MINUTES OF THE DRUG UTILIZATION REVIEW (DUR) BOARD MEETING

Wednesday, June 2, 2021 1:00 p.m. to 3:30 p.m. Virtual meeting via Zoom

DUR Board Members

Present: Steve Tyska, MD Robert Factor, MD Jake Olson, PharmD Michael Ochowski, RPh Jordan Wulz, PharmD Paul Cesarz, RPh Ward Brown, MD Absent:

Gainwell Staff

Present: Tom Olson, PharmD Katie Counts, PharmD Michael Olsen Eric Matyas Willie Wilberg, PharmD Chally Clegg Justin Soniat

DHS Staff

Present: Kelsey Brundage Lynn Radmer, RPh Tiffany Reilly Russ Dunkel, DDS Susan Seibert Pamela Appleby Darla Stachowiak

Welcome and Introductions

Kelsey Brundage called the meeting to order at 1:02 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, Kelsey 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 2021 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 **Michael Ochowski** and a second from **Jordan Wulz**. The motion passed unanimously.

Updates

Lynn began the presentation by reminding the Board of the ongoing analysis of the dental provider data and the potential for an upcoming intervention letter aimed at these prescribers. Dr. Russ Dunkel, DDS, continued the discussion indicating that there are plans for a new letter to be drafted and that it is likely dental providers for both pediatric and adult populations will be included in the intervention. An additional update will be provided at the September 2021 meeting.

Quarterly DUR Reports

Lynn reviewed the quarterly reports with the Board beginning with a discussion of 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. Overall, the downward trends for these medications continue. Lynn noted that enrollment has continued to increase over the fourth quarter. This increase is still attributed to the COVID-19 public health emergency. In addition, trend graphs for average morphine milligram equivalents (MMEs) per member per day and members utilizing buprenorphine from 2018 - 2021 were included. As seen with last quarter, as the average MME has decreased, the use of buprenorphine has increased. A trend graph for Vivitrol[®] was presented to the Board. The number of members remains steady after a notable decrease in the second quarter of 2020. The decrease is being attributed to more limited access to care during the COVID-19 public health emergency. The last trend graph presented was for naloxone. Lynn noted that because of new FDA warnings and prescribing recommendations, the number of naloxone claims has increased over time. Further analysis of the trend graph was done based on opioid use and MME levels. That analysis revealed 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). Lastly, Lynn reminded the Board of the quarterly intervention approved at the September 2020 meeting that targets members who are on multiple CNS depressants. The intervention 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. The intervention focuses on those members considered high risk due to chronic concurrent use. The selected members are reviewed, and a letter is sent to providers regarding the risks of the noted polypharmacy.

DUR alert trends and quarterly deduplicated claims information were also included for Board review and were discussed in more depth. Changes to alerts in response to the COVID-19 public health emergency were noted to have impacted the volume of both the alerts and claims. Total claim volume continues the previous fourth quarter trend and remains lower than in recent quarters. Notable changes to DUR alerts include an increase in the Early Refill alert and a decrease in the Late Refill alert. These changes are attributed to system modifications to some alerts and expanding the number of medications that are eligible to be dispensed for a three-month supply. Lynn also shared a new version of the quarterly deduplicated claims data that will be utilized going forward. The new layout includes information on claims with single and multiple DUR alerts as a result of the recent requirement for pharmacies to respond to each unique DUR alert types instead of a single alert.

Secondary to the requirement that pharmacies respond to each unique DUR alert type, Lynn gave the Board an overview of each DUR alert. Lynn shared how each alert is triggered and how drugs and diseases are included in the alerts (drug class, First Data Bank classification, etc.). Additionally, Lynn shared reports that included the top drugs and/or disease states involved for each alert. It was noted that there is ongoing maintenance to keep the information in the alerts up to date. Further information on the drug inclusion and maintenance of some alerts may be presented to the Board at a later date.

High Cumulative Dose Alert Discussion

Lynn started the discussion by reminding the Board that this alert is part of the State plan to meet SUPPORT Act requires that a prospective safety edit be in place to identify members that exceed the State-identified maximum daily morphine equivalent (MME). She reminded the Board that the current alert was implemented on June 1, 2020, and reviewed the alert message to the pharmacy. The alert will trigger when a single claim has a daily MME that is greater than or equal to 90. She noted that the alert is currently an informational alert, and the pharmacy is not required to respond to this DUR alert. A recommendation was then made to the Board to change the status of this alert from an informational alert to a soft alert. A soft alert is defined as an alert that the pharmacy must respond to with an override added for claim payment. After a motion to accept the recommendation was made by **Steve Tyska** and a second by **Robert Factor**, Lynn opened the floor to discussion by the Board. Discussion topics included potential burden to the pharmacy based on claim volume, concern for lack of system capability to bypass this alert for cancer or hospice patients, and system requirements to reassign the status of the alert. The Board voted 6-1 in favor of changing the status of the alert from an information and system requirements to a soft alert.

Naloxone Retrospective Letters

Katie began the discussion by reminding the Board members that additional SUPPORT Act requirements identifying members at high-risk for opioid overdose who may benefit from co-prescribing naloxone were to be implemented by March 1, 2021. As a result of this requirement, two new retrospective review criteria were operationalized in March 2021 to allow intervention on these high-risk members. Katie shared the current process for the intervention, including the parameters for identifying a member for intervention, the alert message in the prescriber letters, and frequency of review completion. The statistics for the reviews from March 2021, April 2021, and May 2021 were shared with the Board. It was noted that the time frame for prescriber responses was a small window, but responses and comments from the March and April reviews were shared with the Board. A total of 119 letters were sent. A 12% response rate was achieved, with 57% of those responses indicating that positive action was being taken by the prescriber. Many providers indicated that they had sent a prescription for naloxone because of the letter, and others stated that they would be discussing the need for naloxone at an upcoming visit with the member. Katie noted that naloxone use can be difficult to track as there are multiple ways to obtain the medication that may not be reflected through pharmacy claims. Additionally, members may have naloxone on hand that was previously dispensed and also not seen in pharmacy claims. Naloxone utilization will continue to be monitored due to SUPPORT Act requirements.

Medication Adherence Retrospective Letters

Katie shared with the Board that a focused intervention on underutilization of selected antipsychotic agents and asthma agents was completed in February 2021. She noted that overutilization is frequently targeted in the RDUR reviews, but that underutilization is also an issue worthy of being addressed due to the possible extra costs associated with uncontrolled disease states. Several reasons that may lead to non-compliance for these two drugs classes were shared

with the Board prior to discussing the results of the interventions.

Antipsychotic Adherence

Retrospective utilization reviews were performed for three antipsychotic medications during the February 2021 cycle. The drugs included were cariprazine, lurasidone, and brexpiprazole. Systematic requirements for the identification of underutilization and the alert message in prescriber letters were shared with the Board. Katie then shared the statistics for the members identified for each medication, the number of cases created, and the number of letters sent. It was noted that the number of cases created may not reflect the expected number of cases due to systematic limitations in which a member may be identified as non-compliant but upon further manual review was noted to be compliant. A total of 109 letters were sent. A 14% response rate was achieved, with 87% of responses indicating that positive action was being taken by the prescriber. The majority of prescribers responded that therapy is being modified or that the member has an appointment to discuss the issue.

Asthma Adherence

Retrospective utilization reviews were performed for three inhaled asthma controller medications during the February 2021 cycle. The drugs included were fluticasone propionate HFA, budesonide/formoterol, and fluticasone propionate/salmeterol. Systematic requirements for the identification of underutilization and the alert message in prescriber letters were shared with the Board. Katie then shared the statistics for the members identified for each medication, the number of cases created, and the number of letters sent. It was noted that the number of cases created may not reflect the expected number of cases due to systematic limitations in which a member may be identified as non-compliant but upon further manual review was noted to be compliant. A total of 318 letters were sent. A 10% response rate was achieved, with 45% of responses indicating that positive action was being taken by the prescriber. The majority of prescribers responded that therapy is being modified or that the member has an appointment to discuss the issue. Of note, 25% of responses indicated that the member had not been seen recently.

Katie went on to discuss an interesting finding in the comments from the providers. Several providers indicated that the inhaled controller medication was intentionally used on an "as-needed" basis. This regimen does not correspond to the traditional asthma treatment guidelines that support the use of daily inhaled controller medications. As a result, further research was done to investigate the "as needed" regimens. Katie shared that new updates to the traditional treatment guidelines by at least two well-known organizations, the National Heart, Lung, and Blood Institute (NHLBI) and the Global Initiative for Asthma (GINA), do support the use of inhaled controller medications on an as-needed basis. The 2020 updates for both guidelines discuss the rationale and the research used to support this recommendation. This information was shared with the Board members and was noted to likely be a contributing factor to some of the noted underutilization.

CMS Annual Report

Lynn reminded the Board that each year the State is required to complete and submit a report to CMS. Information in the report includes program demographics, prospective DUR alerts, PDL updates, claims activity, and retrospective DUR interventions and activity, including innovative practices. Lynn noted that each year CMS requests more information and this year that included information on the prescription drug monitoring program (PDMP). CMS will be collecting the responses from each state and presenting the information to Congress to show how SUPPORT Act requirements are being met.

Preferred Drug List Update

Lynn provided an update from the May 2021 PA Advisory/PDL meeting. The meeting was held virtually via Zoom. Public and private formats were utilized to allow public testimony. A review of 53 current drug classes and one new drug class was completed. The new drug class will be for glucagon agents. Lynn continued with a review of the clinical aspects of the meeting. Notable changes were made to the following classes: androgenic agents, bone resorption agents, migraine agents, hepatitis C agents, insulin agents, and beta blocker agents. All recommended changes were supported by the committee members and have been approved by the Secretary. Implementation of these changes is anticipated in July 2021.

Adjournment

Paul Cesarz motioned to adjourn. The meeting adjourned at 3:30 p.m. Upcoming meetings are on the following Wednesdays: September 1, 2021, December 1, 2021, March 2, 2022, and June 8, 2022.

Guests: Gary Behrens, Sanofi Genzyme; Doug Johnson, Sobi; Robert Robey, Indivior, Inc.; Kelly Ruhland, Lilly USA; Jason Vandervest, Vertex Pharmaceuticals; Carmel Schwalm, Takeda; Todd Kailas, Alkermes, Inc.; Jeff Knappen, Spark Therapeutics; Matthew Wright, Artia Solutions; Rob Bigham, BioCryst; Kelly Petrowski, AbbVie; Heather Coufal, AbbVie; Bradley Jones, AbbVie; Rudell Christian, Alkermes, Inc.; Patrick Appolonia, Pierre Fabre; Dylan Bassett, Pierre Fabre; Thomas Pletkovich, Pierre Fabre; John Davis, LEO Pharma; John Bullard, Alexion Pharmaceuticals; Taylor Neely, Vifor Pharma; Joseph Cirrincione, Otsuka; Cynthia Tsang, Takeda Pharmceuticals; Rich Dierckens, Astellas Pharma; Jomy Joseph, Sanofi Genzyme; Steve Isaki, Lundbeck; Jon Yochum, Provention Bio; Christopher Dobberpuhl, Ascendis Pharma; Alexandra Sklansky, Unity Point Health – Meriter; Dianne Hansen, DSI; Bradley Kalkwarf, Regeneron; Kelly Draveling, Oncopeptides; Dawn Bina, Mitsubishi Tanabe Pharma America