ILLINOIS DEPARTMENT OF Healthcare and Family Services

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Drug Utilization Review Board
Meeting Summary
February 20, 2020

The Drug Utilization Review (DUR) Board met on Thursday, February 20, 2020, 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; Christopher Schriever*, PharmD, Vice-Chairperson; Radhika Sreedhar, MD; Erica Stevens*, PharmD; Tim Lehan, BSPharm.

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

Interested parties: Tammy Bima, Genetech; Joseph Cirrincione, Otsuka; Palak Desai, Meridian Centene; Anik Dharia, Blue Cross Blue Shield; Sachin Hajarnis, Otsuka; Luenetta Jackson, County Care Health Plan; Casey Johnson, ViiV HC; Doug Johnson, Sobi; Mary Kaneaster, Gilead; Michael LaFond, AbbVie; Karen Malamot, Merck; Dr. Neelesh Nadkarni, County Care Health Plan; Donna Osterlund, Sanofi Genzyme; Ashley Polce, Abbvie; Janet Ritter, Sanofi Genzyme; Carmel Schneider, Takeda; Lisa Traez, Global Blood Therapeutics; Thomas Vayalil, Molina Healthcare; Brad Willie, Neurocrine; Kim Witte, AveXis; Robert Wright, Indivior.

*Attendance via teleconference

Call to Order. Dr. Laff called the meeting to order on February 20, 2020 at 8:30 am. Vote called to allow Dr. Schriever's attendance via teleconference due to work commitments that preclude travel to Chicago. Mr. Lehan made a motion, seconded by Dr. Sreedhar, and the DUR Board members approved telephonic attendance for this meeting. Mr. Lehan was thanked for his service since this is his last meeting.

Agenda, conflict of interest review, and approval of September 18, 2019 meeting minutes. No changes to the February 20, 2020 agenda or the September 18, 2019 meeting minutes requested. Dr. Schriever's motion, seconded by Dr. Sreedhar, to accept the September 18, 2019 minutes and the February 20, 2020 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.

Annual DUR Board training. Dr. Petrykiw thanked the DUR Board members for timely completion of the 2019 Ethics Training for Appointees to State of Illinois Boards and the Sexual Harassment Prevention Training for Agencies of the Illinois Governor.

DUR Board meeting schedule for 2020. Due to cancelation of the November 2019 DUR Board meeting, Board members could not vote on the proposed 2020 Illinois DUR Board meeting dates. The proposed dates were posted at the beginning of 2020 on the DUR Board website. Dr. Schriever made a motion, seconded by Dr. Laff, and the board unanimously approved the 2020 meeting schedule.

Prospective DUR

H_2-blockers. Christina Petrykiw, PharmD, noted that N-nitrosodimethylamine (NDMA) has been found in many medications such as the angiotensin receptor blockers (valsartan, irbesartan, and losartan), H_2 blockers (ranitidine and nizatidine), and most recently, metformin. The NDMA presence is either due to chemical reactions in manufacturing processes of active ingredients, reuse of solvents, manufacturing synthesis, or from changes to finished product due to storage conditions. Although NDMA may be present or formed in food with storage or preparation (meat curing spices, salted or barbecued meat or fish) or formed from nitrites in the stomach, its presence in medications is concerning since it is an animal carcinogen and probable human carcinogen. Toxic and Hazardous Industrial Chemicals Safety Manuals note patients with liver diseases should be protected from NDMA exposure. Other substances that may contain NDMA include medications formulated with aminopyrene, cigarette smoke, pesticides/herbicides, and chlorinated drinking water. Allowances for NDMA in the Clean Water Act and from the Food and Drug Administration (FDA) were reviewed. The FDA deems 0.096 micrograms or 0.32 parts per million (PPM) per day as reasonably safe. Lots of prescription and over-the-counter medications containing NDMA have undergone FDA and manufacturer testing. Manufacturers have either voluntarily recalled products, or recalled products based on testing that revealed higher than safe NDMA levels. All lots of H_2-blockers must now be tested before product is released to consumers. If unacceptable levels of NDMA are present, the product should not be released. The FDA has recommended use of other over-the-counter H_2-blockers not shown to contain NDMA, not discontinuing products before discussing options with the prescriber, and re-evaluation of need for continued therapy with H_2-blockers. Ranitidine or nizatidine samples should not be given to patients. As of December 2019, the FDA also recommends limiting nitrite-containing foods if ranitidine and nizatidine continue to be taken. In February 2020 the FDA launched an education page about nitrosamine impurities in medications that provides updates regarding lot testing. Review of HFS pharmacy claims demonstrates a decrease of ranitidine prescription fills since September 2019 (almost 75% decrease), while nizatidine claims have stayed relatively stable. At this time, HFS will adhere to FDA recommendations. Mr. Lehan noted that nizatidine can no longer be ordered.

Tofacitinib. Indications, place in therapy, and dosing of the Janus kinase (JAK) inhibitor, tofacitinib (Xeljanz) were reviewed. Post-marketing study in patients with rheumatoid arthritis who are 50 years of age and have at least 1 cardiovascular risk factor compared tofacitinib 10 mg twice daily, with 5 mg twice daily and a TNF blocker. Interim analysis in January 2019 identified thrombosis (pulmonary, deep venous, and arterial) in more patients receiving tofacitinib 10 mg than 5 mg twice daily and more deaths (all-cause mortality) in the 10-mg group than in the TNF blocker or tofacitinib 5 mg group. Sudden cardiovascular death also occurred. The FDA added an additional black box warning that in trials, patients with rheumatoid arthritis who had a cardiovascular risk factor and were taking Xeljanz 10 mg twice daily experienced an increased rate of all-cause mortality and thrombosis. New dosing and patient education recommendations from the manufacturer, FDA, and European Medicines Agency were reviewed. High risk patients in which Xeljanz should be avoided were discussed. HFS Xeljanx utilization from June 2013 to November 2019 was reviewed. At least 3,749 prescriptions were filled by 448 unique participants (FFS and MCO). Most patients filled the 5 mg and 11 mg XR dosage forms. Tofacitinib is on the Preferred Drug List but requires prior authorization to ensure appropriate and safe use. From April 2014 through October 2019 FFS prior authorizations requests were

received for 235 participants. Denials were due to contraindications, coverage issues, and clinical appropriateness. Since tofacitinib currently requires prior authorization no changes needed.

Retrospective DUR

Concomitant opioid utilization. Concomitant use of opioids with benzodiazepines or antipsychotics from May through August 2019 was reviewed in the combined HFS FFS and MCO population. Approximately 38% of all participants filling opioids demonstrate chronic use (3 or more opioid prescriptions with a quantity of 30 or more units). Chronic opioid users had more than double use of concomitant benzodiazepines and/or antipsychotics than all opioid users. In the FFS population alone, chronic opioid users had almost triple the use of concomitant benzodiazepine and/or antipsychotic medications compared to all opioid users. Mary Lynn Moody, BSPharm, noted that these are not reflective of oncology patients and that an effective method to improve prescriber education regarding prescribing is academic detailing. Academic detailing may be able to help the prescriber address concerns related to inherited pain patients and use of ILPMP as a tool to enhance appropriate prescribing and decrease abuse or diversion. Dr. Laff noted that although ILPMP provided information about Illinois, it does not address crossover in neighboring states, such as Missouri which does not participate in PMP. Board members noted that about 20% of patients are taking concomitant benzodiazepine and opioid therapy. High alprazolam use is seen. These patients have a difficult time being tapered off their medications because abrupt discontinuation, particularly of benzodiazepines, can precipitate withdrawal. The DUR Board members suggested requiring the diagnosis to be able to assess appropriateness of therapy. A diagnosis requirement for prior authorization may be difficult to operationalize. There is hesitancy to reject the combination therapy due to concern about precipitating withdrawal. It was recommended to reach out to the prescriber for benzodiazepine naïve chronic opioid users prescribed a benzodiazepine. Prescribers of concomitant benzodiazepine and opioid therapy can be considered for academic detailing visits. DUR Board pharmacists are noticing a trend of pets with anxiety and pain getting veterinary fills of benzodiazepines or opioids. Pharmacists should be vigilant regarding doses and quantities to help ensure use of medications is for the pet, not the pet owner. Academic detailing can also target veterinarians and primary care groups. It was recommended to require prior authorization for co-prescribing a benzodiazepine and opioid. A look back period of 90 days was deemed reasonable to determine if a participant was drug-naïve.

Education

Improving safety of ketorolac use. Educational item targeting ketorolac and NSAIDs was reviewed. Overall, the information is presented well. Suggestions included specifying age 18+, addition of a footnote to address risk of bleeding, and clarification of renal impairment so prescriber does not have to look up. Item was approved and new version can be sent out after edits completed.

Call for pharmacists to help patients with asthma. Draft of asthma educational item for pharmacists was reviewed. On page 3 first-line therapy should be noted. Dr. Laff explained that 75% of the time patients may not remember name of albuterol or steroid inhaler they are taking. Prescribers may not know which product is preferred. ProAir and Proventil are on the Preferred Drug List. Generic albuterol is not interchangeable since not A-rated, so prescriber must be called. Some insurers have policy that the products are therapeutic equivalent, thus will pay for whichever is prescribed. A link to the GINA guidelines was recommended for inclusion. Dissemination can include reach out to Illinois Pharmacist's Association to post on their website, social media, state medical and pharmacy organizations. Use of order sets in the hospital or clinic can facilitate appropriate therapy use. Spacers should be provided. Misdiagnosis of asthma, when COPD present should be prevented. Tim Lehan's motion was seconded by Dr. Schriever and the DUR Board approved the educational

item with suggested minor edits.

HHS guide for clinicians on the appropriate dosage reduction or discontinuation of long-term opioid analgesics. The DUR unanimously approved Dr Sreedhar's motion to post link to this document on the DUR education page.

National Academies of Sciences, Engineering, and Medicine 2019. Consensus study report: Framing opioid prescribing guidelines for acute pain. The DUR Board felt that summarizing key findings may be more helpful to prescribers than posing a long document.

Future agenda items. The DUR Board members asked whether locaserin is covered. Patty Steward, BSPharm, noted that this product is not covered federally, thus HFS does not see usage.

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

Adjournment. Dr. Laff adjourned the DUR Board meeting at 9:37 am.

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

Approved September 17, 2020 by the Illinois Drug Utilization Review Board.