MINUTES OF THE DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
Wednesday, June 3, 2020
1:00 p.m. to 3:15 p.m.
Virtual meeting via Zoom

DUR Board Members	DXC Staff	DHS Staff
Present:	**Present:**	**Present:**
Steve Tyska, MD	Tom Olson, PharmD	Kelsey Brundage
Paul Cesarz, RPh	Katie Counts, PharmD	Lynn Radmer, RPh
Jake Olson, PharmD	Michael Olsen	Tiffany Reilly
Michael Ochowski, RPh	Eric Matyas	Russ Dunkel, DDS
Robert Breslow, RPh	Willie Wilberg, PharmD	
Julie Sager, MD	Chally Clegg	
Robert Factor, MD	Randall Cullen, MD	
Absent:	Darla Stachowiak	
Ward Brown, MD		

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. The retirement of Robert Breslow was confirmed. A special thank you was extended to him for his time and dedication to the Board over the years. The resignation of Mike Brown was also announced. A quorum of members attended the meeting. As the meeting was held virtually, Kelsey provided technical instruction on how the meeting would proceed.

Review of the Agenda and Board Materials and Approval of March 2020 Meeting Minutes

The members were reminded of the meeting materials sent via email for reference and review. Lynn walked through the agenda as printed. Prior to this meeting, Board members received the agenda, minutes, and RDUR Quarterly Report via e-mail and had the opportunity to review each document. The March minutes were then briefly reviewed and approved with an initial motion from **Paul Cesarz** and a second from **Julie Sager**. The motion passed unanimously.

Quarterly DUR Reports

Lynn reviewed the quarterly reports with the Board beginning with 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, though a slight increase was noted for the first quarter of 2020. Of note for the first quarter was in increase in enrollment. This increase was attributed to the increase in unemployment during the COVID-19 pandemic. Lynn noted that if the increase continues, the reporting of this information may need to be changed. Board members suggested presenting the data as actual numbers or a rate in place of the current percentage. In addition, trend graphs for average morphine milligram equivalents (MMEs) per member per day and members utilizing buprenorphine from 2016 - 2020 were included. As seen last quarter, the average MME has decreased, and the use of buprenorphine has increased, though may be reaching a plateau. DUR alert trends and quarterly deduplicated claims information were also included for Board review.

DUR alert trends were discussed in more depth in light of enrollment changes and changes to alerts in response to the COVID-19 pandemic. An increase in claim volume was noted for first quarter 2020, thus resulting in an increase in the number of most DUR alerts. Specifically noted were increases for the Early Refill alert. This alert was modified from a "hard" alert to a "soft" alert to allow pharmacists to override the alert in the pharmacy without a phone call to the Drug Authorization and Policy Override call center. As a result, the volume of overrides increased significantly, as expected. Lynn also noted changes to the Patient Age alert and stated that this continues to be monitored and will be presented again at a later date.

MME Alert - SUPPORT Act

Lynn reminded the Board that the SUPPORT Act creates new requirements for Medicare and Medicaid aimed at reducing opioid use which resulted in a claims edit requirement for maximum daily morphine equivalents (MMEs). A prospective informational alert will be displayed to a pharmacy when a single claim has a daily MME greater than or equal to 90. At the March 2020 meeting the Board was informed that the alert will be informational and thus will not stop a claim from paying. Lynn stated the alert was implemented on June 1, 2020. The alert code (HC) and associated pharmacy message were shared with the Board.

Antipsychotic Use in Children – SUPPORT Act

Also, in relation to the SUPPORT Act, Lynn presented new reports in graph form requested by the Board at the March 2020 meeting. The information was provided for the three requested categories for children ages 9 thru 18: all children, non-foster care children, and foster care children. Review of the graphs indicates a downward utilization trend for children 14 years of age and younger in all three groups. The trends in children 15 to 18 years of age remain stable. It was noted that this is not surprising as this age group is when many psychiatric diseases begin to manifest themselves.

Lynn went on to remind the Board members that the State currently requires a prior authorization for the use of antipsychotics in children under 9 years of age before asking Dr. Randall Cullen to discuss the case reviews that are being done to further monitor and address the use of antipsychotics in children. Consultant psychiatrists have been making outreach calls to providers on member's age 9 to 18 who are taking two or more antipsychotic medications, focusing specifically on children with higher doses of both medications. Dr. Cullen stated that these are the most severe cases. Many of these children had multiple psychiatric and behavioral diagnoses. Of note, when polled, most providers stated that the target symptom for the addition of a second medication was patient aggression towards themselves or others. These peer to peer calls will continue as cases continue to be identified and additional information will be shared with the Board at a later date.

Opioid/Benzodiazepine Intervention

Lynn provided a recap of the opioid/benzodiazepine intervention. The intervention targets members receiving 50 morphine milligram equivalents (MME) or more of any non-medication-assisted therapy (MAT) opioid and a daily benzodiazepine for at least 90 days or more. A table that tracks each cycle of letters was provided for the Board members for review. The Board was reminded that a new version of the Phase I letter, which includes naloxone information, was used for the cycle mailed in August 2019 for all identified members. An additional mailing for newly identified members was completed in May 2020 (200 providers accounting for 86 members). Letters will continue to be sent on a quarterly basis, as this intervention is part of the State plan to meet SUPPORT Act requirements.

Lynn remined the Board of the changes discussed at the March 2020 meeting to the Phase II letter process, noting that these letters will be sent to high volume prescribers who are identified by the number of members that qualify for the intervention. Initial Phase II letters were mailed to providers in June 2019. A second set of Phase II letters, utilizing the new version of the letter, were mailed to providers in February 2020 (19 provider accounting for 147 members). While it may be too early to assess the impact of these letters, provider responses were shared with the Board. Responses were received from four providers. All four providers indicated that positive actions were being taken in response to the letters. After further analysis of the providers included in the intervention, peer to peer outreach calls were made to two providers based on their higher volume of identified members (a nurse practitioner and a psychiatrist). Dr. Randall Cullen

shared the results of those calls. He stated that the nurse practitioner was responsive to the call and that extensive communication occurred past the phone call. This provider stated they did intend to make changes to their prescribing practices. The second provider, a psychiatrist, was less responsive to practice changes. However, the office staff did say they planned to make changes to their workflow to help the provider be better informed of the full scope of medications for each patient. Follow up for all identified providers will continue via the intervention and outreach calls, as needed.

There was some discussion among the Board members regarding prescriber PDMP use and responsibility for oversight resides with the Department of Safety and Professional Services (DSPS).

COVID-19 Discussion

Kelsey provided an update on steps that the Division of Medicaid Services have taken during the COVID-19 pandemic to ensure members don't have a lapse in access to medical services and prescription drugs. Changes to support medical services include expedited enrollment processes for new providers and allowing services to be provided via telehealth if the service can be delivered with functional equivalence. Temporary changes to prescription drug policies (excluding Schedule II drugs) include allowing pharmacies to override the Early Refill alert, removing quantity limit restrictions for drugs and diabetic supplies, and allowing pharmacies to dispense a 90 days' supply of medications. Additionally, the list of preferred drug list (PDL) drugs available through the emergency supply process was expanded, and emergency supply prior authorizations are being granted for 90 days.

Gabapentin Discussion

Lynn began by reminding the Board of the December 2019 warning issued by the FDA that the use of gabapentinoids in combination with CNS depressants can result in serious and potentially fatal respiratory depression. Additionally, she reminded the Board of the two new retrospective criteria they approved at the March 2020 meeting. The criteria were implemented for the April 2020 review cycle. After noting the high volume of member 'hits' on the criteria, it was decided that Katie would choose a small subset to review to determine to proceed with these criteria in future cycles. The highdose gabapentin criteria was also selected for review during the April cycle. This criteria identifies members on greater than 3,600mg/day of gabapentin. Katie's review included 124 profiles for the new criteria and 105 profiles for the highdose gabapentin criteria. Reviews were placed in categories according to concurrent medication use (opioid or opioid dependency agents) or diagnoses in history. These groups were selected based on the FDA warning specifically mentioning concurrent opioid use and the fact that gabapentinoids are frequently used in place of opioids.

The 124 new criteria profile reviews resulted in 34% of those members being on either a routine opioid or an opioid dependency agent (19% and 15%, respectively). Additionally, 8% of the remaining members had a dependence diagnosis. Of note, most of these members had been on the drug combination for many months. It should also be considered that this small sample of highest risk members may not be a good representation of the overall population. The 105 high-dose gabapentin reviews resulting in 45% of those members being on either a routine opioid or an opioid dependency agent (25% and 20%, respectively). Another 10% of the remaining members had a dependence diagnosis. The small population size of the high-dose gabapentin reviews indicates only a small percent of the whole population is exceeding recommended doses.

In conjunction with the retrospective reviews, analyses of claims and prospective DUR alerts were completed. The claims analysis included concurrent use of opioids, opioid dependency agents, benzodiazepines, and sedative hypnotics, as well as high dose opioids. The result of the claims review supported the conclusion that the profile review may not be indicative of the whole population. They analysis indicated gabapentin usage is not correlated with other risk factors. The prospective DUR alert analysis revealed two alerts (reported disease and drug-drug) that are available. It was noted that the reported disease alert is not classified as a "major" alert by First DataBank. As such, the alert is not triggered for gabapentin. The drug-drug alert is triggered for the combination use of gabapentin and sodium oxybate, but not other CNS depressants or opioids. One suggestion as to why these alerts are not considered major alerts is that most alerts are based on label use of medications, and the majority of gabapentin use is considered "off-label". Board members suggested that additional educational resources for providers may be useful in addressing the concerns raised in the FDA Warning.

After the presentation of the completed reviews, Lynn presented the DHS recommendations for the utilization of the available criteria to address the use gabapentinoids in combination with CNS depressants. The recommendations include continuing to utilize the current criteria as part of the standard review process. The DHS staff does not feel that focused

interventions are necessary at this time. Reviews for the concurrent use of gabapentinoids and CNS depressants should focus on letters for recent starts. Reviews for high-dose gabapentin should continue and focus on members without previous intervention. The Board voted unanimously to accept the recommendations of the DHS staff.

Benzodiazepine Newsletter

Lynn started the discussion by reminding the Board member of this long-term project to develop a benzodiazepine newsletter. She credited Dr. Randall Cullen for much of the content of the newsletter and commended him for his time and effort. A draft of the newsletter was emailed to the Board for their review with the other meeting materials. Topics included in the newsletter include guidelines for treating anxiety disorders, initiating and discontinuing benzodiazepines, management of the chronic use of benzodiazepines, and use of benzodiazepine in the elderly. Dr. Cullen joined the discussion to share that some of the challenges of this newsletter included finding well written and clearly defined guidelines and good references for deprescribing. As this was a draft, both Lynn and Dr. Cullen welcomed the submission of comments and suggestions from the Board members.

Preferred Drug List (PDL) Update

Kelsey provided an update from the May 2020 PDL meeting. The meeting was held virtually via Zoom. Public and private formats were utilized to allow public testimony. As a result of the virtual format, there were changes to the voting process. Two block votes were held, one for classes with no changes and one for classes with changes. This is different from the usual single block vote and the individual drug classes with changes. Lynn continued with a review of the clinical aspects of the meeting. She noted that no mental health drug classes were reviewed at this meeting. There were 31 classes with no changes, and 24 classes with changes. Notable changes were made to the following classes: hepatitis C agents, opioid dependency agents, and multiple sclerosis agents. All staff recommended changes were supported by the committee members and we are waiting a decision from the DHS Secretary. Implementation of all changes are scheduled for July 1, 2020.

Adjournment

Robert Factor motioned to adjourn. The meeting adjourned at 3:08 p.m. Upcoming meetings are on the following Wednesdays: September 2, 2020, December 2, 2020, March 3, 2021, and June 2, 2021.

Guests: Paul Ford, Johnson & Johnson; Bob Heinsch, Sunovion; Gary Behrens, Sanofi Genzyme; Seth Bernstein, Allergan; Mike Martin, Amgen; Chris Stanfield, Supernus Pharmaceuticals; Ashish Dave, Amgen; Lee Stout, Chiesi USA; Lisa Dunn, Amgen; Kelly Petrowski, Allergan; Casey Johnson, ViiV; Doug Johnson, Sobi; Tom Telly, Ascendis Pharma; Robert Robey, Indivior, Inc.; Joe Cirrincione, Otsuka; Karen Floeder, Biohaven Pharmaceuticals; Jomy Joseph, Sanofi Genzyme; Rick Dabner, Alnylam Pharma; Steven Berardino, Agios; Cassaundra Johnson, Sanofi; Lucy Hernandez, Horizon Therapeutics; Kelly Ruhland, Lilly USA; Jeff Knappen, Spark; Jean Ritter, Zealand Pharma; Craig Haubach, Merck