ILLINOIS DEPARTMENT OF Healthcare and Family Services

JB Pritzker, Governor
Theresa Eagleson, Director

201 South Grand Avenue East
Springfield, Illinois 62763-0002

Telephone: (877) 782-5565
TTY: (800) 526-5812

Drug Utilization Review Board
Meeting Summary
February 17, 2022

The Drug Utilization Review (DUR) Board met on Thursday, February 17, 2022 at 8:30 a.m. via Web-ex for all attendees.

DUR Board members in attendance: Christopher Schriever, PharmD, Chairperson; Radhika Sreedhar, MD, Vice-chairperson; Sam An, PharmD; Bedrijka Nikocevic, PharmD; Erica Stevens, PharmD.

Illinois Department of Healthcare and Family Services (HFS) Representatives: Jen DeWitt, BSPharm, HFS Bureau of Professional and Ancillary Services (BPAS); Donna Clay, BSPharm, Prior Authorization, University of Illinois Chicago (UIC); Sheri Dolan, BSPharm, BPAS; Jose Jimenez, Bureau Chief, BPAS; Arvind K. Goyal, MD, Medical Director, Medical Programs, HFS; Mary Lynn Moody, BSPharm, UIC; Karly Nesnidal, PharmD, UIC; Christina Petrykiw, PharmD, CDCES, UIC; Jonathan Samardzich, PharmD, UIC; Maurice Shaw, PharmD, BPAS.

Interested parties: Michael Hawks, Alkermes, Inc.

Call to Order. Christina Petrykiw, PharmD, noted that the meeting will be recorded in accordance with adjustments to the Open Meeting Act. Guests wishing to speak at the end of the meeting were asked to type their name, affiliation, and that they would like to speak in the Web-ex chat. Speakers will speak in the order listed. Dr. Schriever called the meeting to order on February 17, 2022 at 8:34 am.

Roll call. Dr. Schriever verified presence of each Board member.

Agenda, conflict of interest review, and approval of November 18, 2021 meeting minutes. No changes to the February 17, 2022 agenda or the November 18, 2021 meeting minutes were requested. Dr. Sreedhar's motion, seconded by Dr. An, to accept the November 18, 2021 meeting minutes was approved unanimously. Dr. Schriever's motion, seconded by Dr. Sreedhar, to accept the February 17, 2022 agenda was approved unanimously. No DUR Board members had conflicts of interest pertinent to the agenda. Dr. Schriever reminded DUR Board members to recuse themselves from discussion if conflicts of interest present and to provide an updated *Conflict of Interest* form if new conflicts arise.

Announcements/Updates

Annual training. Christina Petrykiw, PharmD, thanked the DUR Board members for timely completion of the required Illinois Board training.

DUR Board 2022 meeting schedule. The DUR Board members were reminded that the 2022 meetings will solely continue via Webex at this time. The 2022 DUR Board meeting schedule is posted on the DUR Board Webpage at https://www2.illinois.gov/hfs/About/BoardsandCommisions/DUR/Pages/MeetingSchedule.aspx. Meeting invites for the remaining meetings in 2022 will be sent to DUR Board members.

DUR Annual report for FFY2020. The DUR Board members were informed that the Centers for Medicare and Medicaid Services (CMS) has posted the Fee-for-Service (FFS) and Managed Care FFY2020 DUR annual reports. The reports are available at https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/drug-utilization-review-annual-report/index.html. Individual state FFS and Managed Care Organization (MCO) reports as well as CMS national summaries for FFS and MCO Medicaid are available. The DUR Board members were encouraged to review the Illinois reports as well other state reports and the national reports.

Pharmacy-based COVID-19 related services. The DUR Board members were informed that HFS has implemented a structure to accept pharmacy-based claims for COVID-19 related services such as COVID-19 vaccination for children 5 years of age and older and COVID-19 pharmacist or home testing, as well as pharmacist prescribed and administered subcutaneous monoclonal antibodies. More information is available in provider notices posted on the HFS COVID-19 Web page at https://www2.illinois.gov/hfs/Pages/coronavirus.aspx.

Chantix/apo-varenicline. A Chantix shortage occurred after Pfizer instituted a voluntary recall to evaluate product N-Nitrosodimethylamine (NDMA) content. Importation of apo-varenicline manufactured by Apotex in Canada was allowed by CMS. The HFS FFS and MCO programs will cover apo-varenicline 0.5 and 1 mg tablets through the end of February. Generic varenicline was approved in August 2021 and is currently available. A Risk Evaluation and Mitigation Strategy (REMS) program is no longer required by the FDA for varenicline. Six months of varenicline allowed in a year for FFS. A medication guide is available for patients. Dr. Sreedhar requested clarification of what a REMS program entails. Drs. Petrykiw, Schriever and An noted that REMS programs help mitigate risk of taking certain medications. They are in place for products such as long and short-acting opioids, Accutane, or Clozaril, where safety concerns are present. The REMS programs provide additional prescriber training/continuing medical education and frequently require laboratory monitoring data to be provided before the prescription can be dispensed. In response to Dr. Sreedhar's question about why the FDA removed the REMS requirement for varenicline, whether it was deemed safer, Dr. Petrykiw noted that around 2009-10 there were increased reports of neuropsychiatric events with varenicline and bupropion and these medications had a black-box warning added. The FDA required a large safety study to be conducted. The EAGLES trial published in 2016 and a recently published sub-group analysis of patients with schizophrenia in 2021 showed there were no greater neuropsychiatric events than with nicotine replacement products and placebo. As a result of the EAGLES trial, the black box warning was removed as well as the REMS requirement for varenicline. Dr. Goyal noted that the FDA also uses REMS for medications that require more study and verification that those administering the medication are appropriately trained, for example Chimeric antigen receptor (Car) T cell therapy. The REMS programs are primarily required to ensure patient safety.

Retrospective DUR

Naloxone prescriber outreach for patients receiving high opioid MME prescriptions. The SUPPORT Act noted that persons at high risk of opioid overdose should be considered for co-prescription or co-dispensing of an FDA-approved opioid antagonist/reversal agent. One high-risk characteristic is an opioid dose that is at a morphine milligram equivalent of 50 MME or greater since those dosages are associated with a 2 or greater risk than taking an opioid dose less than 20 MME. It is recommended to evaluate risk versus benefit of opioid therapy once the dose is at 50 MME/day and to have good justification if titrating the dose to more than 90 MME/day for non-cancer pain. Naloxone can be offered when MME is 50 MME or greater to decrease risk of fatal overdose with therapeutic opioid use. Participants filling 50 MME and greater opioids from November 2020-November 2021 who had FFS coverage for at least part of that time were reviewed to determine presence of a naloxone fill. Participants had an average of 1.9 opioid prescribers (range 1-13). At least 88% of the prescribers wrote only one high MME prescription. About 12% wrote 2-4 prescriptions. There was an average of 16 opioid prescriptions filled by participants during the review period (range 1-30). Of 3,083 opioid prescriptions, the average MME for those in the 50 MME to < 90 MME was 65 (range 50-89) and for the 90+ MME group, the average MME was 156 (range 90-720). About 75% of the prescriptions included oxycodone, morphine, or hydrocodone. There was also usage of fentanyl, hydromorphone, methadone for pain, acetaminophen with codeine, tramadol, and Xtampza ER. Only 50 participants had ever received naloxone (26% of participants receiving a high MME opioid). Range of naloxone fills was 1-3. Not all prescribers with multiple participants provided naloxone for each high MME participant. Outreach was conducted via fax to prescribers of the 139 participants who had never filled a naloxone prescription. Outreach was done even if the patient had transitioned to a different HFS payor given the public health aspect of this intervention. The average daily MME was 117 (range 15-675) for participants who had never filled naloxone. A total of 122 faxes were sent. A fax was not sent if the participant was no longer receiving any opioids or high MME opioids, was deceased, had expired eligibility, or filled naloxone since November 2021. No naloxone faxes received to date, but 3 naloxone fills done. Telephone intervention is planned.

The DUR Board was asked for input regarding proposed next steps- refaxing and its interval, telephone outreach, monthly naloxone fill checks, continued use of high MME reports to identify patients needing naloxone, other high-risk groups to be targeted, referral to Illinois ADVANCE for naloxone academic detailing, and when to provide an update to the DUR Board. Board members agreed continued outreach needed and use of the standing order by pharmacists is possible- so recommended asking pharmacists to provide naloxone via the standing order for those with 90 MME and over. Lifesaving medication is then provided and a state-approved process is available. Drs Schriever and Sreedhar noted refaxing and telephone intervention may not be as effective and delays provision of a life-saving medication. Dr. Nikocevic questioned whether the naloxone fills since November had been via pharmacist's utilization of the standing order or a prescription. Information will be provided at a future DUR Board meeting. Education targeting the pharmacist's use of the standing order was encouraged. Dr. Sreedhar noted that to educate the patient regarding opioids and to negotiate opioid tapering can take 10-20 minutes. Then repeating the process monthly is time consuming. Adding naloxone takes more time. A recent UIC study investigated prescriber reasons for not prescribing naloxone and found there was no one reason. Dr. Sreedhar noted hard stops work; telephone outreach and academic detailing may work, but may not be worth the amount of effort/resources needed to accomplish. Other DUR Board members agreed. Dr. An offered to spread the word with the Illinois Pharmacists Association members that HFS will be reaching out to pharmacists to utilize the standing order for patients receiving high MME prescriptions without a recent naloxone fill. In terms of pharmacy logistics - can request but can't guarantee will be done. The pharmacist can check the MME, run the naloxone prescription, and then it can take 30 minutes to complete the naloxone checklist and educate/counsel the patient regarding naloxone use per the standing order requirements. There are also patient factors – lack of insurance coverage, a high copay, and overcoming patient stigma regarding naloxone need. Some patients perceive that they are being considered an addict because they may need naloxone. Some prescribers and pharmacists may also feel that naloxone prescribing encourages opioid overuse. Mary Lynn Moody, BSPharm, noted that Medicaid covers naloxone without a copay. Dr. An informed Board members that Medicare does require a copay. Dr. Sreedhar reiterated that at least naloxone will be available for the patient if needed. Dr. Nikocevic felt that outreach to pharmacists via a campaign, like *Dispense naloxone, save a life* can be beneficial. Outreach to pharmacists, corporate pharmacy offices should be done. Dr. Schriever agreed that improving naloxone availability in patients with high MME was needed. Patient can say don't they don't want the naloxone, but due diligence done. Dr. Nikocevic mentioned that each corporate pharmacy system can put in an internal hard edit for high opioid MME prescriptions that would remind the pharmacist to fill a naloxone prescription for the patient. The internal edit can be overridden. If picking up the opioid prescription and the naloxone prescription is also ready, this can increase provision of naloxone and patient more likely to pick up. Pharmacist can say, *"you also have naloxone ready because your opioid is at a high dose".* This would streamline the process. Mary Lynn Moody, BSPharm noted that this suggestion can be put on the agenda for the HFS-corporate pharmacy standing meeting. BPAS will also check with legal to determine if HFS can mandate a hard stop for opioid prescriptions if no naloxone filled. Collaboration with corporate and pharmacy associations can be done. If it is a cancer patient, some oncologists push back regarding naloxone, others incorporate it to optimally manage the patients' time at end of life. Mary Lynn Moody, BSPharm, noted that having naloxone in the home can help if others access the opioid and require naloxone use to prevent a fatal overdose. Naloxone's potentially life-saving aspect provides benefits for many. Dr. Stevens questioned whether a hard edit for monthly opioid fills requiring naloxone presence will result in monthly naloxone fills and potential product waste. Dr. Sreedhar noted that prescriber and pharmacy agreement before implementation of a campaign would be helpful to minimize prescriber pushback. Pushback can occur even though the intervention has good intent. Having talking points available would be helpful. Dr. Goyal reminded everyone that the overdosing patient will not be administering the naloxone - need family involvement. The CDC has not yet provided good clinical trial data to demonstrate co-prescribing naloxone has made a difference in opioid overdoses or mortality. Dr. Goyal represents HFS on the Opioid Crisis Advisory Taskforce and governor's steering committee which have targeted public availability of naloxone. Three areas have made it availability and have shown preliminary data regarding efficacy. Good to encourage co-prescribing, but really need family members to know how to use, where it is kept, etc. If DUR/HFS implements an initiative, it would be good to show outcomes that those for whom naloxone was co-prescribed did not have any overdose events or deaths compared to those who did not have naloxone prescribed. The Board requested staff provide a more cohesive plan after discussion with legal and corporate pharmacies.

Tramadol and codeine utilization. Utilization of tramadol and codeine for FFS and MCO participants for calendar year 2021 (CY21) was presented as requested by the DUR Board. The DUR Board is considering recommending a prior approval requirement for these products for all participants due to metabolic-pharmacokinetic issues that can result in higher or lower concentrations that lead to adverse effects or lack of therapeutic effect. Almost 114,00 participants filled these products via HFS during CY21. Tramadol and codeine-combination products are used more than codeine sulfate and tramadol combination products. Tramadol combination products are currently not preferred. The average number of prescriptions for tramadol is 2.9 per participant and 1.8 per participant for codeine combination products. The tramadol and codeine product Medicaid coverage and edits in the top 8 Medicaid enrollment states (including Illinois) was reviewed. Codeine alone is non-preferred in 5 states, tramadol ER and tramadol-combinations in 2 states. States in which codeine, tramadol or its combinations are preferred, have edits in place for age, daily or monthly quantity, duration, or max number of fills. Texas requires a clinical prior authorization for the tramadol- and codeine-containing products regardless of preferred status. North Carolina allows 5 days for acute use and 7 days for post-operative use for all but codeine monotherapy, which is not preferred. Dr. Sreedhar recommended making the codeine- and tramadol-containing product non-preferred and when used, allowing only short duration use similar to what North Carolina allows. Dr. Schriever noted that the perception that these opioids are not as strong encourages use by some providers. The DUR Board discussed whether education was sufficient or if formulary changes needed. The DUR Board members decided not to recommend consideration of PDL changes at this time given updated CDC guidelines were just released for comment. Decreasing use may be warranted, but DUR Board members were not sure the best way to accomplish this at this time. Once finalized CDC opioid guidelines are made available, this topic can be revisited. Prescriber education with prior authorization requests and academic detailing will continue regarding these medications. The link to the CDC opioid guidelines released for comment will be sent to DUR Board members.

Future agenda items. Board members recommended reviewing finalized CDC chronic pain opioid guidelines and gabapentin for alcohol use disorder, an off-label use that is increasing. Gabapentin is also being prescribed for any type of pain, but not indicated for all types of pain. RetroDUR 300 is showing a lot of gabapentin 400 mg use, which may be underdosing. Additional potential topic suggestions can be sent to Dr. Petrykiw directly.

Public comments. Dr. Schriever noted public comments should pertain to the agenda. No public comments received.

Adjournment. The DUR Board unanimously approved Dr. Schriever's motion, seconded by Dr. Sreedhar, to adjourn the meeting. Meeting adjourned at 9:40 AM.

Meeting summary prepared by Christina A. Petrykiw, PharmD, CDCES.

Approved May 19, 2022 by the Illinois Drug Utilization Review Board.