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Drug Utilization Review Board Meeting Summary

November 19, 2020

The Drug Utilization Review (DUR) Board met on Thursday, November 19, 2020, at 8:30 a.m. via Web-ex for all attendees pursuant to <u>P.A. 101-0640</u>: 5 ILCS 120/7 (e) and the 10-16-2020 Gubernatorial Disaster Proclamation due to the COVID-19 pandemic.

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

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

Interested parties: Nikki Asse, Novo Nordisk; Dawn Bina, Mitsubishi Tanabe Pharma America; Kinsey Caldwell, Artia Solutions; Yvonne Collins, CountyCare; Shadi Deljoomanesh, University of Illinois at Chicago (UIC); Anik Dharia, Blue Cross Blue Shield of Illinois; Jay Elangical, UIC; Karen Floeder, Biohaven Pharmaceuticals; Nicole Fuchs, UIC; Jessica Grussing, Neurelis; Michael Hawks, Alkermes; Erin Hohman, Janssen, Johnson & Johnson; Douglas Johnson, Sobi; Mary Kaneaster, Gilead; Rob Kline, NovoNordisk; Michael LaFond, AbbVie; Tim Ludlam, Theratechnologies; Karen Malamut, Merck; Neelesh Nadkami, CountyCare; Keith O'Hara, Otsuka; Nicholas Orslini, UIC; Tiawana Parker, CountyCare; Samantha Paustian, Blue Cross Blue Shield of New Mexico; Robert Pearce, Teva Pharm; Ashley Polce, Abbvie; Carmel Schwalm, Takeda; Aaron Shaw, Boehringer-Ingelheim; Lisa Tracz, Global Blood Therapeutics; Jason Vandervest, Vertex; Thomas Vayalil, Molina Healthcare; Chris Voyiatt, Intra-Cellular Therapies, Inc; Michael Welton, Molina Healthcare; Matthew Wright, Artia Solutions; Robert Wright, Indivior.

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. Laff called the meeting to order on November 19, 2020 at 8:35 am.

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

Agenda, conflict of interest review, and approval of September 17, 2020 meeting minutes. No changes to the November 19, 2020 agenda or the September 17, 2020 meeting minutes were requested. Dr. Nikocevic's motion, seconded by Dr. Stevens, to accept the September 17, 2020 minutes and the November 19, 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.

Meeting schedule for 2021. Dr. Laff called for a vote to approve the Illinois HFS DUR Board schedule for 2021. Dr. Sreedhar seconded the motion and the DUR Board meeting schedule for 2021 was approved.

Board member training. Christina Petrykiw, PharmD, informed DUR Board members that required annual training including Ethics for Appointees to State of Illinois Boards, sexual harassment, the Health Insurance Portability and Accountability Act provisions, and security awareness, must be completed by the end of December 2020.

Retrospective DUR

Antipsychotic use in children. Christina Petrykiw, PharmD reviewed oral antipsychotic use in 7,754 children 8 to 17 years of age who had one insurer for the period of April 1, 2020 through July 31, 2020. Breakdown by insurer (managed care organization and Fee-for-service), gender, and age was reviewed. Number of prescriptions filled by children ranged from 1 to 17, with 93% of the prescriptions filled for a 28 - 31 day supply. Approximately 60% of children filled 3 or more prescriptions during the review period. Thirteen different medications were being filled. The top 5 medications filled in various oral dosage forms were risperidone, quetiapine, aripiprazole, ziprasidone, and olanzapine. First-generation antipsychotics comprised less than 2% of all prescriptions filled (chlorpromazine, haloperidol, and perphenazine). Case examples of 5 fills during the review period found 5 different strengths of quetiapine being filled - likely dose titration. In one of the cases, 4 prescribers wrote prescriptions, three of which were psychiatry/neurology specialists and the fourth provider a nurse practitioner specializing in mental health. Further evaluation occurred for children filling 3 or more times during the review period, particularly for the 9.9% of children who filled 2-5 medications during the review period. At least 21% of the children filled the same therapy monthly, 6% of children clearly added a second therapy during the review period, and the rest switched therapies during the 4-month review period. In children who switched therapies, 32% switched with no overlap between therapies, 19% switched with a 1-month overlap of therapies, 2.5% switched with a 2-month therapy overlap, and 3% switched therapies 2 to 4 times during the review period. Fourteen percent of children had a therapy switch or addition in the last month of the review. Two children underwent a switch and addition of therapy during the review period. Case review of a child filling 3 medications concomitantly demonstrated fills of olanzapine, quetiapine, and ziprasidone at near or max daily doses for age. The DUR Board members discussed further review that may be indicated, including medication and dosing appropriateness for age and indication, required DocAssist referral, and opportunities for prescriber education. Specialist referral is recommended for antipsychotic therapy, so evaluation of prescriber by type may be helpful. Linda Shuh, BS Pharm, noted that if a prior authorization requirement is applied, it would be for all of the children, as programming to a prescriber specialty is limited based provider information submitted. Donna Clay, BSPharm mentioned that a prior authorization requirement would not identify patients receiving multiple strengths. Dr. Ahluwahlia noted most therapy switches should not require more than a 1-month overlap. It was recommended to conduct prescriber outreach in situations of two or more antipsychotics filled for more than 1 month. In the future, the DUR Board would like to hear back regarding number of prescriber outreaches conducted and the reason for several months of overlap. Posting educational information on the Website was discussed and additional educational efforts, such as a prescriber newsletter or inclusion of information in Bureau Chief prescriber communications was recommended.

Education

Benzodiazepine black box warnings. The FDA has required updated black box warnings for benzodiazepines to address risk of abuse, misuse, addiction, physical dependence, and withdrawal reactions. The patient Medication Guides and sections in the package insert related to warnings/precautions, drug abuse and dependence, and patient counseling are also being updated. FDA recommendations for managing benzodiazepine therapy include consideration of comorbidities and concomitant medications; assessment of risk and monitoring for abuse, misuse, and addiction; limitation of medication dosages and durations of therapy; education of patients about need for medical attention if have difficulty breathing; referral for early substance abuse treatment; and gradual patient-individualized tapering.

Non-steroidal anti-inflammatory drug (NSAID) use in pregnancy. The FDA has issued a Drug Safety communication to address concerns regarding NSAID use in pregnancy. The NSAID-induced kidney problems that may develop in unborn babies result in low levels of amniotic fluid. The labeling for prescription and over-the-counter NSAIDs will be updated to warn not to use the medications at 20 or more weeks of pregnancy.

Sodium glucose cotransporter-2 inhibitor (SGLT2i) warnings. After review of trials and postmarketing surveillance data, the FDA has removed the black box warnings regarding amputation risk with canagliflozin (Invokana, Invokamet, and Invokamet XR).

The DUR Board unanimously approved Dr. Schriever's motion to post information regarding the new safety warnings on the DUR Board education page. The DUR Board members also discussed other ways to educate prescribers such as an educational item about new FDA warnings. Emailing notices of safety warnings is not favored because prescribers currently receive many emails from various organizations and many Internet-based newsletters. A continuing education offering related to FDA Black Box warnings was suggested. Dr. Goyal recommended partnering with specialty societies to put information about the warnings and DUR findings in their newsletters as bulleted summaries, for example, the Illinois chapter of the American Academy of Family Physicians. Inclusion of information in HFS Director communications with prescribers may also be useful.

Future agenda items. Dr. Ahluwahlia noted that prescribers may not be aware of opioid-induced endocrinopathies that can impact 9% - 29% of patients taking opioids chronically. An educational item that could educate prescribers about these conditions was suggested. Dr. Ahluwahlia asked whether HFS had considered potentially making extended-release formulations of alprazolam preferred and moving immediate-release formulations to non-preferred status. Immediate-release formulations are frequently abused and street value promotes diversion. Need for potential taper/cross-taper if a switch was implemented was discussed.

Public comments. Dr. Laff noted public comments should pertain to the agenda. No requests for public comment received in the Webex chat.

Adjournment. The DUR Board unanimously approved Dr. Schriever's motion, seconded by Dr. Nikocevic, to adjourn the meeting by Dr. Laff.

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

Approved February 18, 2021 by the Illinois HFS Drug Utilization Review Board.