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Drug Utilization Review Board Meeting Summary

September 18, 2019

The Drug Utilization Review (DUR) Board met on Wednesday, September 18, 2019, at 8:30 a.m. in Conference Room B-16, University of Illinois at Chicago College of Pharmacy, 833 S. Wood Street, Chicago, Illinois.

DUR Board members in attendance: Stacie Laff*, MD, Chairperson; Aneet Ahluwalia, MD; Bedrija Nikocevic, PharmD; Christopher Schriever*, PharmD, Vice-Chairperson; Radhika Sreedhar, MD; Erica Stevens*, PharmD.

Illinois Department of Healthcare and Family Services (HFS) Representatives: Lisa Ball*, BSPharm, HFS Bureau of Professional and Ancillary Services (BPAS); Nerissa Caballes, PharmD, Prior Authorization, University of Illinois at Chicago (UIC); Donna Clay, BSPharm, UIC; Jen DeWitt*, BSPharm, BPAS; Arvind K. Goyal*, MD, Medical Director, Medical Programs, HFS; Mary Lynn Moody, BSPharm, UIC; Christina Petrykiw, PharmD, CDE, UIC; Chirag Rathod, PharmD, UIC; Patricia Steward*, BSPharm, BPAS.

Interested parties: Nick Boyer, Xeris Pharmaceuticals; Erica Brumleve, GlaxoSmithKline; Michael Chen, Aimmune Therapeutics; Rudy Christian, Alkermes; Michael Hawks, Alkermes; Erin Hohman, Janssen; Luenetta Jackson, County Care Health Plan; Michael LaFond, AbbVie; Michael Lloyd, Pfizer; Huzefa Master, Next Level Health; Neelesh Nadrkani, County Care Health Plan; Amy Patel, Blue Cross Blue Shield; Misty Seidl, Johnson & Johnson.

*Attendance via teleconference

Call to Order. Dr. Laff called the meeting to order on September 18, 2019 at 8:35 am. Vote called to allow Mr. Lehan's and Dr. Schriever's attendance via teleconference due to work commitments that preclude travel to Chicago. Dr. Nikocevic made a motion, seconded by Dr. Sreedhar, and the DUR Board members approved telephonic attendance for this meeting.

Agenda, conflict of interest review, and approval of May 29, 2019 meeting minutes. No changes to the September 18, 2019 agenda or the May 29, 2019 meeting minutes requested. Dr. Sreedhar's motion, seconded by Dr. Nikocevic, to accept the May 29, 2019 minutes and September 18, 2019 agenda, was approved unanimously. No DUR Board members had conflicts of interest pertinent to the agenda. Dr. Laff 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.

DUR Annual report. The federal fiscal year 2018 (FFY18) DUR report was submitted in June 2019 to the Centers for Medicare and Medicaid Services. A new requirement of the DUR annual report was inclusion of managed care organizations' (MCO) reports of DUR activities. The structure the seven Medicaid MCOs in Illinois used for DUR Boards during FFY18 were reviewed. The top 5 claim denial reasons, refill-too-soon thresholds, and Top 10 drug claims by claim count for FFY18 for Fee-for-Service (FFS) and the MCOs were presented. The top 10 by claim count represented therapeutic class groupings, rather than individual National Drug Codes (NDCs). Amoxicillin and asthma medications (Ventolin, Proair, and/or montelukast) appear in the

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top 10 by claim count for every insurer and may represent opportunities for collaboration to improve care. The DUR Board members noted that the first-line medications for asthma, steroid inhalers, did not appear in the top 10 for any of the insurers, further underscoring the need to address appropriateness of asthma care. The DUR Board members asked why stimulants were seen in FFS top claims, but not seen in the top 10 for the MCOs. Mary Lynn Moody, BSPharm, noted that Youth in Care of the Department of Child and Family Services are currently covered by FFS and are the main population represented by these claims. Dr. Sreedhar noted high use of vitamin D (ergocalciferol) in many of the insurers. Dr. Goyal observed that NextLevel Health, a MCO in Cook County, listed no narcotic medications in their top 10 by claim count, but did list chronic care medications, including hydrochlorothiazide. Meridian, one of the larger MCOs, did demonstrate high use of narcotics since both generic Norco and tramadol are in their top 10 by claim count list. Christina Petrykiw, PharmD, mentioned that there was a trend for lower utilization of narcotics yearly in the FFS population. During the last 3 years more attention to prescribing narcotics has been given due in part to the 2016 release of the Centers for Disease Control and Prevention (CDC) guideline for prescribing opioids for chronic pain.

SUPPORT for Patients and Communities Act. Christina Petrykiw, PharmD, reviewed information related to the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) that was enacted January 3, 2018. The SUPPORT Act addresses many issues, including amendments to the Drug Utilization Review (DUR) section of the Social Security Act. The DUR changes are effective October 1, 2019 and apply to both FFS and MCO Medicaid. The new requirements related to opioids, morphine milligram equivalents (MME), concurrent opioid use with benzodiazepines or antipsychotics, and antipsychotic use in children were reviewed. Exemptions may include participants in hospice, palliative care, long-term care facilities, and those undergoing cancer treatment. Opioids. The CDC guideline for opioid prescribing noted that for acute pain therapy should start with the lowest effective dose or an immediate-release opioid. A quantity no greater than needed for the expected duration of severe pain requiring opioids should be used. About 3 days is sufficient and more than 7 days is rarely needed. Opioid use within 7 days of surgery or 15 days of injury increases risk of long-term opioid use. Physiologic dependence may be expected within a few days of opioid therapy. The Washington State Agency Medical Directors Group 2018 recommendations addressed opioid duration and quantity dependent on expected-post surgical procedure recovery. The American Dental Association Policy on Opioid Prescribing 2018 noted that no greater than 7 days of therapy for acute pain may be needed. As of January 2019, Medicare Part D has instituted a 7-day supply limit for opioid naïve patients who have not filled opioids within the past 60 days. At a MME of 90, the pharmacist is to contact the prescriber for justification and care coordination of the Medicare participant. Some states have statutory limits of 3-14 days on certain opioid prescriptions or even MME requirements. Current Department of Health and Family Services (HFS) FFS opioid policies were reviewed. The DUR Board discussed new policies of a 7-day limit for an initial opioid prescription for opioid naïve participants and a high dose edit of no more than 4-6 doses per day that would be specific to the NDC. Dr. Goyal mentioned that the Illinois Department of Financial & Professional Regulation incorporated the April 2017 State Medical Board's Guidelines for the Chronic Use of Opioid Analgesics into the Rules for the Administration of the Medical Practice Act effective July 6, 2018. Dr. Goyal noted that there is enough evidence-based literature about initial opioid use leading to chronic opioid dependence that a 7-day initial opioid prescription is reasonable. The quantity should be specific for example 30 tablets for 28 days, not open-ended. More care must be taken with the opioid-naïve patient because repeat opioid exposure increases risk of opioid dependence. Opioid MME. The CDC adult chronic pain guideline noted harm may be dose-dependent, thus risk versus benefit should be reassessed if increasing doses to or above 50 MME/day and increasing beyond 90 MME daily should be avoided. Serious overdose and overdose death risk increases as MME increases, for example overdose deaths doubling with MMEs greater than 50. Examples of prescriptions and their daily opioid milligrams and MMEs were reviewed. The DUR Board members were notified of the CDC factsheet and mobile app for the opioid prescribing guideline. Board members discussed the new HFS opioid policy requiring prior authorization for

opioid naïve participants who receive more than 90 MME daily and opioid experienced participants who receive more than 120 MME daily. The MME provided will be cumulative if more than one opioid is filled concurrently. Dr. Nikocevic asked how prescribers will be notified about the new prior authorization requirements, in particular because pain relief may be a more immediate need and require fast prior authorization determinations. Dr. Ahluwalia recommended not including buprenorphine, making methadone separate for MME due to its unique pharmacokinetics, and asked whether there were any allowed exceptions. Staff noted that exceptions, for example cancer, will be included. Dr. Schriever seconded the motion and the DUR Board members approved the new prior authorization requirements. Dr. Laff noted that it may be worthwhile to have a prescriber continuing education module regarding MME, which many prescribers may not have learned about in school or don't use since they rarely prescribe opioids. Prescribers may not feel comfortable with this aspect of opioid prescribing. Mary Lynn Moody, BSPharm, informed the DUR Board members that the University of Illinois at Chicago provides the College of Medicine staff a 1-credit hour continuing medication education (CME) on opioid prescribing. Dr. Goyal mentioned that Risk Evaluation and Mitigation Strategies (REMS) CME is provided by the CDC, the Food and Drug Administration (FDA), and by addiction psychology professional organizations. Dr. Nikocevic noted that the REMS education may not be sufficient to meet the new CME requirements for licensing. Prescribers may need to increase awareness of where to look for opioid-related CME. Dr. Schriever's motion was seconded by Dr. Nikocevic, and the DUR Board members unanimously approved posting links to the CDC opioid prescribing guideline factsheet and mobile application. Opioids used concomitantly with benzodiazepines. The CDC chronic pain guidelines and the FDA address the increased risk of potentially fatal overdose with concomitant benzodiazepine and opioid use, recommending avoidance of the combination if possible. Risk versus benefit assessment should be done when adding a central nervous system (CNS) depressant that can potentiate opioid-induced CNS depression. The FDA requires a boxed warning about concurrent use and Medication Guides for 400 opioid analgesics, opioid-containing cough products, and benzodiazepines. The FDA states that the dose and duration of each agent should be minimal and doses of either drug should not be increased when taken concomitantly. Patients must be educated regarding slowed/difficult breathing, sedation, and unresponsiveness. The Surgeon General recommends co-prescribing and education regarding naloxone for patients taking both medications. Previous DUR Board recommendations regarding concurrent opioid and benzodiazepine use were reviewed. HFS will institute a drug interaction edit to identify concurrent opioid and benzodiazepine prescribing. The DUR Board discussed whether the edit should be informative or require prior authorization immediately (hard edit). Board members noted that requiring check of the Illinois Prescription Monitoring Program may be outside the scope of HFS and that an informational edit will not be visible in pharmacy computers that have changed to new programs. Lack of a hard edit in the Pharmacy Benefit Management system will allow the prescription to be processed and the prescriber will not be notified of the messaging. If the intent is to stop concurrent prescribing, a hard edit would be needed with a message cautioning about increased risk of fatal respiratory depression. Soft edits are a weak protection and can be miscommunicated. Once a medication is approved (allowed to go through the system) without a hard edit, there will be no further action by the pharmacist. Patty Steward, BSPharm, suggested an informational edit and retrospective review to determine the scope of the problem among participants. Board noted difficulty of tapering medications such as alprazolam and asked if the edit could differentiate between initial prescriptions and existing benzodiazepine users. The DUR Board recommended a 6-month delay in instituting a hard edit. Prescribers should be educated via a soft edit about the concerns and informed that within 6 months prior authorization will be required for combination therapy. During the 6 months, the prescriber should discuss risks of concomitant therapy with patients and/or begin tapering. Prescriber outreach would be needed. Pharmacists should be notified that a hard edit will be in place in 6 months so that they can start working with the prescriber before prior authorization is required. The Illinois Pharmacists Association's legislative updates may be used to communicate this information. Opioids used concomitantly with antipsychotics. Concerns regarding potentiating opioid CNS depression extend to the use of antipsychotics concurrently with opioids. Long-term use of select illicit substances can cause a psychosis.

Patients with chronic psychoses or schizophrenia may likewise use pro-dopaminergic illicit substances to selftreat negative symptoms of psychoses. While some antipsychotics have demonstrated benefit in decreasing substance use, other antipsychotics have been diverted since about 2005 with the purpose of inducing sleep, managing substance withdrawal, or enhancing effects of buprenorphine/naloxone or methadone. Published analyses of opioid-related deaths demonstrated a doubled risk of opioid-related death associated with psychotropic medication use. The FDA has recommended that if concomitant is use necessary, the initial CNS depressant doses should be lower than if no opioid is present, concurrent treatment course should be minimal, and patients should be monitored for respiratory depression and sedation. Dr. Ahluwalia noted that abuse of quetiapine is well known. Dr. Nikocevic recommended managing concurrent use of opioids and antipsychotics similar to what was decided with benzodiazepine concurrent use. A hard edit was deemed too aggressive given beneficial sedative effects of antipsychotics in treating schizophrenia and bipolar disorder. Targeted prescriber education may be helpful for concurrent therapy prescribers. Dr. Nikocevic's motion, seconded by Dr. Schriever to have an informational (soft) edit regarding the drug interaction was approved unanimously. For both edits, 6 months after implementation of the edit, the DUR Board requested a report of the prescriber outreach. Dr. Laff asked for more information regarding provider outreach. Mary Lynn Moody, BSPharm, noted a 1:1 academic detailing process that consists of a periodic 15 minute conversation has been utilized for prescribers in Chicago and Southern Illinois to educate about the CDC chronic pain guidelines. Provider appointments are done ahead of time to facilitate the visit. Naloxone academic detailing was conducted with retail pharmacists in June 2019. Board members noted that patients are likely to come to discuss therapy changes with the prescriber if the prescriber asks them come in. Patients may be in denial or offended that they need naloxone due to the potentially stigmatizing association with opioid use disorder. Board members noted that naloxone, which is a covered HFS medication, should be part of the discussion regarding the SUPPORT Act initiatives. Dr. Goyal agreed with the noted benefits of HFS communication with participants regarding naloxone. He will work within HFS to get a provider and participant notice regarding naloxone. Antipsychotic use in children. The SUPPORT Act requires monitoring and management to ensure appropriate use of antipsychotics in children ≤ 18 years of age and children in foster care. HFS FFS currently requires prior authorization for atypical antipsychotics for children less than 8 years of age. The American Psychiatric Association Choose Wisely Recommendation regarding antipsychotic use in children was reviewed. DUR Board members unanimously approved Dr. Nikocevic's motion, seconded by Dr. Schriever, to approve the HFS plan to retrospectively review antipsychotic use in children ages 8 to 17 years. Board members requested a review of current usage in Medicaid participants for issues targeted by the SUPPORT Act.

Future DUR Board meetings for 2019. Moving the DUR Board meeting from Wednesdays to Thursdays was proposed. Dr. Schriever's motion, seconded by Dr. Nikocevic, to approve the proposed meeting day change was unanimously approved. The remaining DUR Board meeting for 2019 will be Thursday, November 21, 2019.

Future agenda items. The DUR Board members asked whether glucose monitoring devices, including continuous glucose monitoring devices would be within the scope of the Board and were informed that devices can be addressed within a discussion of overall diabetes management.

Public comments. Dr. Laff noted public comments should pertain to the agenda. No comments made.

Adjournment. Dr. Laff adjourned the DUR Board meeting at 10:05 am.

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

Approved February 20, 2020 by the Illinois Drug Utilization Review Board.