North Dakota Medicaid Drug Use Review (DUR) Board
Meeting Minutes
September 1, 2021

Members Present: Joshua Askvig, Andrea Honeyman, Kathleen Traylor, Gabriela Balf, Mary Aaland, Amy Werremeyer, Laura Kroetsch, Tanya Schmidt

Medicaid Pharmacy Department: Alexi Murphy, Brendan Joyce

Old Business

Chair T. Schmidt called the meeting to order at 1:03 p.m. Chair T. Schmidt asked for a motion to approve the minutes of the June 2, 2021, meeting. J. Askvig moved that the minutes be approved, and A. Werremeyer 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 cost of claims, the top 25 drugs based on the total number of claims, and the top drug classes based on claims and cost for the 3rd quarter of 2021. B. Joyce presented data to the Board that was reflective of the average number of patients enrolled in ND Medicaid expansion from 3Q 2017 to 2Q 2021 which showed a significant increase of patients beginning at 1Q 2020. The rise in number of patients is directly linked to the COVID-19 pandemic and the public health emergency that coincided with the pandemic. B. Joyce also presented utilization data of select medication classes to the Board to illustrate drug utilization trends during this time. Drug classes presented included steroids, immunomodulators, insulins, antidepressants, and antipsychotic agents. During public comment, J. Askvig asked if there was an uptick in antidepressants since the pandemic began in which B. Joyce stated antidepressants and narcotics have both increased. G. Balf noted that she has notice antidepressants being used more for anxiety than depression during the pandemic.

PDL/PA Criteria Updates

A. Murphy shared with the Board all of the changes made to the Preferred Drug List since the last version of the Preferred Drug List was posted. Notable changes include removing tetracycline, Peg 3350, and Clenpig from PA, as well as adding agents such as Ingrezza, Koselugo, Empaveli, Atelvia, and Varubi to already existing PA category criteria. All PDL updates are listed in the handouts for the September 2021 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.

Second Review of Agents Used in the Treatment of Heart Failure

A motion and second was made at the June 2021 DUR Board meeting to place some agents, Corlanor, Entresto, and Verquvo, for the management of heart failure on electronic diagnosis verification. The topic was brought up for a second review. Product specific heart failure criteria for Verquvo and Corlanor were presented to the Board by L. Morgan. Chair T. Schmidt called for a voice vote to approve the updated criteria, which passed with no audible dissent.

Proposed New Criteria for Nasal Polyps
L. Morgan presented the proposed prior authorization criteria for nasal polyps. The proposed updates included adding Xolair (omalizumab) and Dupixent (dupilumab) to preferred agents, requiring clinical prior authorization, and Nucala (mepolizumab) to non-preferred, requiring prior authorization. Xolair recently received the FDA indication for nasal polyps which supports the addition of nasal polyp criteria to the PDL. A. Werremeyer raised the question about requiring the patient to have bilateral nasal polyps for authorization. J. Ritter (guest) answered by stating in the dupilumab trial, inclusion criteria required patients to have bilateral nasal polyps as they are more common than unilateral polyps.

Proposed New Criteria for Chronic Idiopathic Urticaria
L. Morgan presented criteria for the use of Xolair in chronic idiopathic urticaria. Xolair is a preferred agent and will require a clinical prior authorization. It is considered first-in-class therapy for patients with chronic idiopathic urticaria. There were no public comments or concerns about the criteria listed.

Update to the Prior Authorization Criteria for Uterine Fibroid Criteria
L. Morgan presented proposed updates to the prior authorization criteria for agents used to treat uterine fibroids. The proposed update included adding Myfembree (relugolix, estradiol, and norethindrone acetate) to the preferred agents list, requiring clinical prior authorization. During public comment, C. Lickert, with Myovant Sciences and representing Myfembree, brought to the Board's attention the recent update to The American Colleges of Obstetricians and Gynecologists guideline for management of symptomatic uterine fibroids. C. Lickert discussed the use of oral contraception for management of uterine fibroids to be less effective than other agents and the quality of evidence of oral contraception use to be low. C. Lickert added the suggestion to remove or edit the step therapy for oral contraception prior to Oriahnn and Myfembree approval. The Board discussed the requirement for a 3-menstual cycle trial of an oral contraceptive and decided to leave the criteria as is. H. Budlong, with Abbvie and representing Oriahnn, voiced agreement with C. Lickert's assessment of the criteria and thanked the Board for allowing coverage of additional products to treat uterine fibroids. No other public comments were made.

Review of Empaveli (pegcetacoplan)
L. Morgan presented a review of Empaveli (pegcetacoplan) for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) to the Board. A prior authorization form was also presented for ease of prescriber submission, as well as ease of approval determination. Changes between the original handout and new handout were pointed out and discussed, as well. During public discussion, T. Schmidt discussed clarifying how much the Hb levels should increase prior to granting approval for renewal of Empaveli. J. Tobitt, with Apellis and representing Empaveli, clarified that patients eligible for Empaveli do not necessarily need to be transfusion dependent based on the patients included in Empaveli trials not requiring transfusions. G. Balf brought up the concern of documentation to support patient diagnosis for PNH if they are new to North Dakota Medicaid and have limited laboratory documentation. A. Murphy discussed now only requiring documentation of flow cytometry as it is the gold standard for diagnosis of PNH. A motion was made by A. Werremeyer to manage this medication through prior authorization. The motion was seconded by

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

Update to Non-24 Hour Sleep-Wake Disorder Criteria

L. Morgan presented an update to the criteria for agents used for non-24 hour sleep-wake disorder. Hetlioz (tasimelteon) is now indicated for sighted members diagnosed by self-reported sleep diaries or actigraphy for at least 14 days. A. Murphy discussed the drastic price difference between Rozerem (ramelteon) and Hetlioz (tasimelteon) – two agents that have the same mechanism-of-action and efficacy. The higher price and similar efficacy of Hetlioz were used to determine the non-preferred status. No public comment followed presentation.

New Business

Review of Non-Stimulant Agents Used in the Treatment of ADHD

L. Morgan presented a review of non-stimulant agents used in the treatment of attention-deficit hyperactivity disorder to the Board. During public comment, G. Balf commented on the confusion in the mechanism-of-action table which listed viloxazine and atomoxetine as SNRI agents, which is incorrect, as they are norepinephrine reuptake inhibitors. G. Balf also discussed the missing dosing information for atomoxetine which should include the utilization of higher doses, specifically up to 100mg per day. A motion was made by M. Aaland 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.

Utilization Review of Xifaxan and Potassium

A. Murphy presented utilization data to the board regarding the utilization of Xifaxan with and without lactulose, comparing utilization before and after new requirements were implemented that require a PA for Xifaxan for diagnoses other than hepatic encephalopathy, and required concomitant use of lactulose for a diagnosis of hepatic encephalopathy. A. Murphy then went on to discuss the requirement for liquid potassium to require prior authorization for swallow study and quantity limits, as patients were using liquid over tablets due to the inconvenience of swallowing a large tablet.

Retrospective Drug Utilization Review (RDUR) Criteria Recommendations

L. Morgan reviewed the RDUR criteria that were selected for review of each month of the last quarter. 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. L. Morgan discussed the decrease in letters sent during the month of June and correlated the decrease to her taking over after T. DeRuiter. L. Morgan stated she will monitor letters sent in the future and will discuss changes in this process at the next meeting.

Retrospective Drug Utilization Review (RDUR) Criteria Recommendations

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. J. Askvig moved to approve the new criteria and M. Aaland seconded the motion.

Chair T. Schmidt called for a voice vote to approve the new criteria, which passed with all present members voting to approve.

Adjournment and Upcoming Meeting Date

Chair T. Schmidt adjourned the meeting at 2:40 pm. The next DUR Board meeting will be held December 1, 2021, at 1:00 pm at the state capitol building.