ILLINOIS DEPARTMENT OF Healthcare and Family Services

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Drug Utilization Review Board
Meeting Summary
November 18, 2021

The Drug Utilization Review (DUR) Board met on Thursday, November 18, 2021 at 8:30 a.m. via Web-ex for all attendees.

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

Illinois Department of Healthcare and Family Services (HFS) Representatives: 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; Kathy Kasiurak, PharmD, Prior Authorization, University of Illinois Chicago (UIC); Mehta Kiran, Assistant General Counsel, HFS; Khoa Le, PharmD, UIC; Mary Lynn Moody, BSPharm, UIC; Christina Petrykiw, PharmD, CDCES, UIC; Maurice Shaw, PharmD, BPAS; Lori Uildriks, PharmD, BCPS, BCGP, UIC.

Interested parties: Libby Brunsvold, Vertex Pharmaceuticals; Jenny Carrell, Johnson & Johnson; Rudy Christian, Alkermes; Christine Fallabel, Dexcom; Karen Floeder, Biohaven Pharma; Doug Johnson, Sobi; Bradley Kalkwarf, Regeneron; Robert Kilo, Biogen; Karen Malamut, Merck; Rhonda McGivney, Medtronic; Dan Murphy, Abbvie; Ken Ring, Amgen; Joseph Roth, Mirum Pharma; Renee Taylor, Jason Vandervest, Vertex Pharmaceuticals; Thomas Vayalil, Molina Healthcare.

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 November 18, 2021 at 8:31 am.

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

Agenda, conflict of interest review, and approval of May 20, 2021 meeting minutes. No changes to the November 18, 2021 agenda or the May 20. 2021 meeting minutes were requested. Dr. Sreedhar's motion, seconded by Dr. An, to accept the May 20, 2021 meeting minutes was approved unanimously. Dr. Nikocevic's motion, seconded by Dr. An, to accept the November 18, 2021 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

Thank you for service. Christina Petrykiw, PharmD, thanked all board members for their service for the 2020-21 DUR Board year and their willingness to serve for the 2021-22 DUR Board year that started in October. Particular gratitude expressed to Dr. Laff, who is leaving the Board after 4 years of service. The DUR Board members were informed that HFS is actively seeking a physician to replace Dr. Laff on the DUR Board. A provider from the central to southern regions of Illinois is desired to ensure representation from that area of the state.

Annual training. Kiran Mehta, Assistant General Counsel at HFS reminded DUR Board members that annual training must be completed by December 23, 2021. The annual required training programs are accessible via OneNet. John Cernich in HFS can help with access issues. The DUR Board members who may be part of University of Illinois or UI Health must still complete the DUR Board trainings even though similar training conducted at work.

Chair, vice-chair selection. Dr. Laff has completed her Board term. Current vice-chairperson, Dr. Schriever, is chairing the meeting today. Dr. Schriever has indicated willingness to serve as chair. Dr. Nikocevic made a motion to have Dr. Schriever serve as chairperson for the DUR Board. Dr. Petrykiw suggested having one of the physicians serve as co-chairperson since a pharmacist will be chairperson. Dr. Sreedhar volunteered. Dr. Nikocevic made a motion, seconded by Dr. An. The DUR Board members unanimously approved Drs. Schriever and Sreedhar for their new positions.

DUR Board 2022 meeting schedule. The DUR Board members reviewed the 2022 meeting schedule. Dr. Schriever proposed per Open Meeting Act to vote to hold the meetings via Webex in 2022 so that this would not have to be done at the beginning of every meeting. If during 2022 HFS can transition back to in-person meetings, Board members will be notified. Dr. Stevens made a motion and the DUR Board members unanimously approved the 2022 meeting schedule and holding the 2022 meetings via Webex.

Prospective DUR

Christina Petrykiw, PharmD, reminded Board members that since the DUR Board meets quarterly, at inception it had been decided that prospective edits HFS determines are needed immediately would be implemented and presented to the Board at the next meeting. This helps ensure appropriate care is not negatively impacted by waiting for the next quarterly meeting. Two items implemented over the summer-early fall will be presented.

Synagis. An overview of Respiratory Syncytial Virus (RSV) epidemiology, symptoms, and management was provided by Dr. Petrykiw. More severe infection tends to occur in infants and older adults. Severe infection resulting in difficulty breathing or dehydration can require hospitalization for bronchiolitis or pneumonia for children < 1 year of age and bronchitis and pneumonia in older children. Palivizumab (Synagis), a monoclonal antibody, is indicated for the prevention of serious lower respiratory tract disease in children at high-risk of RSV disease. The American Academy of Pediatrics (AAP) guideline for palivizumab prophylaxis for infants and young children at increased risk of hospitalization for RSV defines populations of children that may benefit. Synagis may be given monthly for the duration of the typical 5-month RSV season which is from November to March in Illinois. The COVID-19 pandemic impacted RSV epidemiology. U.S. Department of Health and Human Services (HHS) Regions 4 and 6 demonstrated interseasonal RSV since late March 2021 through June in the National Respiratory and Enteric Virus Surveillance System. A CDC Health Advisory in June 2021 recommended testing for RSV if children with acute respiratory illness were negative for SARS-CoV-2 or exhibited age-specific RSV symptoms. HFS Fee for Service (FFS) and managed care medical claims review confirmed low number of RSV cases in the 2020-21 season. Cases in younger children began to increase in the spring and reached rates in July through September that paralleled rates seen in a typical season. The AAP issued an interim palivizumab guidance regarding atypical interseasonal RSV spread that recommended use of AAP criteria to determine which children may be eligible for Synagis and to reassess monthly. Flexibility was urged, including early initiation of palivizumab and administration of a dose if fewer than 5 doses had been given in the 2020-21 season. Dr. Goyal noted that the large pediatric hospitals in Illinois and St. Louis provided HFS data to show increased RSV caseloads in July. HFS requested monthly data submission. HFS allowed prior authorization requests for Synagis starting August 5, 2021 for FFS and MCO participants. Approval extensions were reviewed monthly and guided by the Illinois percent of positive RSV PCR tests. Provider notices were issued monthly and allowed for a 1-month fill. The Illinois Department of Public Health was supportive of HFS recommendations. The regular RSV season started November 1, 2021. Synagis criteria and forms are posted on the HFS website. The DUR Board members did not have any questions or comments.

Ivermectin. On September 29, 2021 HFS issued a provider notice regarding ivermectin (Stromectol). Ivermectin is FDA labeled for treatment of parasitic disease and has guideline recommendations for resistant pediculosis or scabies after failure of preferred agents. Ivermectin is not FDA-labeled and does not have FDA Emergency Use Authorization for prevention or treatment of COVID-19. A CDC advisory warns about adverse effects with ivermectin therapy. HFS requires prior authorization for ivermectin for all approved indications. Ivermectin will not be approved for prevention or treatment of COVID-19 for any level of care, including during hospitalization.

Continuous glucose monitoring (CGM). The DUR Board members had asked if glucose monitoring could be a topic for review. Newly updated CGM criteria were reviewed. The cornerstone of monitoring glycemic control in diabetes mellitus (DM) is quarterly hemoglobin A1c levels, in addition to daily self-monitoring of blood glucose (SMBG) and now CGM in

select patients. Correlation of SMBG and time in range (TIR) from CGM was reviewed. Glycemic targets are individualized to help prevent microvascular, macrovascular, and neuropathic disease as well as prevent hypoglycemic events. Use of CGM requires a sensor, transmitter, and receiver (device or a smart phone application). Beneficial CGM characteristics include an alarm for glucose values outside pre-determined ranges, predictive alert capability for impending hypoglycemia, and ability to transmit real-time glucose values and alerts to patients and designated others. Training is required for use of CGM as well as to understand results and alerts the CGM provides. Sample CGM alerts and the CGM Ambulatory Glucose Profile (AGP) were reviewed. The HFS FFS CGM criteria including prescriber requirements, need for prescriber attestation of patient CGM training, as well as patient characteristics (Type 1 DM, Type 2 DM, gestational diabetes) for initial and renewal requests were reviewed. Participants who meet criteria will receive a 6-month approval on sensors and transmitters, and a one-time receiver approval every 12 months. In gestational diabetes, the CGM equipment can be approved for the duration of the pregnancy and up to 12 months post-partum as needed. The DUR Board members discussed provider education, medical supply issues related to CGM components that patients bring up (ensuring adhesive keeps sensor in place, removing adhesive without causing skin damage, overpatches), defining uncontrolled, specifying an A1c number, and the requirement to see a specialist (endocrinologist). The need to be more aggressive in treating and monitoring uncontrolled hyperglycemia/high A1c was noted. Benefits of using CGM to help patients understand their diabetes, impact of food and activities on glycemic control, and increasing patient willingness to actively participate in their diabetes care were acknowledged. Given the lack of sufficient endocrinologists statewide, use of other specialists such as board certified diabetes educators and diabetes management specialists as well as pharmacists certified in diabetes care, was suggested so that appropriate care is not delayed just for a CGM prescription or recommendation from the endocrinologist. Dr. Goyal informed Board members that FFS criteria are frequently followed by HFS Managed Care. The MCOs have a requirement to arrange a specialist consultation within several weeks of the request. Dr. Goyal requested being informed if that is not happening in practice. Information on the HFS Website and educational material regarding whom to contact with coverage issues, particularly when patients move from FFS to HFS MCO would be helpful. Dr. An noted the HFS complaint portal about managed care was recently launched. The DUR Board members suggested educating prescribers regarding patient CGM-related questions via a trouble-shooting guide of practical tips. A family medicine educational resource regarding CGM could be useful or a CGM CME certificate training program developed in collaboration with the state pharmacy and family medicine associations. Identification of patients admitted to the ER due to hypoglycemia, DKA, or HHNK, and then informing the prescriber that the patient could benefit from CGM would be useful. Obtaining a CGM during hospitalization for participants frequently admitted for DKA could potentially improve outcomes also.

Retrospective DUR

First-line therapy in patients taking alprazolam. The DUR Board had requested information regarding use of first-line therapy (selective serotonin reuptake inhibitors [SSRI] or serotonin and norepinephrine reuptake inhibitors [SNRI]) in patients filling alprazolam. Utilization review of HFS alprazolam fills January-March 2021 (FFS and MCO) demonstrated that at least 25,364 participants filled an average of 2.2 prescriptions each during the review period. Immediate-release (IR) alprazolam is primarily used, with only 0.2% of prescriptions filled for extended-release (ER) alprazolam formulations. The DUR Board had considered conversion from IR to ER alprazolam- a goal that may not be feasible given the high IR usage. At least 69% of the IR product use is for the 0.5-mg and 1-mg tablets. The majority of fills was for a 15-31 days supply (88%). About 5% of participants had prescriptions with days supply in more than one category. In the 14 days supply group a quantity of 30 was most common (range 1- 75 tablets), while in the 15-31 days supply group 60 or 90 were the most common quantities filled. HFS currently allows up to three tablets daily (90 tablets per month). Ten to 30% of participants filled for only 1 month, thus up to 30% of participants may be filling for an acute need. About 59% of participants filled alprazolam for 2-3 consecutive months. Only about 10-11% of these participants filled first line SSRI/SNRI therapy every month. No first-line therapy was filled during the review period in 66% of participants filling alprazolam for up to a 14 days supply, 64% of participants filling a 15-31 days supply, and 70% of participants filling ≥ 32 days supply. In participants who filled both therapies monthly, dose titration (up and down) of the first line therapy, stable dosing, as well as changes to a different first line therapy within the 3-month review period were evident. The DUR Board suggested a benzodiazepine contract similar to what is done with opioid therapy and noted that by the third month of alprazolam therapy, first line therapy should have been started. Waiting 3 months to start first-line therapy

was not deemed appropriate, especially since may need dose titration and time to see effects. Use of ER alprazolam early if patients continue to fill IR alprazolam at a stable dose was recommended. Board members wondered whether participants received a prescription for first line therapy but chose not to fill it or it was denied because the prescribed agent was not preferred. Data reviewed excluded reversed claims. Prior authorization requests could be reviewed to determine whether a non-preferred agent had been requested. Failure to fill might be more evident if e-prescribed, filled, then reversed. It may be easier to reach out to prescribers directly to determine if first line therapy had been prescribed. Requirements for prior authorization after 14-30 days of alprazolam therapy, start of first line therapy at second month of alprazolam, and taper plan were deemed potentially beneficial to discourage longer-term use since prior authorization would be required to get the second month of alprazolam. Hurdles in optimally communicating need for prior authorization to pharmacists and prescribers after 1 month of alprazolam were discussed. Inducing withdrawal seizures with abrupt alprazolam discontinuation if PA delayed in participants who have become alprazolam dependent was a concern. This is less of a concern if only a short course of alprazolam had been received. A hard edit was deemed more effective than sending provider notices or informational pharmacy system edits. Recommended parameters were an initial 14 days supply of three times a day and a 6-month look back period for a 30-day supply fill to determine if request is an initial benzodiazepine fill. If a second alprazolam fill requested, prior authorization should be required if no first line SSRI/SNRI has been filled. If volume not prohibitive, reaching out to prescribers of participants who received IR alprazolam for 3 months, but no SSRI-SNRI therapy should be considered to discuss first-line therapy and ER alprazolam.

Dental patients filling multiple short days supply opioid prescriptions. Calendar year 2020 opioid fills from dental prescribers in FFS and MCO were reviewed for multiple short days supply prescriptions. At least 95% of prescriptions were for ≤ 5 days supply; 84% were for ≤ 3 days supply. About 3,822 participants filled two or more prescriptions of ≤ 7 days supply. At least 700 prescribers and 1163 pharmacies were used for the prescriptions. About 2% of participants filled 6 or more short days supply prescriptions (range 5-26). Profiles of those filling more than 15 prescriptions were reviewed. The participants had 1 to 2 prescribers and used 3-8 pharmacies. One prescriber had two patients with high quantities of prescriptions who had multiple dental procedures and other pain indications. Other patients had 0-1 dental procedures in medical claims and history of other pain. One participant had a history of opioid dependence/withdrawal. Utilization review helped support DUR Board recommendations to decrease to a max of 5 days supply of opioids for an initial opioid fill for acute pain. The DUR Board members noted that pharmacy review is warranted when only a few pharmacies are filling multiple short days supply prescriptions for the same participant. Some pharmacy software alerts that patients are obtaining multiple opioid fills. This should be noted by pharmacists reviewing the patient's profile prior to dispensing. Perhaps adjusting the pharmacy settings to alert about multiple opioid fills can be recommended.

Education

FAQ- Can chronic opioid use cause endocrinopathies? The DUR Board members were notified that the FAQ has been posted on the Illinois ADVANCE web page at https://illinoisadvance.com/Can-chronic-opioid-use-cause-endocrinopathies/. The FAQ will also be linked on the DUR Board education page.

Prescriber letter – naloxone, high MME. The DUR Board reviewed the naloxone letter that will be faxed to prescribers of high MME opioid prescriptions. The DUR Board members commended the letter and suggested listing the preferred naloxone dosage forms. The state standing order for naloxone lists available dosage forms but does not indicate which dosage forms are preferred. Mary Lynn Moody stated that all naloxone dosage forms are preferred for Medicaid.

Future agenda items. No topics suggested. Dr. Schriever requested notifying Dr. Petrykiw about potential topics directly.

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

Adjournment. Everyone was thanked for their active participation during the meeting. The DUR Board unanimously approved Dr. An's motion, seconded by Dr. Sreedhar to adjourn the meeting. Meeting adjourned at 10:33 AM.

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

Approved February 17, 2022 by the Illinois Drug Utilization Review Board.