MINUTES OF THE DRUG UTILIZATION REVIEW (DUR) BOARD MEETING

Wednesday, June 7, 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, PharmD
Jeff Huebner, MD
Ward Brown, MD
Robert Factor, MD

Gainwell Staff Present:

Tom Olson, PharmD
Justin Soniat
Willie Wilberg, PharmD
Chally Clegg
Elise Ormonde
Emily Gentry, PharmD
Joseph Dunlop (SAS)
Travis Copeland, MD

DHS Staff Present:

Kim Wohler Lynn Radmer, RPh Tiffany Reilly Susan Seibert Pamela Appleby Kris Deblare 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 March 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 March minutes were briefly reviewed and approved with an initial motion from **Jake Olson** 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 increase but is beginning to level off. Lynn pointed out that claim volume and member count are trending upward. There was a significant increase in claim count between 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 four members identified in the last quarter, two members were new, one received a warning, one received an alert, one member was currently suppressed due to a recent letter that had been sent, and one member was non-actionable due to Part D coverage.

Next, Lynn presented graphs for the percentage of adults and children on stimulant medications. The percentage of children has been decreasing, but with a recent rise that could be due to the cyclical use in children with the school year. The percentage of children and adults on stimulants are very similar now. 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. Additional DUR alert trend graphs were presented. Lynn indicated that all alert graph and some of the other graphs are trending up due to the increased number of claims. 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 recent alert changes that took place in November 2021, there has been a sharp rise in late refills as well as a sharp decline for therapeutic duplication. 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 reminded the Board that pharmacies are also able to pre-override these alerts when appropriate. A new slide was added to show that the percentage of overrides has remained stable. Overall, approximately 75% of the claims do receive an override currently. The total

denied increased in the past quarter, but the override percentage did show a decline. 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 change in dispensed quantity. 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 during the COVID-19 public health emergency. 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 93% increase of members receiving naloxone from 2020 Q4 to 2023 Q1.

Two graphs were presented to the Board looking at Naloxone member trends from 2020-2023. Naloxone usage has increased dramatically from Q4 2020 to Q1 2023. 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 Q1 2023, we saw a reduction in members with 90 MME as well as a slight increase in Naloxone dispensed. The average percent of members with 90 MME or greater and receiving a Naloxone fill in Q1 2023 was 14%.

Opioid Script Limit

Lynn began by presenting the average MME by override. There was a recent increase in the number of overrides in second and third quarter 2022 but has leveled off. This increase was due to two outlier claims during this time frame for members with cancer diagnoses and high MME claims for a small day's supply. Moving forward we plan to create a process to monitor for these outlier claims for members who got an override on a quarterly basis. The percent of override trend was also presented and has remained stable overall.

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 Q1 2023, there were 204 members on all four drugs, 85 members with 45 or more total days' supply, and only 20 members that were considered new and were lettered on for this intervention. Lynn reminded the board that all of these numbers can be located and will be updated quarterly on the continuing intervention spreadsheet.

High MME Reset

Lynn began reminded 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. The current letter message was also reviewed with the Board. 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 127 members identified at this threshold. Data was not yet available for how many letters were sent involving these members, but plan to present this information at the next Board meeting. 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. Mike Ochowski raised a question regarding the CDC's decision to change the MME table in either late 2022 or early 2023. He was curious if that had a significant impact on the number of members who were judged to have a high MME. Lynn stated that this could be something that the team could take back to analyze further for future discussions.

Opioid/Benzodiazepine Intervention

The continuing intervention spreadsheet was then reviewed for the opioid/benzodiazepine intervention. For this intervention there are two phases. 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. 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 first quarter, there were 234 members identified who were on this combination and 394 prescribers. Letters were only sent on new members and for first quarter, 34 new members with 69 prescribers were identified. These numbers continue to decline over time. The top prescribers with five or more members meeting the criteria were also reviewed. Twenty-three members involving four prescribers were identified in the recent quarter, and three of these were considered a new prescriber. In general, these numbers have continued to show a positive trend overall.

Naloxone Impact Analysis

Lynn pointed out that this topic was previously discussed at the March meeting, however, has been expanded upon and there are some new updates to provide. The discussion began with a brief overview of this intervention for the Board. Naloxone intervention letters started in March 2021 and continue on a monthly basis. Letter criteria is based on opioid usage plus a diagnosis of either opioid dependence or poisoning with an opioid or benzodiazepine. The alert messages for each letter were reviewed. The impact analysis of the March 2021 intervention was presented at the March 2023 meeting. Nearly two years after the initial letters were sent, the overall Naloxone success rate was 53%. This initial analysis is being considered analysis one for the purpose of this impact analysis review. Two additional analyses of the naloxone data were then discussed. Analysis two looked at a greater time period of recommendation letters sent from March 2021 to December 2022. For this analysis, 455 members and 486 prescribers were identified for naloxone recommendation. Analysis two reviewed all members along with the opioid dependency group and the poisoning group separately. From 2021 Q1 to 2022 Q4, 391 members were identified by the dependency criteria and 63 members were identified by the poisoning criteria, with one member being identified in both groups. Two years after the letters were sent, the success rate for this analysis was 48.68% for all the members identified, which was very similar to the success rate of 53% for the initial one-month analysis. The Success Rate was found to be 48.66% for the members identified by the dependency criteria and 48.89% for the members identified by the poisoning criteria. Analysis three looked at naloxone recommendation letters sent from March 2021 to December 2021. There were 245 members and 278 prescribers identified for naloxone recommendation. Utilization was reviewed through 1Q 2023 for naloxone fills and changes in opioids, opioid dependency, and benzodiazepine drug use. A decrease was seen in the number of eligible members with opioid dependency agents from 2021 to 2023 Q1. Overall, there was approximately 50% success rate across all three impact analyses as well as decreased utilization within opioids, opioid dependency agents and benzodiazepine drug groups. Jeff Huebner added that he thought these results were very impressive and he was very glad to see this work. Lynn also reminded the Board of the CMS interest in this work.

Gabapentin and Pregabalin Impact Analysis

Lynn began by pointing out that this has been an ongoing focused intervention since April 2022. Gainwell receives a member-prescriber list from Kepro detailing members and prescribers who hit the criteria for concomitant gabapentin and pregabalin use. To be identified for review, a member must have a 30-day supply or more of both gabapentin and pregabalin within the last 90 days with a claim for both gabapentin and pregabalin within 28 days of each other. The focused intervention letters were sent in 2022 Q2 for those members identified in April 2022. There were 106 members and 167 prescribers identified for the intervention. Nearly one year after the letters were sent, the Success Rate was 82%. This is the highest Success Rate we have seen for an intervention. For prescribers who received a letter and have at least

one member above criteria, the prescriber trend shows a decrease from 163 in 2022 Q1 to 46 in 2023 Q1. Three of the four prescribers who were not included in the intervention were prescribing to members who no longer met criteria. It was found that the members who received prescriptions from more than one prescriber decreased more quickly than members who went to only one prescriber. A follow-up letter was also sent to the multiple prescribers for the members with a seizure diagnosis who are still above criteria. Given the high success rate of this intervention, the recommendation was made to continue this focused intervention on a monthly basis by continuing to review all members who are hitting this criteria. Brook Passolt and Jeff Huebner were both in agreement with continuing this intervention. Jeff asked for clarification regarding the members with seizure diagnosis. Lynn verified that these members may also be lettered on and there is no additional filtering that takes place based on diagnosis.

Dental Discussion

Lynn began by explaining to the Board that this intervention has been ongoing since 2017 and with the involvement of Dr. Dunkel 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. The criteria was updated in August 2022 to include adults as well. In May of 2023, the intervention has been 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%. For 2022, the number of prescribers identified was 107 for Q1 and Q2 and 97 prescribers for Q3 and Q4. For the phase I intervention letters, 28 new prescribers were identified to receive a letter. 28 dental prescribers were also identified for a phase 2 letter. The 28 dental prescribers include six prescribers that Dr. Dunkel identified for outreach calls. A copy of the dental letter spreadsheet

was displayed for the Board to review.

Narcotic Cough Syrup Intervention

Lynn began by reminding the Board that this topic has been discussed several times previously and is a follow-up on the discussion from our December meeting. Beginning in January 2023 the criteria was being reviewed monthly as a focused intervention when a new criteria was developed specific to the state of Wisconsin. The original letter message was voted on at the March 2023 meeting and revised as of April 2023. In April a full-send was done and letters were sent to providers identified when diversion, abuse or chronic use is a potential concern, even if they had received the previous version of the letter. The current letter message was reviewed. Overall claim trends were also reviewed from Q1 2017 through Q1 2023. This showed that there has been a dramatic decrease that has occurred, from 13,264 claims in 2017 Q1 to 2,739 claims in 2023 Q1. At the March meeting it was recommended to continue the intervention through second quarter 2023; however, based on available data and due to the seasonality factor the new recommendation is to continue the intervention through first quarter 2024. The plan is to present an impact analysis, to measure the effectiveness of the intervention, at the September 2024 DUR Board meeting.

Mental Health Consultant Update

Dr. Copeland began by providing an update and proposal for change with the polypharmacy sedating medications in children intervention. The new proposal is for the addition of clonidine to this intervention. The screening criteria looks for children 18 years and younger who are on sedating medications from three or more drug groups for 90 days or more in the last quarter. Currently clonidine is not included in the list of sedating medications and drug groups used. There have been 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. In 2023 Q1 the addition of clonidine in its most sedating formulations was researched. During this research, clonidine was identified as the most prescribed agent replacing trazodone and was most prominent in younger age groups, although was still noted to be common across all ages. When reviewing member counts, total members identified without inclusion of clonidine for 2023 Q1 was 86. With the addition of clonidine, in its most sedating formulations, this number rose to 306 members that were identified. The recommendation is to add clonidine (excluding ER and TTS) to the drug groups already included and anticipate sending a letter during 2023 Q3, for those members identified using data from 2023 Q2. Additionally, Dr. Copeland pointed out that the members who were lettered on in 2022 Q4 will be excluded from the dataset. Jake Olson raised a question regarding how many of these children may also be taking Adderall and other stimulants. Dr. Copeland stated that currently that has not been looked at but agreed that it would be a logical thing to

look further into in the future. Brook also added that guanfacine is commonly prescribed in children with ADHD and often would be prescribed alongside stimulants from a behavioral standpoint. Dr. Copeland agreed and again reinforced the fact that the recommendation currently would be to only add the most sedating formulations of clonidine for this intervention.

Dr. Copeland then moved into a discussion for the benzodiazepine intervention letter including recent feedback and clinic consultation that was held. Dr. Copland provided a brief background for this intervention. A letter was sent to prescribers alerting them to members with long-term utilization of a benzodiazepine drugs with one of four benzodiazepines at high doses. The letter, which was signed by Dr. Huebner and Dr. Copeland, included the member's prescription information, a summary of concerns about long-term utilization of a high dose benzodiazepines, a discussion of the understood challenges for prescribers involved in reducing and deprescribing benzodiazepines, a list of reference materials for assistance to prescribers, and DUR mailbox contact information with an offer for additional assistance. At the end of April 2023, a general psychiatrist, who received a letter regarding two members, reached out to thank the Department for the helpful information and inquired about a possible clinic consultation to assist providers with efforts to reduce use of benzodiazepines. In May 2023, Dr. Copeland provided a clinical consultation via Zoom. At the end of the consultation, Dr. Copeland requested feedback from providers about the intervention letter they received. Positive feedback was received, and one of the main highlights was the difference in this letter was the tone and the letter provided helpful resources. Dr. Copeland noted that moving forward this may be something to consider for future letters. Jake Olson remarked that he agreed that often the notification only type letters are not as well received as these letters that also provide helpful resources and specific assistance and information regarding the issue.

Proposed Targeted Intervention for Sickle Cell Disease

Tom Olson began the discussion with an overview of the disease, epidemiology, and available treatment options. Lynn then explained the Kepro criteria that is currently available which looks at members diagnosed with sickle cell disease (SCD) who are regularly using opioids but are not using a disease modifying medication. For this criteria, member's must have a diagnosis of SCD, at least 60 days' supply of opioids in a 90-day period, and less than 21 days' supply of a disease modifying drug in a 90-day period. Lynn explained that we would not likely move forward with the Kepro criteria that is currently available, but plan to make modifications and develop a targeted intervention. Lynn explained that for a targeted intervention Gainwell would be involved with pulling the data needed for this intervention and then the team would develop a specific letter that can be sent to identified prescribers. Some questions were raised for further Board discussion including, determination of which disease modifying agents should be included for this intervention (hydroxyurea, Adakveo, and Endari), which SCD diagnosis codes should be included (potentially excluding sickle cell trait or other codes), and what threshold (less than an x days' supply) of a disease modifying drug and opioid would be needed to trigger the letter. Lynn noted that some data had been reviewed, and approximately 1,800 members were identified with a SCD diagnosis. When the sickle cell trait was excluded from this list of diagnosis codes, the number of members was reduced to 811. For May 2023, Kepro found that there was a total of 64 members hitting their specific criteria, for the current month. Dr. Huebner added that he thought this was a great intervention and wants to ensure that members are receiving better treatment for their SCD while also avoiding any potential bias or inequality associated with treatment of pain in these individuals. He stated that one of the key things that other states have done is looking more closely at the specific diagnosis codes for this disease. Brook and Mike added that they also agreed that excluding the sickle cell trait diagnosis code would be most appropriate. Brook stated that adding as many of the disease modifying drugs as possible to the wording of the letter would be beneficial and less confusing for providers upon receipt of the letter. Mike then raised a question about ER visits and if these members often end up in the ER due to acute pain crisis related to SCD. Lynn stated that it may be difficult to identify these members as requiring an ER visit specific to this diagnosis, but that we could potentially do some additional consideration of data and look at this further as well. Overall, the plan is to explore this further and bring back decision points and further discussion at the September 2023 Board meeting.

PDL Update

Lynn wrapped up the meeting with a brief PDL update from the May 3, 2023, PDL meeting. Public testimony was given from 14 manufacturer representatives and written testimony was also received. There were 55 previously reviewed drug classes and one new drug class, HIV/AIDS. 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, 2023. The HIV/AIDS drug class will use the PA/PDL exemption form and the alternate PA criteria will also be available for this drug class. There will be established exceptions for members who are currently on HIV/AIDS medications that will now be changing to non-preferred. This will be called legacy exemption to bypass the PA requirement for these members. This will involve a small list of drug products and will not be applicable for generic/brand name conversions. Two other drug classes were discussed briefly, in the glucagon agents, Gvoke is a non-preferred product and written testimony was reviewed regarding this product for consideration of changing to a preferred agent. After discussion with the PA committee, it will remain non-preferred, however a PA bypass will be applied for children less than six years of age beginning July 1, 2023. For the hypoglycemics, GLP-1 class, currently preferred drugs in this class do not require PA, however a diagnosis code requirement will be added for both preferred and non-preferred agents. The diagnosis code requirement will be effective August 1, 2023. Mike asked which diagnosis codes would be required for the GLP-1 drug class. Lynn confirmed that they will be limiting to a diagnosis of Type II diabetes.

Adjournment

Mike Ochowski motioned to adjourn the meeting. The meeting adjourned at 4:01 p.m. Upcoming meetings are on the following Wednesdays: September 13th, 2023, December 6th, 2023, and March 6th, 2024.

Guests: Doug Johnson, Sobi; Kelly Ruhland, Lilly USA; Kelly Hamilton, Takeda; Scott Mills, Karuna Therapeutics; Jody Jensen, Biogen; Lisa Gronneberg, Biogen; Clemise Hurst, Eisai