

MINUTES OF THE DRUG UTILIZATION REVIEW (DUR) BOARD MEETING

Wednesday, December 6, 2023

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

Absent:

Jordan Wulz, PharmD
Ward Brown, MD

Gainwell Staff Present:

Tom Olson, PharmD
Kara Varney
Willie Wilberg, PharmD
Chally Clegg
Kristie Chapman
Katie Counts, PharmD

DHS Staff Present:

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

Welcome and Introductions

Kim Wohler called the meeting to order at 1:05 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 September 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 September minutes were briefly reviewed and approved with an initial motion from **Mike Ochowski** and a second from **Paul Cesarz**. 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. Highest enrollment first quarter 2023. 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. 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 seven members identified in the last quarter, one member received an alert, one member received a warning, one member was locked in, and four 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 very cyclical due to the school year in this age group. The percentage of children has been trending down since 2020, but now seems stable. The percentage of children and adults are very similar, but the percentage of adults is still rising. A comparison graph of the number 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. Both the number of children and adults in Medicaid show a slight decrease for third quarter 2023.

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. Most of the other alerts are trending downward. It was noted that the Drug/Pregnancy alert has started trending upward. 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, 75 to 80% of the claims get an override. 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 had been a significant rise in claims since Q4 2022, however this is starting to decrease. Lynn noted that the changing 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. Naloxone usage remains steady though slightly lower for the last quarter, which may be a result of the population change.

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, we saw a reduction in members with 90 MME as well as an increase in naloxone dispensed. The average percentage of members with 90 MME or greater and receiving a naloxone fill in Q3 2023 was 17%. Board discussion on this topic included possibly evaluating this trend over a longer period.

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 Q3 2023, there were 177 members on all four drugs, 78 members with 45 or more total days' supply, and 26 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/Benzodiazepine Intervention

The continuing intervention spreadsheet was then 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 third quarter, there were 190 members identified who were on this combination and 316 prescribers for phase one. Letters were sent to prescribers of newly identified members for the third quarter (29 members involving 69 prescribers). The top prescribers with five or more members meeting the criteria were also reviewed for phase two letters. There were 11 members involving two prescribers identified in the recent quarter, and neither of these were considered a new prescriber. In general, these numbers have continued to show a positive trend overall. An update to the letter process is being implemented to include all prescribers on an annual basis. Letters will be sent to all prescribers identified in phase 1 annually based on second quarter data. For phase two, letters will be sent to all prescribers identified based on fourth quarter data.

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. 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 are planned for 12 providers in December.

Opioid Script Limit

Lynn began by presenting the average MME by override graph. There was a slight increase in the average MME by override over the last quarter, but 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.

Sickle Cell Medication Underutilization

Lynn began by reminding the Board that this was a topic of discussion at the June meeting and the focus at that time was on opioid use in members without a disease modifying drug in history. Since the June meeting, the DUR workgroup decided to focus more on the underutilization of the disease modifying agents rather than opioid use to improve outcomes regardless of opioid use. Lynn indicated to the Board that three new focused interventions for underutilization of the oral disease modifying agents will be run as standard RDUR criteria in the Kepro system. Lynn went on to share the evaluation of claims data based on criteria parameters that indicates the intervention will likely identify a small subset of the population. The alert message that will be utilized in the letters was also shared with Board members. Additionally, Lynn indicated that the DUR workgroup does still want to pursue an intervention involving chronic opioid use in members without a disease modifying agent in history. However, the current criteria available does not meet the needs of the workgroup and will be modified for use. This will be brought back to the Board when further details are available. Board member comments included information from state and national level discussions on this topic. It was noted that the sickle cell population is not contributing to the opioid problem and that access to disease modifying agents is a concern.

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. Additionally, a phase two letter was developed and sent to prescribers who received a phase one letter and had members with consistent use of concomitant therapy. These letters were sent in mid-2017. It was noted that in August 2016, the FDA issued a warning regarding concomitant use of these medications. At that time, the warning did not include drugs used for MAT, but the FDA indicated that further guidance would be published when it was available. 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. The DUR workgroup felt that a review of the buprenorphine/benzodiazepine criteria was warranted given expanded access to buprenorphine. Katie shared the current Kepro criteria and indicated that it is the same as was used in 2016. A copy of the educational letter associated to the criteria was also available for the Board to review. A review of a small subset of the 500 monthly members that are identified for this criteria were reviewed in October 2023 for trends. No letters were sent during this review. For the population reviewed, less than 10% of members were noted to be on high doses of benzodiazepines, less than 10% of members were on multiple benzodiazepines, and over 50% had different prescribers for the MAT drug and benzodiazepine. Lynn then continued the discussion indicating that based on this review, the DUR committee felt continuing intervention was warranted. However, modifications to the criteria and letter will be made before further intervention occurs. Board discussion included support for the intervention given the removal of the X waiver requirements. Board members also shared their ideas on appropriate parameters for inclusion in the intervention. This topic will be brought back to the Board after further review.

Buprenorphine & Opioid Intervention

Katie began the discussion reminding the Board that use of opioids during treatment for opioid use disorder is an area of concern. While short-term use is indicated and supported in literature in some situations, long-term use is not supported.

The Wisconsin DUR program does monitor the use of this medication combination with two criteria, the Lock-In criteria and the concurrent use criteria. The Lock-In criteria is aimed at identifying long-term use of the combination, while the concurrent use criteria is aimed at identifying those who may have problematic use but not meeting the level of a Lock-In review. Katie shared the criteria parameters and alert messages for both criteria, the medications included in both criteria, and then went on to discuss the focused intervention that was done in July 2023. The concurrent use criteria identified 53 members for intervention, with 37 of those members selected for intervention. A total of 76 prescriber letters were sent to 71 prescribers. Provider response was typical at 20%, with most indicating that positive action will be taken. Most prescribers who provided a comment indicated that the opioid was for short-term use. The Lock-In criteria, which is reviewed monthly, identified 28 members for intervention, with five members selected for intervention. Letters were sent to five prescribers. It was noted that some members were identified for both interventions. Crossover reviews accounted for 16 members, with 14 members being selected for review. Overall, 42 of 65 members identified for intervention were selected for intervention. Katie noted that some reasons for not sending a letter include a member receiving a previous lock-in letter (eight members), members identified by claims as in a long-term care situation, and clinical indicators not supporting a letter. The DUR workgroup indicated that the volume of letters does support ongoing review of this medication combination. The Lock-In criteria will continue monthly, and the concurrent use criteria will be run quarterly for a year. Results will be shared with the Board. Board discussion included the need for reviewers to be cognizant of the approach to taper opioids while titrating buprenorphine and consider this prior to sending a letter.

Lock-In Days' Supply

Katie began the discussion with a brief overview of the Lock-In program objectives and the current parameters used for review for the standard lock-in criteria (#3147). She provided a historical review of the changes made to the days' supply parameters for the criteria. It was noted that the initial change from 240 to 210 was prompted by contractual changes that allowed for an increase in the volume of reviews. Additional changes were made to ensure the most effective use of the criteria with the goal being to identify problematic use while limiting the number of unnecessary reviews. The changes span over multiple years (2016 – 2023) and the days' supply parameters have ranged from 120 to 240. The current days' supply parameter is 230 days, with other changes having occurred in February 2016 (120 to 240), April 2022 (240 to 210), October 2022 (210 to 220), and February 2023 (220 to 230). Data was presented from November 2021 (240 days) thru October 2023 (230 days) to help determine the impact of the changes and the need for further changes. The data shared included profile volume, case volume, alert volume, warning volume, and lock-in volume. Katie noted that trends for lock-in letters have not been what was expected given the increase in the volume of reviews. There has not been a significant increase in the number of members progressing through the lock-in process, despite an increase in the number of reviews. The inclusion of members who would be considered lower-intensity reviews with a lack of significant evidence of misuse and/or abuse does seem to be contributing to the minimal changes in the warning and lock-in volume. There was some discussion around reviewer variability given that there were two different reviewers during the time the data was collected. In light of reviewer changes, the DUR workgroup feels that a return to 220 days is warranted. Results from this change will be presented at a later date.

Mood Stabilizers in Children

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

PDMP Discussion

Lynn began the discussion by providing an overview of DMS access to the PDMP data and the allowed uses of that data. She indicated that the Department of Public Health (DPH) has access to the actual PDMP data and utilizes a data match process to determine what data is sent to DMS. DPH sends the data to the Data Warehouse for use by DMS and Gainwell. The data parameters provided by DPH were shared and it was noted that DMS does not have direct access to the PDMP data. DMS and Gainwell are only a recipient of the data that DPH determines DMS should receive. This limitation does present some challenges to matching the PDMP data to the Medicaid claims data. Lynn also shared that there is a user agreement in place that limits how DMS may use this data. Currently, DMS only uses the data for the Fraud, Waste, and Abuse PDMP section of the annual CMS DUR survey. Lynn reviewed the questions included in that survey section. She indicated that answering the question about the percentage of providers who check the PDMP prior to prescribing a controlled substance was previously optional, but in 2024 will be required. States are allowed to determine their own methodology to collect this information. Lynn noted that the PDMP vendor is unable to provide this information, thus DMS has decided to utilize a provider survey to collect this data. The Department has contracted with Mercer to administer the survey in early 2024 for inclusion in the June 2024 CMS annual report. She reviewed the methodology, parameters, and questions on the provider survey, indicating it may be complete either online or via fax. Results will be

presented to the Board at a later date.

PDL Update

Lynn provided an update from the November 2023 PA Advisory/PDL meeting. Public and written testimony was received. A review of 47 current drug classes was completed. There were no new drug classes for review. Lynn indicated that 25 of the drug classes had no changes. The committee accepted all recommended changes to the remaining classes. Lynn continued with a review of the clinical aspects of the meeting. Notable concerns included shortages within the stimulant class, brand name medication discontinuation of products that are 'brand preferred', and many new biosimilars for Humira. Significant fiscal impact is anticipated with the discontinuation of 'brand preferred' products. Implementation of the November PDL product changes are planned for January 1, 2024.

Adjournment

Mike Ochowski motioned to adjourn the meeting. The meeting adjourned at 4:03 p.m. Upcoming meetings are on the following Wednesdays: March 6, 2024, June 5, 2024, and September 11, 2024.

Guests: Rocco Iannetta, PTC Therapies; Robyn Bruining, Sanofi; Scott Mills, Karuna Therapies; Gary Parenteau, Dexcom; Robert Robey, Indivior; Clemice Hurst, Eisai; Doug Johnson, Sobi, Kelly Ruhland, Lilly; William Friend, Regeneron.