ILLINOIS DEPARTMENT OF Healthcare and Family Services

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Drug Utilization Review Board
Meeting Summary
May 29, 2019

The Drug Utilization Review (DUR) Board met on Wednesday, May 29, 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; Tim Lehan*, BSPharm; Bedrija Nikocevic, PharmD; Christopher Schriever, PharmD; Radhika Sreedhar, MD.

Illinois Department of Healthcare and Family Services (HFS) Representatives: Donna Clay, BSPharm, Prior Authorization, University of Illinois at Chicago (UIC); Sheri Dolan*, BSPharm, HFS Bureau of Professional and Ancillary Services (BPAS); Arvind K. Goyal*, MD, Medical Director, Medical Programs, HFS; Mary Lynn Moody, BSPharm, UIC; Corinne Puchalla, PharmD, UIC; Christina Petrykiw, PharmD, CDE, UIC; Linda Schuh*, BSPharm, BPAS; Patricia Steward*, BSPharm, BPAS; Lori Uildriks, PharmD, UIC.

Interested parties: Michelle Cho, PharmD candidate, University of Illinois at Chicago College of Pharmacy (UIC COP); Michael Hawks, Alkermes; Mary Kaneaster, Gilead Sciences; Michael LaFond, AbbVie; Michael Lloyd, Pfizer; Swarup Mehta, Gilead; Linh Nguyen, PharmD candidate, Roosevelt University College of Pharmacy; Philip Schorsch, PharmD candidate, UIC COP; Tom Theiss, Ipsen; Kavya Vaitla, PharmD candidate, UIC COP.

*Attendance via teleconference

Call to Order. Dr. Laff called the meeting to order on May 29, 2019 at 8:32 am. Vote called to allow Mr. Lehan's attendance via teleconference due to a work commitment that precluded travel to Chicago. Christopher Schriever, PharmD, made a motion, seconded by Dr. Nikocevic, and the DUR Board members approved telephonic attendance for this meeting. Dr. Erica Stevens, a new DUR board member based in Champaign, IL will need to attend all meetings via teleconference since distance precludes travel to Chicago. Dr. Nikocevic made a motion, seconded by Dr. Schriever, and the DUR Board approved attendance via teleconference by Dr. Stevens for all meetings.

Agenda, conflict of interest review, and approval of February 20, 2019 meeting minutes. No changes to the May 29, 2019 agenda or the February 20, 2019 meeting minutes requested. Dr. Schriever's motion, seconded by Dr. Nikocevic, to accept the February 20, 2019 minutes and May 29, 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.

New DUR Board members. Christina A. Petrykiw, PharmD, welcomed new DUR Board members Aneet Ahluwalia, MD; Radhika Sreedhar, MD; and Erica Lynn Stevens, PharmD. The DUR Board members who have completed their DUR Board terms, Rachel Caskey, MD; John Tulley, MD; and Anitha Nagelli, PharmD, were thanked for their service. A review of the Illinois DUR Board mission, responsibilities, websites, prospective and retrospective DUR, and DUR tools was provided.

Retrospective Drug Utilization Review

Ketorolac utilization update. Christina A. Petrykiw, PharmD, provided the additional information DUR Board members had requested regarding ketorolac utilization subsequent to the last discussion of Fee-for-Service participants who filled ketorolac between January 1, 2017 and April 23, 2019. **Prescriber types.** In the majority of cases, the National Plan and Provider Enumeration System (NPPES) National Prescriber Identifier (NPI) Registry did not note the type of prescriber. Among the 38% of ketorolac prescribers that listed a taxonomy, the majority were physicians. Other prescribers in order of frequency included physician assistants, Advanced Practice Nurses/Nurse Practitioners, dentists, a podiatrist, and a chiropractor. Ketorolac prescribers represented 12 specialty areas (in order of frequency): Family Medicine, Emergency Medicine, general internal medicine, pediatrics, surgery, obstetrics/gynecology, non-surgical dentists, internal medicine specialties (urology, rheumatology, adult health, endocrinology, allergy/immunology, otolaryngology, and interventional radiology), psychiatry/neurology, pain medicine/rehabilitation, geriatrics, and sports medicine/athletic training. The sole hematologist/oncologist practiced in pediatrics. **Pain diagnosis.** Previous assumption was pediatric patients receiving ketorolac instead of narcotics for sickle cell disease. Review showed that in the pediatric participants there was no medical claim for a pain-related condition within a few days of ketorolac dispensing in the majority of cases. For medical claims close to date of the ketorolac claim, the diagnoses in order of frequency were trauma (fracture/dislocation/ strain/ tear/contusion), migraine/headache, abdominal pain/appendicitis, a cyst, post-operative/procedural use, back pain/spasm, kidney stones or cystitis, chest pain, oral/ear pain, and scrotal pain. In the 6 adults who had multiple ketorolac fills, arm pain, migraines, chest/lung pain, cervical pain, cystitis, hip or back pain/strain, and abdominal pain were noted. One adult patient had the sickle cell trait and one had sickle cell disease and two pediatric patients had a history of sickle cell disease, but ketorolac administration did not coincide with sickle cell crises. **Contraindications.** Ketorolac black box warnings and conditions that may warrant review with ketorolac use were reviewed. Within 12 months prior to ketorolac administration 7 pediatric participants had medical claims for epigastric pain or gastroesophageal reflux disease (GERD), stage 2 chronic kidney disease, and melena, anemia, or hematemesis. Within 2 weeks to 4 months after ketorolac administration, three participants experienced gastritis and epigastric pain and within 12 months after ketorolac use, 5 pediatric participants had anemia, melena, hematuria, or hematemesis. **Concomitant medications.** Pharmacy claims for pediatric participants receiving ketorolac were evaluated to determine presence of other pain medications as well as medications for the treatment of gastrointestinal (GI) disorders, CABG surgery, renal impairment, cardiovascular thrombotic events, bleeding prevention, corticosteroids, and anticoagulants. At least 23 participants filled opioids, 20 participants filled a GI medication (H_2-blocker, proton pump inhibitor, or Carafate), and 7 participants filled a corticosteroid within 1 to 3 months before ketorolac use. **Discussion.** The DUR Board members were surprised regarding types of practitioners prescribing ketorolac, lack of information regarding practitioner type or specialty in the NPI database, uses in pediatrics, as well as migraines being treated with ketorolac without prior use of standard of care therapies. Dr. Goyal noted that it is likely that ketorolac use will increase as alternatives to opioids are investigated for pain management. At present ketorolac does not require prior authorization. Total course of therapy maximum, quantity maximum and refills were discussed. A refill look-back duration of 90 days was deemed reasonable in the last 365 days. For migraines, DUR Board members recommended trials of standard of care medications, reserving ketorolac for unresponsive refractory disease. Dr. Goyal recommended a one-page provider notice to remind prescribers of issues related to ketorolac prescribing. Six months after instituting the edits ketorolac use should be re-evaluated to determine if further action needed. Dr. Sreedhar noted that adverse reactions may occur with nonsteroidal anti-inflammatory drugs (NSAIDs) and education may be needed for patients and prescribers about medications that belong to the NSAID class to prevent co-administration that can worsen side effects. The DUR Board members voted unanimously to institute a duration limit of 5 days, 20 tablet maximum quantity, and no refills within 90 days for ketorolac.

Hepatitis C infection. Christina Petrykiw, PharmD, reviewed the following information regarding hepatitis C infection: epidemiology, burden, risk factors, natural history, goals of therapy based on living guidelines, treatment regimens, current therapies, use of sustained virologic response (SVR 12) as a marker for virologic cure, the HFS preferred hepatitis C agents, and location of HFS prior authorization criteria and forms for medications to treat hepatitis C infection. Donna Clay, BSPharm, reviewed adherence with direct acting antiviral (DAA) therapy from May 2018 through 2019 in Fee-for-Service participants. No adherence issues were noted for Harvoni, Sovaldi, Vosevi, and Zepatier regimens. There were 5 cases each of non-adherence with Epclusa and Mavyret. All of the cases were related to end of Medicaid eligibility or transitions between Medicaid managed care organizations (MCO) or third party insurance and Fee-for-Service (FFS) Medicaid. Donna Clay, BSPharm, noted that FFS Medicaid continues therapy for participants who were taking a DAA and are transitioning from a Medicaid MCO to FFS. Overall, 12-week regimens are the most common. Fill history is tracked and if more than 4 weeks have passed since a fill, the prescriber is contacted. For Mavyret, the 8-week regimen is most common. Christopher Schriever, PharmD, stated that the 8 to 12 week regimens have definitely simplified adherence. In his clinic the biggest new issue is patients not returning for the SVR 12 after finishing therapy. The clinic providers no longer tell patients the disease is cured after therapy completion without obtaining SVR 12 laboratory results first. Therapy is successful if patients are highly motivated. The clinic sees more Suboxone users currently who demonstrate less motivation. Some providers will choose patients who are more likely to complete therapy, although treating more patients facilitates prevention of hepatitis C spread. Seamless patient transition between insurance plans depends on whether a specialist consult is required. To enhance treatment uptake, there is a national desire to incorporate more primary care providers. Utah's Project ECHO-HCV and University of Chicago's ECHO-Chicago provide 10-week education programs for primary care providers so that they can initiate therapy in patients with mild hepatitis. A specialist consult is recommended for more complex patients. The program provides continuing education credits. Dr. Schriever will provide HFS with contact information for the ECHO-Chicago program. Bedrija Nikocevic, PharmD, noted that the specialist consult requirement may require patients to travel far and also often requires a long wait to be seen. It was suggested that HFS reconsider the specialist requirement, for example, not requiring the consult for FO through F2 patients. A specialist does not need to be seen to obtain a fibrosis score using a non-invasive test. Perhaps primary care providers could prescribe and call the prior authorization office with documentation of completed ECHO course and REMS requirements. This would streamline the approval process so that therapy is not delayed because a provider failed to submit documentation. Corrine Puchalla, PharmD, noted the importance of ensuring the prescribed regimen is appropriate for patients with concomitant disease states. Dr. Laff reminded DUR Board members of recent liability cases related to phone consults without seeing the patient, which may be a concern for providers. Dr. Goyal stated that the true number of cases is unknown because current data does not capture asymptomatic/undiagnosed cases. He noted that since criteria for hepatitis C medication treatment were updated in November 2018 there has been a significant increase in the number of cases treated. Complete MCO and FFS data that captures all patients would demonstrate the scope of non-adherence. Dr. Goyal informed DUR Board members that Louisiana Medicaid FFS and MCO removed prescriber specialty and fibrosis score criteria in 2018. Effective July 1, 2019 their innovative subscription-type fixed-monthly cost program will allow Medicaid or correctional facility patients to receive free medication over the next 5 years from Asegua Therapeutics. Testing will also be free. Louisiana Medicaid will put money currently paid for hepatitis C into this program to have unlimited access to the generic medication in an effort to eliminate the hepatitis C virus.

Naloxone. Christina A. Petrykiw, PharmD, provided an overview of opioid-related adverse effects, naloxone, preferred naloxone dosage forms, and Illinois Public Act 099-0480 (Lali's Law). Overall and per dosage form naloxone utilization for Medicaid FFS and MCO was compared from 2016 through 2019. The DUR Board members noted that patients or caregivers pay for 1 naloxone fill at a time. Bedrija

Nikocevic, PharmD, mentioned that nasal naloxone is most frequently stocked in the pharmacy so will be most used. Insurance coverage varies for injectable naloxone and the nasal formulation is easiest to use/administer. Increased dispensing is not being seen at pharmacies. Anecdotally, DUR Board members have heard about increased copays for naloxone. Mary Lynn Moody, BSPharm, informed the DUR Board members that the Illinois Department of Public Health asked the University of Illinois at Chicago College of Pharmacy to help educate approximately 1,000 retail pharmacists about the standing order and related procedures to facilitate patients being able to get naloxone if needed. Bedrija Nikocevic, PharmD mentioned that despite the law being in place, there may be a stigma regarding naloxone due to a perception that a person requesting it is an addict. Attitudes need to change to help ensure practitioners facilitate naloxone provision. Mary Lynn Moody, BSPharm, mentioned that at the recent Opioid Summit in Rockford that was attended by approximately 150 prescribers, one presenter focused on education to decrease the stigma of addiction, noting that it is a disease. Some pharmacies make naloxone available automatically under the standing order if the patient is prescribed 50 or more morphine milligram equivalents (MME) of an opioid. Pharmacists dispense and provide education which takes about 30 minutes. Soft edits educate regarding the process and a hard edit is in place once high MME is reached.

Education

Surgeon General's Advisory on naloxone and opioid overdose. Christina A. Petrykiw, PharmD, informed DUR Board members about national efforts to increase availability of naloxone. Less than one percent of persons that may benefit receive a naloxone prescription. As a result, the Surgeon General released recommendations for co-prescribing of naloxone in patients receiving opioids. Additionally, patients taking or using opioids and their caregivers should be educated about their risk factors, types and durations of opioid prescriptions, how to decrease overdose risk with naloxone use, how to use naloxone, and address concerns about persons who may benefit from naloxone administration with prescribers. Bedrija Nikocevic, PharmD, made a motion, seconded by Christopher Schriever, PharmD, and the DUR Board members unanimously approved posting the Surgeon General's Advisory as well as Illinois Department of Public Health Naloxone page links on the DUR education Website. Dr. Goyal noted that numbers of those co-prescribed naloxone may be low and it is unknown how many family members or caregivers may obtain naloxone. Elk Grove Village in Illinois and Albuquerque, New Mexico implemented programs to increase public access to naloxone in libraries, community centers, schools, city/village halls, and private businesses. Addiction treatment access is also being increased.

Future agenda items. The DUR Board members suggested sharing MCO ketorolac data with the MCOs and addressing naloxone for greater than 50 MME opioids. Dr. Sreedhar suggested addressing NSAID education of participants by providers and an overview of metformin and new medications for diabetes for providers. Dr. Sreedhar asked whether all forms of birth control were available for Medicaid patients due to concerns that Plan B was being used as an alternative to birth control. Evaluating use can help educational efforts with primary care providers if there is overuse. Patty Steward, BSPharm, informed about the different types of contraceptives available to participants.

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

Future DUR Board meetings for 2019. The remaining DUR Board meetings for 2019 include September 18, 2019 and November 20, 2019.

Adjournment. Dr. Laff adjourned the DUR Board meeting at 10:13 am.

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

Approved 9/18/2019 by the Illinois Drug Utilization Review Board.