North Dakota Medicaid Drug Use Review (DUR) Board
Meeting Minutes
June 1st, 2022

Members Present: Joshua Askvig, Andrea Honeyman, Kathleen Traylor, Amy Werremeyer, Laura Kroetsch, Tanya Schmidt, Kevin Martian, Kristen Peterson, Jennifer Iverson, Gabrielle Balf, Mary Aaland

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

Old Business

Chair T. Schmidt called the meeting to order at 1:01 p.m. Vice Chair election was held during this meeting in which T. Schmidt was nominated and voted again to serve as the Board meeting Chair for the following year. Chair T. Schmidt asked for a motion to approve the minutes of the March 2nd, 2022, meeting. J. Askvig moved that the minutes be approved, and K. Martian seconded the motion. The chair called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Review Top 25 Drugs

B. Joyce presented budget updates and 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 1st quarter of 2022. B. Joyce went on to discuss "per member per month" (PMPM) average cost which is the net of all rebates. Within the last eight quarters, the PMPM average has decreased since managed care is no longer involved in the process. However, the total expenses from 2020 to 2021 increased by 21%. B. Joyce presented the 5 drug classes which account for 75% of the cost increase. These classes include agents used for cystic fibrosis, oncology, immunomodulators, HIV, and eczema. The question was brought up about if there is a way to determine how many members will fall off once Medicaid enrollment redetermination begins again. B. Joyce answered that there is currently no way of knowing how many will fall off.

PDL/PA Criteria Updates

A. Murphy 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 Pyrukynd, Ferriprox, and Vijoice to PA for the Over 3000 criteria. A couple notable changes in the Antifungals section and Glucose Rescue Medications section include changing Noxafil and Vfend to preferred and Gvoke to preferred, respectively. All PDL updates are listed in the handout for the June 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. During public comment, Vruti Patel from Xeris thanked the Board for allowing Gvoke to become a preferred agent.

Update to Sedatives/Hypnotics

L. Morgan presented the proposed changes to the Sedatives/Hypnotics section in which Smith-Magenis Syndrome was added with initial and renewal criteria. The preferred agent requiring a clinical PA is Hetlioz. M. Aaland asked how there will be confirmation of a specialist being involved in the member's treatment for this disease state. L. Morgan discussed that the provider submitting

the PA must list the specialist involved in the treatment of the member. M. Aaland expressed concerns about the requirement for a sleep-disorder specialist to be involved, as it seemed vague about who is considered a specialist in the field. After discussion amongst the Board members, clarification was made about the requirement for a sleep-disorder specialist.

Update to Lupus Nephritis

L. Morgan presented changes made to the Lupus Nephritis section in the PDL. Initial approval duration for Lupkynis was adjusted from 12 months to 6 months. Additionally, more specific criteria about required documentation to support member clinical benefit and improvement since starting Lupkynis were added for renewal.

Update to Chronic Kidney Disease

L. Morgan presented updates to Kerendia in the Chronic Kidney Disease section. For this agent, the member must have a history of diabetes and meet the parameters listed for estimated glomerular filtration rate (eGFR) and urinary albumin-to-creatinine ratio (UACR). K. Martian asked if the requirement of the labs will be enforced for all facilities, including those that do not possess the ability to produce such labs. A. Murphy responded that if this does come up during review, then exceptions can be made depending on the situation. For now, that concern will be monitored. During public comment, Bashir Kalayah from Bayer Pharmaceuticals gave an overview of Kerendia. He made a request to the Board to allow Kerendia without concurrent use of an ACE-inhibitor, or ARB, and a SGLT-2 inhibitor. During discussion, A. Murphy stated that the requirement for concurrent use of those agents will be waved if the member has a contraindication, allergy, or other extenuating circumstance for why the member cannot take the agent.

Update to Heart Failure

L. Morgan presented updates to the Heart Failure second line agent's section. The prescriber must now be, or be in consult, with a cardiologist for approval of Verquvo and Corlanor. All other criteria remained the same.

Update to Drug Utilization Review Policies

L. Morgan presented an update to the Preferred Drug List (PDL) that discussed the Drug Utilization Review Policies. This policy was already in effect prior to the update; however, the policy was added to the PDL for provider clarity on the topic. A. Werremeyer discussed her concerns of this policy and how it may limit medical care for a member if his or her provider does not advocate for the member's need for the requested treatment. A.Werremeyer explained how many agents are used in practice based on literary support versus FDA-approval. A. Murphy answered that per federal law, clinical literature cannot be used as a basis for approval of agents not compendia supported. B. Joyce also added that Kepro, the contracted prior authorization reviewer, will not be utilized to review non-compendia supported use of agents. Rather, letters and emails may be submitted to ND Medicaid resources to discuss the use of non-compendia supported use of agents. G. Balf added her concerns also of the Drug Utilization Review policy and the restrictions it can pose on members. B. Joyce responded that this policy has always been in place, but it is just now being added to the PDL for reference. L. Kroetsch was also in favor of changing the language in this section to let practitioners know there is a route they can take to advocate for their patients to use non-compendia supported agents.

Synagis Discussion
A Murphy presented data on RSV and the use of Synagis in recent years. A. Murphy presented the seasonal cost of Synagis from 2016 to 2021 for ND Medicaid. She also presented Region 8 reported seasons and how North Dakota matched up to the start and end of those seasons. Overall, ND Medicaid started covering Synagis earlier than other states in Region 8. A. Murphy went on to discuss how to determine "seasonality" and how to measure consistency of RSV detection. This topic will be discussed more at the next meeting.

Second Review of Familial Cholestasis Pruritis
L. Morgan presented initial and renewal criteria for Bylvay and Livmarli. These agents will be approved for 6 months initially and 12 months for renewal. Bylvay and Livmarli both have product specific criteria listed which requires genetic testing to support appropriate diagnosis and medication use. Bylvay and Livmarli are listed as preferred agents that require clinical PA. 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 Wilson's Disease
L. Morgan presented a review of the disease state and agents used in the treatment of Wilson's Disease to the Board. A motion was made by A. Werremeyer 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 Cushing's Syndrome
L. Morgan presented a review of the disease state and agents used in the treatment of Cushing's Syndrome to the Board. During public comment, Vruti Patel from Xeris gave an overview of Recorlev and requested it be added to the PDL. K. Martian asked what, if any, clinical benefit would come from using the racemic mixture of ketoconazole (Recorlev) versus ketoconazole. Vruti Patel answered that there is currently no clinical benefit showing superiority of Recorlev over ketoconazole, but rather there is a broader indication and prescriber support for using Recorlev. A motion was made by K. Martian to manage these medications through prior authorization. The motion was seconded by A. Honeyman. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Review of Presbyopia
L. Morgan presented a review of the disease state and agents used in the treatment of presbyopia to the Board. During public comment, Nathan Blake from AbbVie made himself available for questions from the Board. A. Murphy then asked the Board if they want to consider this agent for cosmetic use or add it to the PDL for prior authorization. K. Martian and B. Joyce brought up the medical need for some members who may not be able to wear glasses. A motion was made by K. Martian 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.

Review of Vernal Keratoconjunctivitis

L. Morgan presented a review of the disease state and agents used in the treatment of vernal keratoconjunctivitis to the Board. 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.

Retrospective Drug Utilization Review (RDUR) Criteria Recommendations

L. Morgan reviewed the RDUR criteria that were selected for review of January and March of Q1 2022. Presented data included number of profiles reviewed, number of cases identified for intervention, and the number of letters sent, as well as an overview of what RDUR interventions were identified as most prevalent for each monthly cycle. There was a special mailing sent in February to providers about neuropsychiatric events reported with the use of Singulair. Additionally, L. Morgan presented Q1 2022 RDUR response rate data from prescribers and pharmacies. M. Aaland discussed her concerns about the low response rate from prescribers and pharmacies, and from there, the Board discussed ways to increase the response rate. Some mentioned making the response form shorter and more direct, choosing more useful RDUR criteria, and narrowing down and communicating with the non-responders. 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. M. Aaland moved to approve the new criteria and K. Martian 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 3:25 pm. The next DUR Board meeting will be held September 7th, 2022, at 1:00 pm at the state capitol building.