

MINUTES OF THE DRUG UTILIZATION REVIEW (DUR) BOARD MEETING

Wednesday, March 6, 2024

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

Virtual meeting via Zoom

DUR Board Members Present:

Jake Olson, PharmD
Michael Ochowski, RPh
Paul Cesarz, RPh
Brook Passolt, MD
Robert Factor, MD
Jeff Huebner, MD
Jordan Wulz, PharmD

Absent:

Ward Brown, MD

Gainwell Staff Present:

Tom Olson, PharmD
Kara Varney
Ashley Baderstadt
Chally Clegg
Katie Counts, PharmD
Travis Copeland, MD

DHS Staff Present:

Kim Wohler
Lynn Radmer, RPh
Tiffany Reilly
Darla Stachowiak

Welcome and Introductions

Kim Wohler called the meeting to order at 1:06 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 December 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 December minutes were briefly reviewed and approved with an initial motion from **Jeff Huebner** 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 continues to decrease. First quarter 2023, highest member enrollment number. Lynn pointed out that claim volume is trending downward. While 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 policy changes made on December 1, 2022, the population has started to decrease and so have claim volumes. 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. Stimulant percentage continues to remain elevated. 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 five members identified in the last quarter, one member received an alert, one member received a warning, one member was locked in, and two members were currently suppressed due to a recent lock-in letter being sent.

Next, Lynn presented graphs for the percentage of adults and children on stimulant medications. The percentage of children on stimulant medications remains cyclical due to the school year in this age group, but that trend has become less obvious in the data over time. The percentage of children on stimulants declined during the public health emergency, but now seems stable. There has been a sustained increase in the number of members taking stimulants since 2020, but we are starting to see a slight decrease in both children and adults due to a decrease in member enrollment. 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, and the current percentages remain steady. 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. This rise remains steady over the last few quarters but is starting to decline. The other alerts are stable, if not trending slightly downward. 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 because of this change. Lynn noted that the percentage of overrides has remained stable, around 75 to 80%. 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 had been a significant increase in claims from Q4 2022 to Q4 2023. However, the claims volume from Q1 2023 to Q4 2023 is starting to decrease. Lynn noted that the decreasing member population could be a component of the decreasing claims volume. 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 remain stable. As seen in previous quarters, as the overall average MME has decreased, the overall use of buprenorphine has increased, however there has been a slight increase in the average MME and a decrease in the number of members on buprenorphine for the past two quarters. Naloxone usage remains steady though slightly lower for the last quarter, which may be a result of the population change.

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 sent quarterly to providers of newly identified members and annually to prescribers of previously identified members. For Q4 2023, there were 183 members on all four drugs, 80 members with 45 or more total days' supply, and 21 members were selected for intervention. Lynn reminded the board that all of these numbers can be located and will be updated quarterly on the continuing intervention spreadsheet.

Opioid Script Limit

Lynn began by presenting the average MME by override graph. There was a slight decrease in the average MME by override over the last quarter, and the average remains below 90 MME. There is a process in place to review high MME outlier claims. There were no claims identified for review this quarter. The percent of override trend was also presented, and overrides are consistently issued for less than 1% of the total opioid claims. While the opioid script limit policy impacts a very small number of claims, trends indicated it is an effective policy.

Naloxone Breakout Analysis

Lynn began the discussion by reminding the Board that naloxone use is a topic that we track quarterly. Safety monitoring is required by the SUPPORT Act and for the annual CMS program report. She then presented two member trend slides that are presented at each meeting. These slides cover 2021 – 2023. It was noted that the number of members receiving naloxone has decreased in the last two quarters but is still higher than in 2021 when the naloxone letter intervention was started. This may be due to decreasing member enrollment and member demographics. Also, as in past quarters, the majority of members receiving naloxone are either on no opioids or low MME opioids. Lynn added that letters are sent to prescribers who have a member with a poisoning or dependence diagnosis and do not have a naloxone dispensing in history.

Next Lynn presented further analysis of naloxone use in three separate tables. Table 1 included quarterly tracking of naloxone fills for members with an average MME of 90 or greater from 2021 – 2023. This table indicates almost a continuous decline in the number of members with an average of 90 MME or greater. The average fill rate for naloxone is 10% of members. Table 2 reviews naloxone use for a subset of members from Q4 2022 who had an opioid claim with an average MME of 90 or greater (1,258 members). This review looked one year back and one year forward from Q4 2022 for these members to track the naloxone fill rate. Analysis revealed that 52% of members had at least one fill for naloxone during that time period and the majority of members got that fill in the same quarter as the opioid claim. Table 3 reviewed the number of total naloxone fills for 2021 – 2023 stratified by MME and opioid dependency diagnosis. Analysis revealed the majority of members have one to five fills. Additionally, 42% of the members with a fill during that time had a diagnosis for opioid dependency versus only 4% of the members with an average MME of 90 or greater. This indicates that opioid dependency is the major driver for naloxone use.

Sickle Cell Medication Underutilization

Lynn began by reminding the Board of the timeline for this topic of discussion. The discussion at the June 2023 meeting

focused on opioid use in members without a disease modifying drug in history. After that meeting, the focus transitioned to underutilization of the disease modifying agents rather than opioid use to improve outcomes regardless of opioid use. At the December 2023 meeting, the new underutilization criteria were presented, and additional information was discussed with the Board for introducing a modified intervention involving chronic opioid use in members without a disease modifying agent in history. Lynn continued by reminding the Board of the underutilization criteria alert messages and presenting a small subset of data for January and February on the underutilization intervention letters. As expected, the volume of letters is small. These interventions will continue to be selected for monthly review. Lynn went on to share the newly created criteria to address chronic opioid use in members without a disease modifying agent in history. The alert message and parameters for the intervention were presented. Lynn noted that there were some adjustments to the parameters after the December meeting and highlighted those changes. The changes included an updated alert message and identifying members with no use and under use of disease modifying agents. This criteria will be active and selected for the March 2024 review cycle.

Long-Term Use of High Dose Benzodiazepine Impact Analysis

Lynn began the discussion by reminding the Board of the history of this intervention. At the December 2022 meeting, an intervention was proposed to address members taking long-term diazepam, alprazolam, clonazepam, or lorazepam above designated dose thresholds. Prescribers received letters if they had at least two members exceeding the dose threshold for the identified drugs for six or more months. Lynn indicated that members with a seizure diagnosis were excluded, except for alprazolam. Letters were developed and signed by both Dr. Copeland and Dr. Huebner. In March 2023, 93 prescribers received letters accounting for 334 members identified from July 2022 – December 2022. An impact analysis for July 2023 – December 2023 was completed.

Lynn continued the discussion by presenting the findings of the impact analysis. Of the 305 members available for remeasurement, 44% had either no benzodiazepine claims or had claims that were now below the dose threshold (15% and 29%, respectively). The other 56% of members continued to have claims for benzodiazepines above the dose threshold. While the initial run of this intervention was successful, it was noted that further intervention is warranted. Additional data was evaluated for July 2023 – December 2023 for new and existing members. A total of 84 prescribers accounting for 267 members were identified for a letter to be sent in March 2024. It was noted the majority of prescribers had two to three members identified. There were 12 providers that had five or more members. Dr. Copeland will review these cases for possible outreach. Additional impact analysis on this run will be presented at a later date.

Buprenorphine & Benzodiazepine Intervention

Lynn began sharing the history of this intervention. Initial concerns about this medication combination were brought to the Board in June and September 2015. At that time, criteria and education letters were created to be sent to providers with members on both buprenorphine and a benzodiazepine that were sent in 2016 and early 2017. It was noted that in September of 2017, the FDA released additional information regarding the use of benzodiazepines and MAT medications. The FDA indicated that while the combination was a risk, treatment should not be withheld but careful management should be implemented by providers. Considering this guidance, the focus of the intervention was moved to non-MAT opioids and benzodiazepine use. In late 2023, the DUR committee felt that a review of the buprenorphine/benzodiazepine criteria was warranted given expanded access to buprenorphine, and this information was presented at the December 2023 meeting. Based on Board discussion at that meeting, additional data analysis and literature reviews were conducted to help direct future intervention on this topic.

Dr. Copeland continued the discussion by reviewing the rationale for why buprenorphine and benzodiazepines may be used concurrently, which included better retention of patients with anxiety disorders and use to treat specific issues during initial phases of buprenorphine treatment. He went on to discuss the risks associated with this therapy regimen and presented the results of his literature review. It was noted that prior to the 2016/2017 FDA communications, only small-scale data was available for review. However, recent larger reviews in 2021 and 2022 provided additional insight on the risks associated to the combination use as it relates to drug related poisonings. Available data does indicate that benzodiazepine use does increase buprenorphine treatment retention, but also increases the risk of both fatal and non-fatal overdoses, in addition to all-cause mortality. Additionally, data indicates that the dose of the benzodiazepine does impact the risk for drug related poisoning. Low dose benzodiazepine with buprenorphine use does not increase the risk of poisoning, while high dose benzodiazepine with buprenorphine use is associated with an increased risk of poisoning.

Lynn resumed the discussion by indicating that based on Dr. Copeland's research, the decision was made by the DUR

Committee to focus on members receiving both buprenorphine and a high-dose benzodiazepine. Claims analysis indicated that alprazolam, clonazepam, diazepam, and lorazepam are the benzodiazepines of concern for this intervention. The parameters for identifying members for inclusion in the intervention will be long-term concurrent use of buprenorphine and a benzodiazepine. The benzodiazepine dose must exceed the drug-specific threshold for inclusion. Claims analysis supports that the number of members that will be identified for inclusion is low. This intervention may include both letters and peer outreach. Further information will be brought back to the Board at a later date.

Lock-In Annual Report

Katie began the annual Lock-In Report with an overview of the program's functionality and objectives, which are to identify and reduce drug-seeking behavior and to identify inappropriate prescribing patterns. The program currently reviews three criteria that look for excessive use of controlled medications (#3147), combinations of buprenorphine with opioid agonists (#5304), and the use of controlled substances with a history of drug poisoning (#9995). The Board was reminded of member rights, negating criteria used during reviews, and the types of letters sent to providers. A list of drugs that are included and excluded from the program was provided. There was a minor change made to criteria #3147 in 2023 for the days' supply required to hit this criteria. In February 2023 the total days' supply required for a member to hit criteria was increased from 220 days to 230 days' supply.

A review of case counts for 2023 revealed a slight decrease in the number of cases identified for alert likely due to the decrease in the number of profiles being reviewed. The trend in the number of cases identified for warnings and lock-ins has decreased. Katie noted that due to the time between review for an alert and review for a warning or lock-in, changes in case counts do often take more time to see. It was noted that letters are sent on average every six months to allow the reviewer to better see changes to utilization patterns. Additionally, a change in reviewers occurred in July 2023 and reviewer variability may have impacted these numbers. Other trends noted for 2023 include a continued decrease in prescriber responses. However, December data for responses was not available at the time this report was created. Despite the lower percentage of overall responses, the percentage of responses with comments remained relatively stable. The overall response rate was 12% with a comment rate of 54%. It was noted that the decrease may be related to the inclusion of lower risk members in the review pool and less provider concern for these members. Most comments were positive and indicated positive actions are being taken, however as expected, there were comments that indicate the program can be a source of frustration for providers. Katie noted that prescriber frustrations may be related to a lack of prescriber understanding of the review process, however it is also understood that many of these patients have very complex history and all background information for each member is not always easy to interpret during these reviews.

Mood Stabilizers in Children

Dr. Copeland began the discussion by reviewing the goals of this presentation, including investigating polypharmacy patterns for mood stabilizers, review these patterns based on current initiatives involving mood stabilizers, and identify ways to include members and prescribers for further intervention. Dr. Copeland reviewed the categories of mood stabilizers utilized in practice, primary and secondary. He indicated that primary mood stabilizers consist of antipsychotics, lithium, and anticonvulsants, while secondary mood stabilizers include medications to stabilize sleep (sedating), medications to reduce impulsivity (ADHD medications), and other mood medications (antidepressants). It was noted there are existing initiatives that address the use of antipsychotics in children, sedating medications in children, and polypharmacy with sedating medications. There are no initiatives to address lithium medications or anticonvulsant medications.

Dr. Copeland went on to present a data review that was completed to address the use of polypharmacy including multiple antipsychotics and one or more non-antipsychotic mood stabilizer (criteria one) or the use of multiple non-antipsychotic mood stabilizers (criteria two). Members with seizure disorders were excluded from evaluation. Dr. Copeland presented the data based on criteria and the data was stratified by age. It was noted that the drugs identified in each criteria changed based on patient age, but the overall data indicated that further intervention around these polypharmacy cases involving non-antipsychotic mood stabilizers is warranted. Going forward, as part of the current initiatives around the use of multiple antipsychotics, the data will be expanded to capture and include the use of these additional mood stabilizers (criteria one). The concern for use of multiple non-antipsychotic mood stabilizers (criteria two) will continue to be evaluated for the creation of an independent initiative to address this use. Consideration is being given to the creation of a letter to address this topic. Additionally, the use of lab and diagnostic information will also be considered for inclusion in the review parameters of existing initiatives.

Dental Intervention Update

In the interest of time, this topic was tabled until the June 2024 meeting.

Adjournment

Robert Factor motioned to adjourn the meeting. The meeting adjourned at 3:58 p.m. Upcoming meetings are on the following Wednesdays: June 5, 2024, September 11, 2024, and December 4, 2024.

Guests: Robert Firnberg, Gilead; Clemice Hurst, Eisai; John Bullard, Alexion; Mariah Scott, Sick Cells; Kimberly Eggert; Jenna Doerr, Artia Solutions; Gary Parenteau; Robert Robey, Indivior; Akesha Coleman, Johnson & Johnson; Bethany Howell, Links2Equity; Kelly Ruhland, Lilly; Laura Etheridge, SK Life Science; Jason Dohm, Viking Healthcare Solutions; Scott Mills, Karuna Therapeutics; Ethleen Peacock, Alaafia; Jon Vlasnik, Alexion; Bethany Howell