ILLINOIS DEPARTMENT OF Healthcare and Family Services

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Drug Utilization Review Board
Meeting Summary

May 16, 2018

The Drug Utilization Review (DUR) Board met on Wednesday, May 16, 2018, 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; Tim Lehan, BSPharm; Anitha Nagelli, PharmD, M.Ed; Bedrija Nikocevic, PharmD; Christopher Schriever, PharmD, MS.

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; Scott Miller, PharmD, MHA (UIC); Mary Lynn Moody, BSPharm, UIC; Christina Petrykiw, PharmD, CDE, UIC; Linda Schuh*, BSPharm, BPAS; Patricia Steward*, BSPharm, BPAS; Lori Uildriks, PharmD, BCPS, CGP, UIC.

Interested parties: Jeffery Cassar, Mater Dei Hospital; Lisa Dunn, Amgen; David Large, Supernus Pharmaceuticals; Danielle Leonard, Johnson & Johnson; Ken Ring, BMS; Timothy Scicluna, University of Malta Department of Pharmacy; Kim Witte, Avexis.

*Attendance via teleconference

Call to Order. Stacie Laff, MD called the meeting to order on May 16, 2018 at 8:38 am. Dr. Laff called for a vote to allow Dr. Schriever to call into the meeting due to commitment that precluded travel to Chicago. The DUR members approved attendance via telephone at this meeting.

Agenda, conflict of interest review, and approval of February 14, 2018 meeting minutes. No changes to the February 14, 2018 minutes or the May 16, 2018 agenda were requested. Tim Lehan, BSPharm, made a motion, seconded by Bedrija Nikocevic, PharmD, and the DUR Board unanimously approved the February 14, 2018 minutes.

Prospective Drug Utilization Review

Preferred Drug List (PDL) status updates. Christina Petrykiw, PharmD, informed DUR Board members about recent PDL changes. Products containing codeine or tramadol have an age edit effective April 6, 2018, requiring prior authorization for use in children less than 18 years of age. Differences in the hepatic cytochrome-p450 isoenzyme 2D6 cause poor, rapid, or ultra-rapid metabolism of codeine and tramadol. Adverse effects include serious, slowed or difficulty breathing with both medications and deaths in codeine-treated children. These medications are also not recommended for use in women who are breastfeeding. New preferred medications include memantine (January 12, 2018) and Brilinta (May 9, 2018). New preferred medications that require prior authorization include all long-acting narcotics (April 1, 2018), Eucrisa (March 7, 2018) and Hemangeol (March 7, 2018). New non-preferred medications that require prior authorization include Aptensio XR, Copaxone 40-mg injection, Kevzara, Mitigare, Qvar Redihaler, and Xatmep. Dr. Goyal requested clarification about the non-preferred status of Copaxone. Donna Clay, BSPharm, clarified that the 20-mg dosage form is preferred and the once-weekly 40-mg dosage form is not preferred. The DUR Board members noted difficulties in using the new Qvar Redihaler dosage form for children younger than 8-10 years of age. The Drugs & Therapeutics Committee cited availability of inhalers that are easier to use in their recommendations.

Ocaliva. Christina Petrykiw, PharmD, provided an overview of primary biliary cholangitis (PBC), its management, and the role of Ocaliva in the treatment of PBC. Ocaliva is usually added to ursodiol in situations of treatment failure or intolerance. The Food and Drug Administration issued Ocaliva boxed warnings regarding incorrect daily rather than weekly dosing in patients with hepatic disease that has contributed to at least 19 deaths. The PBC-specific Child-Pugh score must be calculated for the patient prior to first dose to ensure correct dose and with routine monitoring, the score and dose, may need readjustment. Patients must receive a Medication Guide for Ocaliva and education about symptoms

of worsening liver function. Ocaliva should be stopped if liver function worsens. Risk versus benefit of restarting Ocaliva should be assessed. Managing drug interactions facilitates therapeutic outcomes. Other states' initial and renewal criteria were reviewed. Lori Uldricks, PharmD, presented the HFS initial and renewal criteria for Ocaliva. Dr. Nikocevic questioned initial approval of 6 rather than 3 months. Dr. Nagelli noted that a 3-month approval allows for assessment of response and an opportunity to increase the dose. The DUR Board members were concerned that due to need for specialist involvement, the 3-month approval may not provide sufficient time in areas lacking specialists. Risk versus benefit of an initial approval for 3 vs 6 months was discussed. Dr. Goyal asked whether any requests were received and was informed that there are no pending requests. He noted package insert step therapy requirements of ursodiol and raised a concern about managing patients who may have rapidly progressing disease. Anitha Nagelli, PharmD, reminded everyone that for safety, regular quarterly monitoring should be done, so opportunities to check patient progress with medications exist. Christopher Schriever, PharmD, made a motion, seconded by Dr. Nikocevic, to recommend approval of the Ocaliva criteria with changes of 1) initial approval "up to 6 months" to allow adjustment as needed for individual patients and 2) adding rapidly progressing disease while taking ursodiol to the criteria.

Retrospective Drug Utilization Review

Asthma. Christina Petrykiw, PharmD, CDE reviewed asthma-related retrospective reviews and prescriber outreach done to date. A retrospective review of pediatric patients with asthma and no chronic obstructive pulmonary disease who had more than one Emergency Room and medical visit for asthma and used 8 or more short-acting beta-agonist inhalers and underutilized steroid inhalers was done. Challenges during the review including significant shift of patients from Fee-for-Service to Managed Care and database limitations. Prescribers were called to obtain more clinical information and subsequently received a fax detailing the patient's adherence with asthma medication and recommendations based on HFS history review and prescriber interview. The intervention was well received based on prescriber comments, but only 23% of patients demonstrated some improvement with adherence at follow-up. Post-intervention, no patients were adherent with first-line controller therapy (steroid-containing inhaler) for 12 consecutive months. Initial medication review demonstrated very high use of montelukast, but not necessarily in addition to steroid inhaler therapy. Steroids address underlying pathophysiology of asthma and are thus a cornerstone of therapy. The DUR Board recommended an educational item for prescribers about the role of montelukast in asthma from a guideline perspective. The article is posted on the DUR Board Website at https://www.illinois.gov/hfs/MedicalProviders/Pharmacy/Pages/DrugUtilizationReview.aspx. Ongoing Four Prescription Policy adjudication reveals continued limited use and/or adherence with first-line steroid inhaler therapy. During quarter 1 of calendar year 2018 approximately 38% of Fee-for-Service participants filled montelukast with no steroid inhaler. Use of montelukast monotherapy in Fee-for-Service participants has been greatest in children 5 to 18 years of age and adults. Over half of patients filling montelukast received a steroid inhaler once and about 25% of participants filled twice. At least 42% of patients filled more than one steroid inhaler. Adherence falls significantly after the first fill of a steroid-containing inhaler. An inhaled corticosteroid prescription request form was developed to help remind prescribers of the need for steroid inhaler therapy, educate about the montelukast review, and facilitate starting patients on first-line therapy. The prescriber fills out the prescription form and sends it to the pharmacy to be filled. Dr. Laff noted difficulty in getting a spacer device for use with a steroid inhaler with the Medicaid MCOs. This has pushed prescribers to use montelukast rather than first-line therapy. Fee-for-Service Medicaid allows 1 spacer device every 6 months without a prior authorization requirement. Many of the MCO's cover Aerospan, which is not used much in practice due to difficulty in using the barrel-type device. Additional concerns exist about the reformulated Qvar Redihaler which is more cumbersome to use than the previous design. Inhaler education and use of an inhaler is more time intensive than taking an oral montelukast tablet. The DUR Board members asked about frequency of steroid inhaler use and whether number of prescribed versus filled inhalers was known. More detailed data is needed to determine this. This year's relatively mild influenza season and ER prescriptions without continuity of care with a primary provider impact refills. Dr. Nikocevic, PharmD, noted lack of awareness of different billing codes for patient counseling versus proper inhaler use education. She suggested an educational item targeting pharmacists to inform of HFS asthma initiatives to improve care and to encourage appropriate medication fill review and counseling of asthma patients. Other MCO-related difficulties with asthma care include prior authorization requirements for spacers and limited availability of different inhaler strengths to facilitate step-up therapy. Suggestions included re-evaluating unrestricted montelukast coverage, antihistamine approval for management of allergies, and allowing Flonase nasal spray for allergies in children. Tim Lehan, BSPharm, noted pharmacies can figure out how to obtain spacer coverage. Mary Lynn Moody, BSPharm, notified DUR Board members that HFS will be reaching out to patients regarding asthma medication adherence. Dr. Goyal requested members provide specific cases of MCO asthma-related issues so that HFS can help resolve them.

Adherence with direct-acting oral anticoagulant therapy (DOAC). Donna Clay, BSPharm, presented the pilot retrospective review of adherence with long-term direct (novel) oral anticoagulant medications in Fee-for-Service participants from December 2016 through December 2017. The majority of patients filled Xarelto or Eliquis. Participants were primarily treated for atrial fibrillation, recurrent DVT/PE, and coagulation disorders/thrombophilia. Adherence review demonstrated that one patient never filled therapy despite a prior authorization approval being on file, 24% of participants filled 1-4 times, 17% of participants filled 5-8 times, and 56% of participants filled 9 or more times. Occurrence of embolism could not be correlated to poor adherence since patients with no fills and those with up to 13 fills experienced an event. Limitations included the amount of clinical information provided with pharmacy and medical claims, potential delay in submission of medical claims because up to 6 months allowed for claim submission, hospitalization billing targeting primary admitting diagnosis rather than all diagnoses, and difficulty in determining if embolic event is acute, new onset, or part of past medical history. The review time may have been too short to capture embolic events and adherence may not be the only contributing factor. HFS will develop a plan to monitor compliance to alert prescribers about lack of adherence at time of prior authorization renewal requests. On a quarterly basis prescribers of new requests will be notified of medication adherence. Plans include determination of a method to monitor event rate and patient education materials. Dr. Nikocevic, PharmD, noted ramifications of not allowing automatic refills. Pharmacies use lack of picking up a prescription that has automated refills to start a patient discussion regarding medication adherence. Causative factors may be identified and fixed immediately. Dr. Nagelli mentioned that medication fill synchronization and medication management may be more helpful. For example, the Centers for Medicaid and Medicare Services (CMS) Pharmacy EQUIP database helps identify outliers. The HFS staff asked why pharmacists only notice lack of automated refills. Dr. Nikocevic, PharmD, stated that store volume may impact review time. Sensitivity of the pharmacy's Drug Utilization Review (DUR) tool and pharmacists' alert fatigue may also contribute. Medication management has mostly targeted diabetes and hypertension. The DUR Board members asked about other drug classes that may be targeted for adherence monitoring. Currently HFS monitors adherence for cystic fibrosis and hepatitis C medications.

Fibrate-statin therapy. Adjudication reveals fibrate therapy without first-line hyperlipidemia therapy (statins). Staff reach out to prescribers to document the reason for lack of statin therapy. The DUR Board was asked to provide input on needed prescriber education. To date, a summary of the ATP-IV guidelines and guidance regarding non-statin use was written. Dr. Nikocevic, PharmD, mentioned that reluctance to use the statins, despite guideline recommendations, may be due to fear of inducing adverse effects. Rhabdomyolysis is a particular concern if patients are taking medications that interact with statins, such as diltiazem or verapamil. This may be most true for older practitioners unaware of new guidelines. The DUR Board members recommended a 1-page graphic educational item about statins and extent of lipid improvement with fibrates. Reminders or information about checking other medications may be useful as well.

Education

Use of medications containing tramadol and codeine in children. Christina Petrykiw, PharmD, notified DUR Board members about the educational letter sent to 641 prescribers of tramadol and codeine in children during quarter 1 of calendar year 2018. The letter addressed metabolic and safety issues that prompted an age limit for tramadol- and codeine-containing products as well as treatment options for pain and cough for children less than 18 years of age. As recommended by the DUR Board, prescribers were faxed prior to implementation of the age edit. The letter is posted on the DUR Website (https://www.illinois.gov/hfs/MedicalProviders/Pharmacy/Pages/DrugUtilizationReview.aspx).

Future agenda items. Dr. Nikocevic suggested reviewing gabapentin use, which has been associated with abuse. Prescriber guidance and potentially requiring review for participants needing higher doses, i.e., 2,400 mg were suggested. Extended duration of ketorolac use has been noted it practice. It is indicated for short-term use due to significantly increased risk of bleeding. Review of ketorolac use may reveal need for prescriber education.

Public comments. Dr. Laff noted that comments should pertain to the day's agenda. There were no public comments.

Adjournment. Dr. Laff adjourned the DUR Board meeting at 10:21 am.

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

Approved September 19, 2018 by the Illinois Drug Utilization Review Board.