

MINUTES OF THE DRUG UTILIZATION REVIEW (DUR) BOARD MEETING

Wednesday, September 13, 2023

1:00 p.m. to 4:00 p.m.

Virtual meeting via Zoom

DUR Board Members Present:

Jake Olson, Pharm D
Michael Ochowski, RPh
Paul Cesarz, RPh
Brook Passolt, MD
Jordan Wulz, MD
Jeff Huebner, MD
Ward Brown, MD

Absent:

Robert Factor, MD

Gainwell Staff Present:

Tom Olson, PharmD
Justin Soniat
Willie Wilberg, PharmD
Chally Clegg
Kristie Chapman
Katie Counts, PharmD
Joseph Dunlop, Pharm D (SAS)

DHS Staff Present:

Kim Wohler
Lynn Radmer, RPh
Tiffany Reilly
Susan Seibert
Pamela Appleby
Travis Copeland, MD
Darla Stachowiak
Russell Dunkel, DDS

Welcome and Introductions

Kim Wohler called the meeting to order at 1:04 p.m. and began with a welcome and thanks to the Board members for their attendance at the meeting. As the meeting was held virtually, Kim provided technical instruction on how the meeting would proceed. A quorum of members attended the meeting.

Review of the Agenda and Board Materials and Approval of June 2023 Meeting Minutes

The members were reminded of the meeting materials sent via email for reference and review. Prior to this meeting, Board members received the agenda, minutes, and RDUR Quarterly Report via email and had the opportunity to review each document. The June minutes were briefly reviewed and approved with an initial motion from **Paul Cesarz** and a second from **Mike Ochowski**. The motion passed unanimously.

Quarterly DUR Reports

Lynn began by reviewing member enrollment. The enrolled member count does continue to be higher than in the past but the first dip in enrollment was noted in the second quarter 2023. Lynn pointed out that claim volume is trending upward. There was a significant increase in claim count between the fourth quarter 2022 and first quarter of this year which is most likely due to the changes made on December 1, 2022, when we rolled back to previous policy regarding dispensed quantity. Lynn then reviewed the quarterly reports with the Board beginning with the multiple drug classes report. Lynn reminded the Board that this report identifies members who have claims for all five drug classes (opioids, stimulants, benzodiazepines, sedative hypnotics, and opioid dependence medications) that are tracked for use. Members that are receiving drugs from all five classes are reviewed by a pharmacist for possible inclusion in the Lock-In program or sending physician alert letters. Of the six members identified in the last quarter, two members received alerts, two members received warnings, one member was currently suppressed due to a recent letter that had been sent, and one member was deceased.

Next, Lynn presented graphs for the percentage of adults and children on stimulant medications. The percentage of children on stimulant medications remains very cyclical due to the school year in this age group but there has been a recent increase since the 2020 Public Health Emergency. Overall, we are seeing a slight downward trend in the percentage of both children and adults on stimulants, in the children and adult Medicaid population, respectively. A comparison graph of children and adults within the total Medicaid population shows that the greatest increase of members receiving stimulants has been within the adult population. Overall, the increase in stimulant use appears to be driven by the increased number of adults in Medicaid.

Additional DUR alert trend graphs were presented. Lynn reminded the Board that the DAPO early refill alert, which has been turned off since the 2020 Public Health Emergency, has now been turned back on as of December 1, 2022. Lynn pointed out that due to alert changes that took place in November 2021, there has been a sharp rise in late refills. The early refill, late refill, and drug/drug alerts all are trending up due to increased claims volume. Most of the other alerts are trending downward. It was noted that the reported disease alert did have a sharp increase, and this is being attributed to

the increased claims volume after the reinstatement of the day supply limits. A trend graph for high cumulative dose was also presented. Lynn discussed the high cumulative dose alert and the changes associated to the October 2021 implementation of a soft alert in place of the informational alert. Pharmacists are required to respond to the new soft alert and alert trends have shifted as a result of this change. Lynn noted that the claim count and percentage of overrides has remained stable but is starting to trend downward. In a comparison graph of all the alerts, Lynn noted that the steady rise in late refill over early refill is most likely related to the recent alert changes previously discussed. An overview of claim volume was presented to the board and the percentage of claims per quarter has continued to remain stable overall and approximately 50% of paid claims are paid with no DUR alerts. Slides were presented to review claim count changes. There has been a significant rise in claims since Q4 2022. Lynn noted that the change in policy back to most medications being a one-month supply could be a component of the larger number of claims. Trend graphs for average morphine milligram equivalents (MMEs) per member per day and members utilizing buprenorphine from 2020 - 2023 were also included. The average MME remains below 50 and continues to trend downward. As seen in previous quarters, as the average MME has decreased, the use of buprenorphine has increased. Naloxone usage shows a 92% increase of members receiving naloxone since 2020 Q4, when intervention letters were implemented.

Two graphs were presented to the Board looking at naloxone member trends from 2020-2023. Naloxone usage has increased dramatically since Q4 2020. Further analysis of the trend graph was done based on opioid use and MME levels. This analysis continues to reveal that most members with a claim for naloxone either had no opioid claims or claims for low MME values (less than or equal to 50 MME per day). Lynn presented a slide which was introduced at the December 2022 meeting, tracking naloxone fills for members at 90 MME or greater. From Q3 2022 to Q2 2023, there was a reduction in members with 90 MME as well as a slight increase in naloxone dispensed. The average percentage of members with 90 MME or greater and receiving a naloxone fill in Q2 2023 was 11%. Board discussion on this topic included possibly looking at this trend on an annual basis versus quarterly basis as that seems to be a more common prescribing practice for naloxone.

Multiple CNS Depressants

Lynn began by reminding the Board that for this quarterly intervention, the methodology has recently changed as of Q1 2022. The new methodology identifies members who are concurrently receiving at least one medication from each of the following drug classes: benzodiazepines, opioids (non-MAT), sedative hypnotics, and skeletal muscle relaxants, and are receiving 45 or more actual days' supply of each of the four medications during the quarter. The selected members are reviewed, and a letter is sent to prescribers regarding the risks of the noted polypharmacy. Letters are now being sent to the prescribers annually or when there has been a noted prescriber change. For comparison, Lynn reminded the Board that with the old methodology only members on 90 or more days' supply were identified, and the prescriber letters were only sent one time per member rather than annually. Lynn noted that this change was made to increase the outreach and letters involved with this intervention. In Q1 2022 there were 107 members identified as receiving greater than or equal to 45 days' supply of each drug and letters were sent to the prescribers associated with these members. For Q2 2023, there were 186 members on all four drugs, 79 members with 45 or more total days' supply of each drug, and 67 members were selected for intervention. Lynn reminded the board that all these numbers can be located and will be updated quarterly on the continuing intervention spreadsheet.

Opioid/Benzodiazepine Intervention

The continuing intervention spreadsheet was reviewed for the opioid/benzo intervention. For this intervention there are two phases. The phase one letters are focused on members who have chronic opioid (non-medication-assisted treatment) and benzodiazepine use and who exceeded 50 MMEs per day. Chronic use is defined as 90 days each of opioids and benzodiazepines in 90 days. The phase two letters involve members who have chronic opioid (non-medication-assisted treatment) and benzodiazepine use and who exceeded 50MMEs per day, but phase two specifically identifies the top 2% of prescribers with members meeting the criteria and who previously received the phase one letter. Lynn noted that for the first quarter, there were 216 members identified who were on this combination and 367 prescribers. Letters were sent to all prescribers for the second quarter. These numbers continue to decline over time. The top prescribers with five or more members meeting the criteria were also reviewed for phase two letters. There were 10 members involving two prescribers identified in the recent quarter, and one of these was considered a new prescriber. In general, these numbers have continued to show a positive trend overall.

High MME Intervention

Lynn began by reminding the Board that letters are currently being sent monthly beginning December 2019 regarding

members on the highest MME, in the Top 1%. Monthly letters are sent to all new prescribers identified as well as annual letters for repeat prescribers. Lynn reviewed the history of the High MME intervention. The MME was lowered from 250 MME to 180 MME in March of 2022, and most recently was lowered from 180 MME to 150 MME in May of 2023. Starting in May 2023 intervention letters were sent to all prescribers who have members with 150 MME or greater. Lynn pointed out that before letters are sent the member's profile is reviewed by a clinical pharmacist to ensure that the member is truly receiving at least 150 MME and letters are not typically sent for members with hospice, cancer diagnosis, or sickle cell disease. The continuing interventions spreadsheet was displayed to review the current number of members receiving these intervention letters. With the reduction in MME to 150, there were 86 members identified at this threshold in July, with 82 letters being sent. Additionally, prescribers are selected for an outreach call based on no change to the MME or an increase in the MME after receipt of an intervention letter. Provider outreach calls were made to 12 providers in July.

Opioid Script Limit Update

Lynn began by indicating that the expanded discussion of this normal topic is a result of the desire to make changes to the current presentation of the data. The history of the opioid script limit was reviewed. The edit was implemented in January 2011 and limits a member to five opioid prescriptions in the same calendar month. Denied claims require provider intervention via the DAPO to request an override. Overrides may be granted on a one-time basis in most cases, or up to three months for a cancer/palliative care patient. It was noted that buprenorphine and methadone products used to treat opioid use disorder and narcotic antitussives are excluded from the script limits. There was a recent increase in the average MME for opioid overrides in the second and third quarter 2022. This increase was due to outlier claims during this time frame for members with cancer diagnoses and high MME claims for a small day's supply. As a result of this, a process was put into place to review these outlier claims for members who got an override on a quarterly basis. The percent of override trend was also presented, and Lynn indicated that this graph will no longer be shown. The Board does not feel that it accurately depicts ongoing trends with the overrides. The new graph provides a better understanding of the override trends and accurately depicts that the percentage of overrides is a small subset of the total opioid claims. Overrides are consistently issued for less than 1% of the total opioid claims. This graph will be presented on a quarterly basis and will allow identification of any significant changes to the override percentage in a timely manner.

Retrospective DUR Criteria Update

Katie began by reminding the Board that the retrospective DUR process was a monthly process. She gave an overview of the current volume of profiles reviews and how those profiles are generated systematically with a monthly data load. The selection of profiles can be based on specific criteria, patient risk scores, or a combination of those choices. It was noted member profiles included pharmacy and medical information for review by the pharmacist. Intervention letters, or cases, may be created for one or more criteria and letters are generated for one or more providers. Next Katie discussed the criteria development and maintenance processes. It was noted that criteria can be standard or client specific. Examples of Wisconsin-specific criteria were shared. Criteria is created based on data from multiple sources, including industry product information, clinical resources, clinical guidelines, and peer reviewed literature. Criteria creation parameters include determining criteria type and the drug triggers that are associated to the criteria. Primary, secondary, and tertiary drugs and/or diagnosis codes may be utilized to accurately narrow the scope of the criteria. Other parameters include alternate qualifiers for criteria inclusion/exclusion and creating alert messages with appropriate references. Available criteria types and how they work were discussed with the Board. Katie indicated that the criteria maintenance process is always ongoing reviewing resources for new criteria and updates to existing criteria. Reviews for new drugs for potential criteria are done monthly. Ongoing periodic reviews of clinical resources are done to keep existing criteria up to date. She noted that the system is updated monthly with new drugs and new NDCs for existing drugs, as well as implementing newly created and updated criteria. A document containing all new and updated criteria for the first two quarters of 2023 was provided to Board members. These updates will continue to be included in the Board member materials on a quarterly basis.

Updated CDC Opioid Guidelines Discussion

Lynn began by sharing with the Board that this topic was generated as a result of Board member discussion at the June meeting regarding recent CDC changes to some MME conversion factors and impacts those changes may have on the High MME edits. She then went on to give an overview of the 2022 CDC Clinical Practice Guidelines for Prescribing Opioids for Pain which was published November 4, 2022. It was noted that the guideline was created as a clinical tool to encourage providers to work with patients to manage pain together. Additionally, the guideline is indicated for use in treating pain in adult outpatients in a flexible, patient-centered manner. Lynn indicated that the guidelines are not laws or regulations to dictate clinical practice; and they were not intended to be a replacement for clinical judgement. The

guidelines were also not intended to be applied to certain populations, including patients with sickle cell disease, cancer-related pain, or patients undergoing end-of-life care.

The discussion continued with how the guidelines have impacted conversion factors for large data sets. Lynn noted that previously, the CDC had provided access to an NDC conversion factor file, but this file will no longer be updated. The DUR group utilizes the MME conversion factors found in this file for all MME calculations (proDUR, RDUR, DUR reports). Lynn indicated that the MME conversion factors for hydromorphone, methadone, and tramadol were adjusted in 2022 guidelines and that they are slightly different than those the DUR group is currently utilizing. After review, it was determined that these MME changes will not have a significant impact on the DUR group calculations due to claim volume associated with methadone and hydromorphone, and the low conversion factor for tramadol. The DUR group will continue to utilize the current MME factors to preserve the data integrity and continuity of the ongoing comparative analyses. Board members voiced support for continued use of the current conversion factors to maintain consistent data due to the volume of data being analyzed.

Dental Intervention Update

Dr. Dunkel began by reminding the Board that this intervention has been ongoing since 2017 and he reviewed historical criteria changes and letter counts associated to those versions of the criteria. The criteria was updated in 2021 to include adults, to include members age 18-25 who are at increased risk for substance use disorders. Children and adults are being tracked separately. The current criteria, updated in August 2022, identifies prescribers who have three or more members under the age of 16, who received more than 10 pills or who have members 16 years of age and older who received more than 12 pills. The initial set of letters was mailed in August of 2022. The intervention has been broken down into two phases. For the phase I intervention letters, only new prescribers who meet the criteria received a letter. A phase II letter was developed for prescribers who still meet the criteria and the number of members remained high, these prescribers were considered to be in the top 5%. These letters include a list of members for the prescribers to review. The phase I letters were mailed in May 2023 and phase II letters were mailed in June of 2023, and were discussed at the June Board meeting. Additional data analysis for the January – June 2023 data set was completed and revealed that while the number of identified providers and patients continues on a positive trend, the percentage of prescriptions written by those prescribers identified for phase II letter is very high (60-70%). A table that included the top six prescribers was presented to show changes to member counts and previous rankings for these prescribers. Letters are not being sent for the January – June 2023 data set. Peer-to-peer outreach by Dr. Dunkel is planned for the top prescribers for phase II. This topic will be brought back with further information about the outreach calls.

Mental Health Consultant Update

Polypharmacy Sedating Medications in Children with Clonidine

Dr. Copeland began by reminding the Board of the addition of clonidine IR to this intervention at the June meeting. He then reviewed that the screening criteria looks for children ages 0-18 who are on agents from three or more drug groups for 90 days or more in the last quarter. He also reviewed the drug groups and reminded the board of several modifications and additions to this intervention over the past several years. In 2022 Q2 additional antipsychotics were added. Aripiprazole and risperidone are consistently among the most prescribed agents across age groups. Changes to member counts over time due to medications changes were reviewed. Additionally, the top sedating drugs for first and second quarter based on all age groups and smaller subsets of age groups were reviewed. It was noted that clonidine was the top drug in all age groups until age 18. With the addition of the clonidine, 306 prescribers and 310 members were identified for inclusion in the letter process and letters will be mailed in September 2023.

Stimulant Initiatives

Dr. Copeland started this discussion by reminding the Board that the current stimulant initiatives consist of three parts: quantity limits for stimulant prescriptions, prior authorization requirements for selected stimulants, and member case reviews. There are three scenarios that are identified for a member case review: any child under the age of four being started on a stimulant, any member of any age utilizing methamphetamine as their stimulant medication, and children receiving high dose prescriptions. The Board was reminded of the drugs requiring prior authorization, and that the list was recently updated to include Xelstrym, a dextroamphetamine patch. Dr. Copeland went on to further discuss the dose monitoring, screening, and case review process. He shared the clinical thresholds for identifying high dose prescription outliers. High dose thresholds are determined based on safety data, FDA initial approval dosages, and common doses utilized in clinical practice. It was noted that the high dose threshold for methylphenidate is, at times, more difficult to discuss due to a recent meta-analysis concluding that there is lack of data to support the limitation of methylphenidate

doses. Dosing patterns are reviewed for each stimulant on a quarterly basis to identify outlier prescription patterns and members on high dose stimulants. He reminded the Board that the polypharmacy methodology was added in 2023 to aid in identification of members on multiple stimulants who may also be considered as high dose and need further intervention. Prior to this addition, members were reviewed based on single agent doses. For second quarter 2023, the addition of the polypharmacy component resulted in identification of five members at greater than 120% threshold. Interestingly, these five members were from two groups of prescribers. Dr. Copeland made outreach calls to these groups on these members and shared his experiences with these calls. He stated that, overall, most providers appreciate the input on what usually are identified as difficult cases to manage, though not all providers are as receptive. It was noted that the pattern for these particular members was that there were continued issues with aggression and impulsivity that led to the higher doses and combination therapy. Dr. Copeland stated that this set of calls had several that extended past the member identified and ended in discussions that included other members and discussions of prescribing patterns and other assessment options based on patient history. These interventions will continue quarterly, and intervention success will be determined by two parameters: dose or prescribing reductions where appropriate, and increased side effect awareness.

CMS Annual Report Update

Lynn walked through the individual sections included in the CMS Annual Report which is completed before the end of June each year. Lynn discussed that the Fraud Waste and Abuse portion is the biggest section included with this report and went over the individual components including Lock-In Program, PDMP, Opioids, MME Daily Dose, Opioid Use Disorder Treatment, Outpatient Treatment Programs, and Antipsychotics and Stimulants. She indicated that the reporting on some of these components of the PDMP section has been voluntary but will become mandatory next year. Lynn also provided the Board with the link to the recent CMS annual report.

Adjournment

Brook Passolt motioned to adjourn the meeting. The meeting adjourned at 4:01 p.m. Upcoming meetings are on the following Wednesdays: December 6, 2023, March 6, 2024, and June 5, 2024.

Guests: Doug Johnson, Sobi; Kelly Hamilton, Takeda; Matthew Wright, Artia Solutions; Kevin Hall, Sanofi; Sherry Betthausen, Jazz Pharmaceuticals; Bradley Kalkwarf, Regeneron; Akasha Coleman, Johnson & Johnson; Phillip Lohec, Viatrix; Bradley Jones, AbbVie; Sakib Hassan, AbbVie; Jon Vlasnik, Alexion; Mark Friederich, D2 Consulting; Gary Parenteau