MINUTES OF THE DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
Wednesday, June 5, 2024
1:00 p.m. to 4:00 p.m.
Virtual meeting via Zoom

DUR Board Members Present:	Gainwell Staff Present:	DHS Staff Present:
Jake Olson, PharmD	Tom Olson, PharmD	Kim Wohler
Michael Ochowski, RPh	Kara Varney	Lynn Radmer, RPh
Paul Cesarz, RPh	Ashley Beaderstadt	Tiffany Reilly
Brook Passolt, MD	Chally Clegg	Darla Stachowiak
Robert Factor, MD	Willie Wilberg	Russell Dunkel, DDS
Ward Brown, MD	Katie Counts, PharmD	Pamela Appleby
Jordan Wulz, PharmD	Travis Copeland, MD	

Absent:
Jeff Huebner, MD

Welcome and Introductions
Kim Wohler called the meeting to order at 1:03 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 March 2024 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 March 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 continues to decrease. Lynn pointed out that claim volume, while trending downward, has leveled off. 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 six members identified in the last quarter, one member received an alert, one member was locked in, and four members were currently suppressed due to a recent lock-in letter being sent.

Lynn then 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. There has been a sustained increase in use since 2020 in both children and adults, but we are starting to see a downward trend in both children and adults. 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. There has been a sharp decrease in the adult population which is likely due to changes in enrollment status. 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. 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 soft alert and alert trends have shifted because of this change. Lynn noted that the percentage of overrides has

remained stable. As a follow-up to the high volume of late refill alerts, Lynn presented further analysis on this trend and indicated this is the highest volume alert. She noted that this alert included maintenance drugs only and is triggered when a refill claim exceeds 120% of the days' supply on the previous claim in drug history. Lynn pointed out the late refill and early refill alerts are both set at the same variance of 20% under or over utilization. The full list of drug classes included in this alert was shared and then the top ten classes for alerts were shared. The top classes were then broken down into the top five drugs in each class. Lynn indicated that most of the top drugs had a late refill alert on less than 10% of all claims. She then reminded the Board of the changes made to this alert in 2021 and went on to compare the changes in the classes and individual drugs identified for the alert for 2021 versus 2024. Many of the top ten classes and drugs were the same for both years. A high number of the late refill alerts are for mental health drugs. Further analysis of the percent threshold was presented, including how changes to that threshold would impact the number of alerts. Lynn indicated the DUR core team does not feel any changes are warranted at this time, but that this data is helpful for any review going forward.

Next, 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. Claim volume has been decreasing but is currently holding steady. Lynn noted that the changing member population and policy changes could be a component of the steady claims volume. Trend graphs for average morphine milligram equivalents (MMEs) per member per day and members utilizing buprenorphine from 2021 - 2024 were also included. Lynn noted that the calculation for this graph has been updated to exclude buprenorphine from the MME calculation according to CMS guidelines. With this adjustment, the average MME remains below 45 and continues to remain stable. An additional trend graph was presented to show the decrease in the average MME from 2010 to 2024. The average MME in 2010 was nearly 90. Over time, the average MME has decreased to 45 in 2024. The Board noted that this graph was valuable and showed the impact of the interventions. Historically, as the overall average MME has decreased, the overall use of buprenorphine has increased, however there has been a slight decrease in the number of members on buprenorphine over the last three quarters. This may be a result of enrollment changes. Naloxone usage remains steady though slightly lower for the last two quarters, which may be a result of the population change.
Two graphs were presented to the Board looking at naloxone member trends from 2021-2024. 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 Q2 2021 to Q1 2024, 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 Q1 2024 was 15%, with the average fill rate being 10%. Additionally, a new slide was introduced as a result of the March 2024 meeting. This slide tracks naloxone fills for members receiving buprenorphine for opioid use disorder (OUD). From Q2 2021 to 2023 we saw a persistence of about 10% of members with OUD receiving a naloxone claim. The percentage of members with OUD receiving a naloxone fill in Q1 2024 was 8%, with the average fill rate being 11%. It was noted that the slight drop in members and naloxone fills may be a result of the enrollment changes. Lynn indicated that further evaluation of naloxone use in members without an opioid use will be presented at a future meeting.

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, ranging from 70 to 90. 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 0.5% 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.

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 Q1 2024, there were 199 members on all four drugs, 80 members with 45 or more total days' supply, and 23 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.

Sickle Cell Medication Underutilization
Lynn began by reminding the Board of the timeline for this topic of discussion and that we have two types of criteria for review for this disease state: underutilization of disease modifiers (January 2024) and overutilization of opioids with concurrent underutilization of disease modifiers (March 2024). She continued by reviewing the alert messages and the parameters for selection and review for each criteria. Then the most current data for the monthly interventions was presented. As expected, the volume of letters is small. These interventions will continue to be selected for monthly focused review.

Dental Intervention Update
Dr. Russel Dunkel began by reminding the Board that this intervention has been ongoing since 2017 and that over time, several changes have been made. The current criteria identify 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. In May of 2023, the intervention was broken down into two phases. For the phase I intervention letters, only new prescribers who meet the criteria received a phase I 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%. The current data on the intervention was shared with the Board. The most recent mailing took place in March of 2024. For Q3 and Q4 2023, the phase I analysis included 59 prescribers with 19 new prescribers identified to receive a letter. Phase II data analysis identified 13 prescribers for a phase II letter. Top prescribers have been tracked during the entirety of this intervention and a subset of those prescribers were referred to Dr. Dunkel for review. Dr. Dunkel indicated that seven prescribers were identified for peer-to-peer outreach calls, with four of those prescribers being reached for consultation. He went on to discuss his approach to the calls as being that of a fellow practitioner and that the calls were received in a positive manner. Generally, the prescribers were aware of guidelines and indicated they are trying to follow the guidelines. The practitioners were also receptive to suggestions made by Dr. Dunkel and most agreed to try to implement changes to their prescribing practices.

Narcotic Cough Syrup Impact Analysis
Lynn began by reminding the Board that this topic has been discussed several times previously and this is a follow-up on the discussion from our June 2023 meeting. Beginning in January 2023 the criteria was being reviewed monthly as a focused intervention. The criteria was developed specific to the state of Wisconsin. She reminded the Board that members are identified for a letter when they have at least 24 days' supply of narcotic cough syrup in the last 90 days. Lynn went on to share the impact analysis data for the members identified for letters during Q1 2023. During the quarter, 113 members were identified for letters. For the same period one year later (Q1 2024), all members were still eligible, and only 29 of the members would still meet criteria for intervention. The intervention had a 74.3% success rate. She then discussed the prescribers identified for the intervention during Q1 2023. There were 118 prescribers that received a letter during the intervention period. A year later (Q1 2024), 30 of those 118 prescribers would potentially receive a letter. Overall, during the follow-up period Q1 2024, 78 prescribers met criteria with 62 unique members. Lynn also presented three trend graphs to support the effectiveness of the narcotic cough syrup intervention (claim count, member count, and prescriber count). She reminded the Board since 2017 when the FDA issued a warning letter regarding the use of opioids and narcotic cough syrups in children, we have identified use of these drugs for DUR interventions The trend graphs include data from Q1 2017 through Q1 2024. Each trend graph indicates a dramatic decrease in the use of narcotic cough syrups, the number of members receiving prescriptions, and the number of prescribers writing those prescriptions.

To wrap up this discussion, Lynn indicated the DUR core team feels this focused intervention should be continued on a monthly basis, but a change in the alert message is needed. She reviewed the history of the letter message, reminding the Board that the current letter message was voted on at the March 2023 meeting and revised as of April 2023. It was noted that the current message indicates that the patient has received "multiple prescriptions" for narcotic cough syrups. As the criteria is triggered by a 24 days' supply, this could, and sometimes does, result from a single claim. Lynn indicated the message will be updated to say that the patient "appears to be frequently using" a narcotic cough syrup, rather than stating that the patient has received "multiple prescriptions".

Long-Term Use of High Dose Benzodiazepine Impact Analysis
Lynn began the discussion by reminding the Board that this intervention was discussed at the March 2024 meeting. She

indicated that an adjustment to the impact analysis was required, and she was going to present the data again. Prior to presenting the updated analysis, Lynn reviewed the criteria for inclusion in the intervention and reminded the Board that letters for this analysis were sent in March 2023. This intervention addresses 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. She noted that the members with a seizure diagnosis were the reason for the adjustment to the impact analysis. During the March 2024 presentation, these members were not excluded from the analysis. Once these members (23) were removed from the impact analysis, there were 282 members available for remeasurement. Of the 282 members available for remeasurement, 40% had either no benzodiazepine claims or had claims that were now below the dose threshold (8% and 32%, respectively). The other 60% of members continued to have claims for benzodiazepines above the dose threshold. This resulted in a change from a 44% success rate to a 39% success rate. Even with this small decrease in the success rate of the initial intervention in March 2023, the DUR core team feels there are still positive changes as a result of this intervention, and it will be continued. She reminded the Board that letters were sent again in March of 2024 and an impact analysis will be conducted on this second intervention and presented at a future meeting.

Buprenorphine & Benzodiazepine Intervention & Benzodiazepine Dose Discussion

Dr. Copeland began by sharing background information on the concerns of concurrent use of benzodiazepines and buprenorphine. Initial concerns about this medication combination were a result of a 2016 FDA warning letter regarding benzodiazepines with other drugs that could depress the central nervous system (including buprenorphine). In 2017, the FDA clarified the 2016 warning letter stating that while the combination was a risk, treatment should not be withheld but careful management should be implemented by providers. 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 or poisoning.

Lynn continued the discussion by reminding the Board that intervention on this topic was started in 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. She also reminded the Board that at the December 2023 meeting, the DUR core team felt that a review of the buprenorphine/benzodiazepine intervention and current literature was warranted given expanded access to buprenorphine. Based on Board discussion at that meeting, additional data analysis and literature reviews were conducted, and a letter was created and signed by Dr. Huebner and Dr. Copeland. A copy of that letter was shared with the Board. Lynn completed this portion of the presentation by reviewing the parameters for inclusion in the new intervention. She indicated that members will be identified when they are taking both buprenorphine and a benzodiazepine for at least 80% of the time in a 90-day period. Additionally, members must exceed the benzodiazepine dose threshold for inclusion. The dose thresholds are alprazolam 3mg, clonazepam 1.5mg, Diazepam 30mg, Lorazepam 6mg.

Dr. Copeland resumed the discussion to address the considerations used to create the parameters for the new intervention and to discuss the rationale used for the selection of the dose used for the benzodiazepine threshold. He noted that interventions are generally created to reduce the risks associated with higher doses, polypharmacy, utilization patterns, and/or prescribing patterns. While creating interventions, resources have to be considered as they may be limited and need to be utilized for the members at highest risk. This intervention was complex due to several issues being addressed at the same time including drug interactions and multiple medications with different doses. Dr. Copeland

indicated that research on the doses for all of the benzodiazepines is lacking, but there is literature around alprazolam use with buprenorphine. Literature indicated that doses 3mg and higher, when used in combination with buprenorphine, place a patient at higher risk for overdose and death; and this is the rationale for using the 3mg threshold for this intervention. He reminded the Board that there have been several other benzodiazepine interventions, one of which addressed high dose and long-term use of benzodiazepines. He went on to explain why the doses from that intervention were not utilized for this new intervention, which included being able to address a larger member population.

Senior Care Program & Anticholinergic Medication Use

Tiffany began with an overview of the SeniorCare program. She shared that it is required by Wisconsin statute and is a drug benefit for Wisconsin residents who are over the age of 65 that are not receiving full Medicaid benefits. There are two programs under the SeniorCare umbrella, a federally funded waiver program and a state funded pharmaceutical assistance program. The federal waiver program was the focus of the rest of the discussion. Tiffany provided the Board with the history of the waiver program in Wisconsin. SeniorCare was started in 2002 when CMS approved the first waiver application for the program for a demonstration period of five years. Extension of the waiver is requested with each waiver expiration. In April 2019, CMS approved the waiver for a 10-year demonstration period. As part of the review and extension process, CMS requires that two Interim Evaluation Reports be submitted during the current demonstration period. She went on to explain that these evaluations must be completed by an independent evaluator and provide recommendations that the Department may want to review. One of the current evaluations noted a possible issue with duplicate anticholinergic use in the SeniorCare population. To address this issue, a focused intervention was created.

Katie continued the discussion by providing the Board with additional details on the intervention, which was implemented in April 2024. She indicated that multiple sources were consulted to create a comprehensive list of medications to include in the intervention. The evaluation report provided a list of medications as a foundation, then more medications were selected based on existing anticholinergic criteria, and a literature review identified other medications of concern. The criteria alert message and parameters for selection were shared with the Board. Katie noted that the parameters for selection were slightly different than those utilized for the report, and that the intervention parameters would allow identification for recent concurrent use of duplicate medications. She then reviewed the medications included in the intervention and provided data on the first two cycles of the intervention (April and May 2024). In April, 500 members were identified for intervention, 250 were selected for review, and 199 were selected for intervention with 347 letters being sent. Of note, 77% of those receiving letters were in the SeniorCare program. Complete data for the May cycle was not available, but 321 members were identified for intervention and 250 members were selected for review. Katie went on to discuss a change made to the medication list for the May cycle that may have changed the number of members identified. After the initial cycle, the DUR core team felt that the removal of ipratropium from the criteria was clinically appropriate. One goal of DUR letters is to provide actionable information. It was felt that asking a provider to consider discontinuation of a medication that is a standard of care was not in the best interest of the member. Additional insights from the first two cycles were shared, including number of medications and rationale for not sending a letter. She indicated that most members identified for review had two or three concurrent medications, but there were some that had up to five concurrent anticholinergic medications which supported a need for this intervention. Some reasons for not sending a letter included systematic limitations, short-term use of anticholinergic medications, and clinical judgement. The discussion was closed by indicating that the intervention would be run monthly for the first three months and then quarterly starting in September 2024. An intervention analysis is being considered for a future meeting.

PDL Update

Lynn provided a brief PDL update from the May 1, 2024, PDL meeting. Public testimony was given from 13 manufacturer representatives, three clinicians, and written testimony was also received. There were 56 previously reviewed drug classes with no new classes reviewed. The Prior Authorization Committee voted to endorse all staff recommendations and the DHS secretary has now accepted all recommendations. They are still in the process of publishing update materials for the changes that will be implemented on July 1, 2024. Lynn noted there was significant discussion around the GLP-1 drug class due to drug shortages. She reminded the Board that a diagnosis code requirement is in place for both preferred and non-preferred agents. Current PA criteria for non-preferred GLP-1 agents requires step through of two preferred products for approval. Due to drug shortages, one additional product was temporarily added as a preferred agent (Ozempic®). The PA criteria will be revised on July 1, 2024, with the step therapy requirement changing to use of one preferred product. There will be no PA exemption for Ozempic® when the preferred products revert to their previous status. There is no estimated date for when Ozempic® will return to non-preferred status.

Adjournment

Brooke Passolt motioned to adjourn the meeting. The meeting adjourned at 3:58 p.m. Upcoming meetings are on the following Wednesdays: September 11, 2024, December 4, 2024, and March 5, 2025.

Guests: John Bullard, Alexion; Kimberly Eggert; Gary Parenteau, Dexcom; Robert Robey, Indivior; Akesha Coleman, Johnson & Johnson; Kelly Ruhland, Lilly; Laura Etheridge, SK Life Science; Shannon Meece, Pfizer; Sherry Betthauser, Jazz Pharma; Robyn Bruining, Sanofi; Kellie Murry, Neurelis; Kelly Hamilton, Takeda; Danielle Brolsma, Teva.