, Dr. Hostetter was introduced as the Ex-Officio MD for the Department.

Review Top 25 Drugs

L. Morgan presented the quarterly review of the top 25 drugs based on total claims cost, the top 25 drugs based on the total number of claims, and the top drug classes based on claims and cost for the 2nd quarter of 2022. There were no budget updates presented during this meeting.

PDL/PA Criteria Updates

L. Morgan shared with the Board all the changes made to the Preferred Drug List since the last version of the Preferred Drug List was posted. Notable changes include adding Camzyos, Radicava, and Tegsedi to PA for the Over 3000 criteria. All PDL updates are listed in the handout for the September 2022 DUR Board meeting. When a new version of the PDL is published and posted to the website, all updates/changes made since the last version are called out at the top of the document itself.

Update to Eosinophilic Esophagitis (Dupixent)

L. Morgan presented the proposed criteria for the Eosinophilic Esophagitis section. The preferred agent requiring a clinical PA is Dupixent. Initial approval will be granted for 6 months, and renewal will be for 12 months. There was no public comment made during this section. Within the Board room, a member asked if the esophageal intraepithelial eosinophil count needed to be a requirement, considering it would require the member to receive an upper endoscopy. After further discussion, it was agreed upon that the criteria should remain. A. Werremeyer followed up asking why it was felt this information was pertinent for renewal. considering the requirement for documentation showing that the member achieved a significant reduction in dysphagia symptoms.

A. Murphy responded that even if the member no longer has symptoms of the disease, he or she may still have the disease itself. Therefore, an endoscopy is utilized to determine if the member still has eosinophilic esophagitis regardless of symptom presentation. A. Murphy stated that this topic will be investigated further and will be addressed at the next meeting whether an endoscopy is essential for renewal criteria.

Update to Bardet-Biedl Syndrome (Imcivree)

L. Morgan presented changes made to the Imcivree section in the PDL. The main addition to this section is the criteria added for Bardet-Biedl Syndrome which is a new indication for Imcivree. Additionally, the renewal criteria were updated. L. Kroetsch asked for clarification about the subsequent renewal criteria requirement for a 10% weight reduction to be achieved or maintained and whether that applies to baseline weight or weight from the prior approval. A. Murphy answered that the 10% weight reduction will be assessed from baseline weight.

Update to Heart Failure (Camzyos)

L. Morgan presented updates to the Heart Failure section regarding Camzyos. The initial approval duration was reduced from 12 months to 6 months. Initial and renewal criteria was updated, as well. During public comment, Dr. Sara Hovland from Bristol Myers Squibb gave testimony for Camzyos. Dr. Hovland presented two requests for changes to the criteria which included: 1) To remove the ≥90% oxygen saturation at rest requirement and 2) To change the concurrent medication requirement from Entresto, a beta-blocker, a SGLT-2 inhibitor, and a mineralocorticoid receptor antagonist to just a beta-blocker and a calcium-channel blocker. L. Kroetsch agreed with the requested changes, as they corresponded with the research she did. Members in the room questioned Dr. Hovland about North Dakota Medicaid's proposed criteria and how it relates to criteria seen in other states. Dr. Hovland responded that she has not seen the ≥90% oxygen saturation at rest requirement and concurrent medication requirement in other states at this time. Another question from the members in the room was if the diagnostic criteria for cardiomyopathy and heart failure were similar, in which Dr. Hovland stated that the diagnosis for HCM is typically a diagnosis of exclusion. Dr. Hovland added that there is a genetic test that can be done which can determine HCM in about 20-40% of patients and there are also subjective NYHA class symptoms that can be assessed for exclusion of any other disease state to determine a diagnosis of HCM. Lastly, the members in the Board meeting room asked Dr. Hovland about the ≥90% oxygen saturation at rest requirement being listed as an inclusion criterion for the EXPLORER-HCM trial and why it was not considered relevant for the proposed criteria. Dr. Hovland said she would look into it and get back to the Board with information.

Second Review of Presbyopia

L. Morgan presented initial and renewal criteria for Vuity. This agent will be approved for 3 months initially and 12 months for renewal. Vuity is listed as a preferred agent requiring clinical PA. During discussion, the Board members questioned if an optometrist and ophthalmologist can be listed as the prescriber or consulted prescriber instead of just an optometrist. A. Murphy responded that since this medication relates to vision, then an optometrist may be more appropriate for prescribing. G. Balf responded that since ophthalmologists can prescribe corrective lenses, then perhaps they should be included for prescribing Vuity. The Board members agreed with G. Balf; therefore, an ophthalmologist will be included in prescriber requirement criteria. Standing In for

Standing in for Chair T. Schmidt, A. Honeyman called for a voice vote to approve the updated criteria, which passed with no audible dissent.

Second Review of Cushing's Syndrome

L. Morgan presented group criteria for all agents requiring prior authorization for Cushing's Syndrome. This criterion included that the member must have failed a 3-month trial of combination treatment with ketoconazole tablets and metyrapone. There were also product specific criteria listed for Recorlev and Korlym. During public comment, Dr. Patel from Xeris Pharmaceuticals gave testimony for Recorlev. Dr. Patel respectfully requested for Recorlev to be added to the preferred drug list (PDL) without the requirement of stepping through ketoconazole and metyrapone prior to approval. The Board members within the meeting room asked Dr. Patel if it would cause the patient any harm to trial step-therapy with ketoconazole and metyrapone first, considering the cost differences between the generic products and brand name Recorlev. Dr. Patel answered that allowing patients to try a compendia-supported agent with a broad indication gives patients with adrenal issues or outside tumors more options. G. Balf asked about the enantiomers (ketoconazole and levoketoconazole) and how they may affect patients differently, specifically when it comes to liver toxicities, QT-prolongation, etc. G. Balf also address concern about Korlym not being a viable solution to some patients in regard to recent abortion laws. Dr. Patel answered that studies have found that Recorlev is more potent than ketoconazole, and in vitro, Recorlev could have less effect on liver toxicity. Additionally, Dr. Patel stated that Recorlev was found to have all of the inhibition of cortisol levels, in vitro; whereas, ketoconazole had no activity towards inhibition of cortisol levels. Standing In for Chair T. Schmidt, A. Honeyman called for a voice vote to approve the updated criteria, which passed with no audible dissent.

Second Review of Vernal Keratoconjunctivitis

L. Morgan presented initial and renewal criteria for Verkazia. For initial approval, Verkazia will be allowed for 6 months and 12 months for renewal. Verkazia was listed as a preferred agent with clinical PA required. L. Kroetsch asked about the list of agents the member can trial prior to Verkazia and if the member must trial all listed agents prior to approval. L. Morgan responded that the member could trial any agent listed rather than all agents listed under each medication class. L. Morgan stated that the wording can be adjusted to reflect the intent of the trial requirement more accurately. G. Balf also clarified that cyclosporin ophthalmic emulsion does not come as a 0.5% concentration, but rather, it comes as a 0.05% concentration. This concentration was updated to 0.05% on the handout and will be reflected in the criteria. Standing in for Chair T. Schmidt, A. Honeyman called for a voice vote to approve the updated criteria, which passed with no audible dissent.

Second Review of Wilson's Disease

L. Morgan presented product specific criteria for trientine hydrochloride and non-preferred agent criteria for Cuprimine, penicillamine capsules and tablets, and Syprine. Once Cuvrior launches in 2023, it will be added to the proposed criteria. There was no public comment. Standing In for Chair T. Schmidt, A. Honeyman called for a voice vote to approve the updated criteria, which passed with no audible dissent.

New Business

Review of Amyloidosis (Vyndaqel, Vyndamax, Tegsedi)

L. Morgan presented a review of the disease state and agents used in the treatment of amyloidosis to the Board. G. Balf asked if the member can still be on a transplant list while taking one of these agents. L. Morgan and A. Murphy both answered they did not find any information which stated the member could not be on a transplant list while taking such agents. A motion was made by A. Werremeyer to manage these medications through prior authorization. The motion was seconded by J. Askvig. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Review of Amyotrophic Lateral Sclerosis (Radicava)

L. Morgan presented a review of the disease state and agents used in the treatment of amyotrophic lateral sclerosis (ALS) to the Board. A motion was made by J. Askvig to manage these medications through prior authorization. The motion was seconded by K. Martian. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Review of Chelating Agents (Ferriprox)

L. Morgan presented a review of chelating agents and their indications to the Board. A motion was made by J. Askvig to manage these medications through prior authorization. The motion was seconded by A. Werremeyer. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Synagis Discussion

A. Murphy presented data on respiratory syncytial virus (RSV) seasonal data which was provided by the CDC. A. Murphy went on to discuss the rationale for why ND Medicaid chose the Midwest region to determine seasonality. Since North Dakota is bordered by Minnesota and South Dakota, the data will be more applicable to the members within North Dakota. The other option to choose from included Colorado which would not be a good representation of the population within North Dakota. Additionally, A. Murphy explained how ND Medicaid will define the start and end of the RSV season. The season will be defined as onset (1st of 2 consecutive weeks when percentage of PCR tests positive for RSV is > 3% and offset (Last of 2 consecutive weeks when percentage of PCR tests positive for RSV is < 3%) as reported by The National Respiratory and Enteric Virus Surveillance System (NREVSS) Midwest Region. Additionally, the decision was made to only allow 5 weight-based doses within a 6-month period. This way, members will be limited to an appropriate amount of doses, and ND Medicaid will have a more cost-effective way of monitoring Synagis distribution.

RDUR Response Letter Discussion

L. Morgan presented the updates made to the RDUR response letter to allow for a more straight-forward and less time-consuming response from providers. The reason for making this response form more user-friendly is to hopefully improve response rates amongst providers. The members within the Board room asked for “Optional” to be added to the comments section of the new response form to let the providers know they do not have to fill-out that section. The update will be made accordingly.

Retrospective Drug Utilization Review (RDUR) Criteria Recommendations

L. Morgan reviewed the RDUR criteria that were selected for review for April, May, and June (Q2 2022). Presented data included number of profiles reviewed, number of cases identified for intervention, and the number of letters sent. An overview of what RDUR interventions were identified as most prevalent for each monthly cycle was given, as well. The recommended RDUR criteria enclosed in the packet were developed from product information provided by the manufacturers and are consistent with new indications, new drugs added, and new warnings. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles. A. Honeyman moved to approve the new criteria and J. Askvig seconded the motion. Standing in for Chair T. Schmidt, A. Honeyman called for a voice vote to approve the new criteria, which passed with all present members voting to approve.

Adjournment and Upcoming Meeting Date

A. Honeyman adjourned the meeting at 3:42 pm. The next DUR Board meeting will be held December 7th, 2022, at 1:00 pm at the state capitol building.