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Drug Utilization Review Board
Meeting Summary
Wednesday, May 18, 2016

The Drug Utilization Review (DUR) Board met on Wednesday, May 18, 2016, 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: Rachel Caskey, MD; Tim Lehan, BSPharm; Anitha Nagelli, PharmD, M.Ed, Vice-chairperson.

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; Christina Petrykiw, PharmD, CDE, UIC; Linda Schuh*, BSPharm, BPAS; Patricia Steward*, BSPharm, BPAS.

Interested parties: Chris Gillette, Pfizer; Judy King, MD; Mike LaFend, Abbvie; Steve Lash, Genentech; Dawn Lease, Johnson & Johnson; Randi Lewandowski, Teva; Marcia Luckett, Genentech; Scott Mills, Allergan; David Skibicki, Pfizer; Chris Stanfield, Supernus; Gary Thurnauer, Pfizer.

*Attendance via teleconference

Call to Order. Rachel Caskey, MD, called the meeting to order on May 18, 2016 at 8:31 am.

Agenda, conflict of interest review, and approval of February 17, 2016 meeting minutes. Illinois DUR Board members had no changes to the May 18, 2016 meeting agenda or the February 17, 2016 minutes. Tim Lehan, BSPharm, made a motion, seconded by Anitha Nagelli, PharmD, and the DUR Board unanimously approved the February 17, 2016 minutes. Rachel Caskey, MD, requested DUR Board members to recuse themselves from discussion if a conflict of interest exists and to update their Conflict of Interest form when conflicts arise.

HFS Bureau of Professional and Ancillary Services report. Patty Steward, BSPharm, noted that prescribers need to re-enroll via IMPACT because HFS is replacing their 30-year old Medicaid Management Information System (MMIS). Prescribers and pharmacy providers who are currently registered are being re-validated. New categories of prescribers will be registered. IMPACT will facilitate access to the Pharmacy Benefits Management system's provider portal, e-prescribing, and viewing status of prior authorization requests. An ongoing 6-9 month outreach program is encouraging providers to register as active Medicaid providers via Impact at https://www.illinois.gov/hfs/impact/Pages/default.aspx.

Mary Lynn Moody, BSPharm, mentioned that the Illinois Pharmacists Association (IPhA), in response to the Heroin Crisis Act (HB1), is offering an on-demand, online, opioid antagonist training program at http://www.ipha.org/isoatp-registration. The Heroin Crisis Act aims to improve opioid prescribing and make naloxone more available for narcotic and heroin overdoses. Prior to naloxone dispensing, pharmacists in outpatient settings must be trained. Pharmacists should check with their organization/work site if a group discount is available. HFS is actively determining how HB1 impacts federal regulations for Medicaid coverage only subsequent to a presented prescription.

Prospective Utilization Review
Methadone. Christina Petrykiw, PharmD, highlighted indications, pharmacokinetics, and overdose information for methadone. The Methadone Safety Clinical Practice Guideline from the American Pain Society College on Problems of Drug Dependence and Heart Rhythm Society was reviewed. Prolongation of the QTc interval, a risk factor for the potentially fatal arrhythmia, Torsades de Pointes, was discussed. Other recommendations include use of patient-

prescriber opioid/pain management plans and pain contracts, avoidance of benzodiazepines in patients taking methadone, and use of urine drug screens for illicit drugs, arrhythmogenic drugs, and methadone. The DUR Board and Centers for Medicare and Medicaid Services (CMS) encourage methadone non-preferred status. The CMS recommends state Medicaid agencies educate providers about appropriate opioid prescribing and dispensing practices and use various strategies for managing opioid prescribing, including clinical criteria, prior authorization, step therapy, quantity limits, and/or DUR processes. On April 5, 2016, HFS made methadone non-preferred for the management of pain. At that time remaining long-acting narcotics on the HFS Preferred Drug List included fentanyl patches and extended-release morphine sulfate oral tablets. Staff identified 373 unique HFS participants who had filled at least one methadone prescription between November 2015 and March 2016. These participants were served by 237 unique prescribers. In March 2016, these prescribers were called and then received informational faxes about the change of methadone to non-preferred status. Prior authorizations were entered for participants to ensure therapy continuation while prescribers with patients determined future pain management options. In April 2016, prescribers received patient-specific *Methadone Use in Pain Management Program Letters of Medical Necessity for Long-term Opioid Use* for participants who had non-cancer, non-sickle-cell pain. Methadone prior authorization criteria require the prescriber to be an actively registered HFS provider. Methadone must be for chronic pain after established failure of preferred short-acting and long-acting narcotics. Required reviews include Illinois Prescription Monitoring Program history and medication screening for potential drug interactions that can cause QTc prolongation, respiratory depression, or changes in methadone levels. Objective assessments include a recent EKG, potassium and magnesium blood levels, and a urine drug screen. Participants who meet criteria may receive a 3-month approval, while those that do not meet criteria may end up switching to a different long-acting opioid, correcting risk factors, tapering off opioids, or paying for the methadone out-of-pocket. The DUR Board discussed the criteria. Mary Lynn Moody, BSPharm, noted that there is a percentage increase of overdoses as methadone doses increase. Dr. Goyal asked about HFS progress with HB1 legislation effective January 1, 2017. This legislation removed prior authorization requirements and lifetime limits on medication-assisted addiction treatment (MAT), including methadone. Coverage is being determined since MAT will shift from the Division of Alcoholism and Substance Abuse (DASA) within the Department of Human Services (DHS) to the Department of Healthcare and Family Services (HFS). Concerns exist that participants use high doses for pain that are traditionally used for treating addiction. Lack of communication may result in opportunities to abuse methadone. Splitting doses was discussed. Methadone clinics facilitate treatment and are useful abuse deterrents. Dr. Goyal noted that methadone is not a first choice for pain management and before is made available to treat pain, safety concerns should be addressed. Dr. Caskey suggested that methadone use be discouraged and prescribers/patients receive education regarding therapy risks. Mary Lynn Moody, BSPharm, noted it can take 5-10 years to see shifts in practice occur after guidelines are published. DUR Board members unanimously approved the prior authorization criteria for methadone use in pain management.

Retrospective Drug Utilization Review

Tramadol use in children. Christina Petrykiw, PharmD, reviewed the potential safety issues with tramadol use in children that were discussed at the last meeting. The DUR Board members had requested pediatrician input before finalizing a decision regarding tramadol. Tramadol has been used off-label in children for treatment of pain. Post-tonsillectomy use of tramadol in children has caused difficult or slow breathing that required hospitalization. Children may be ultra-rapid metabolizers of tramadol, which results in more active metabolite, O-desmethyl-tramadol, in the body. The Food and Drug Administration is monitoring off-label use in children. For HFS, the tramadol 50-mg dosage form is preferred. Review of tramadol use in children covered by HFS revealed that 2,350 children less than 18 years of age received tramadol 50 mg in 2014 and 1,521 children received it in 2015. The DUR Board discussed the implications of different types of limits or prior authorization options for tramadol in children. Dr. Goyal questioned whether the off-label use made this an indispensable medication in children and whether it should be limited to certain diagnoses, such as pain associated with sickle cell disease or cancer. Mary Lynn Moody, BSPharm, stated that the current HFS system cannot limit to a diagnostic code. Dr. Caskey noted that tramadol is not used much in children routinely because other pain medications are first-line in this population. Off-label use supports restriction to adult use only. The DUR Board voted unanimously to restrict tramadol to age 18 and older. This will facilitate education of prescribers about safety issues related to tramadol use in children.

Medication use in fibromyalgia. Christina Petrykiw, PharmD, provided an overview of fibromyalgia, a condition in which the brain/central nervous system changes the way peripheral pain is perceived. Different body regions are affected at different times. Fibromyalgia symptoms include multifocal, migratory chronic pain in the neck, shoulders, back, hips, arms, and legs. Augmented pain is felt in response to touch, pressure, or temperature. Besides pain,

symptoms include tenderness and psychological/cognitive issues. Neurotransmitters that control pain and sensory sensitivity may also control sleep, mood, memory, alertness, and fatigue. This explains all of the symptoms in addition to pain that patients with fibromyalgia may experience. Guidelines for diagnosis of fibromyalgia require widespread pain for at least 3 months and in the past required tenderness in 11 of 18 sites. Self-reported patient surveys identify pain location and all symptoms. Conditions that may cause similar symptoms must be excluded. The International Classification of Diseases (ICD) version 10 (ICD-10) has a fibromyalgia-specific code. Non-pharmacologic therapy that sustains improvement in function for more than a year includes patient education, graded exercise and cognitive behavioral therapy. Patients must be educated to understand that symptoms are not due to damage or inflammation and that pharmacologic therapy has limited efficacy. Effective pharmacologic therapy for fibromyalgia includes combinations of pain and sleep medications, antidepressants (select tricyclics and serotonin norepinephrine reuptake inhibitors [SNRIs]), gabapentinoids (gabapentin, pregabalin), γ-Hydroxybutyrate, muscle relaxants, and tramadol. Less effective therapies are cannabanoids, selective serotonin reuptake inhibitors (SSRIs), and naltrexone. Non-steroidal anti-inflammatory agents, strong opioids, and corticosteroids are not effective. Centrally-acting analgesics help with co-occurring symptoms or are completely ineffective. Fibromyalgia patients may need pain medication even for minor surgery or procedures, and opioids or surgery often do not relieve pain. FDA-approved medications for fibromyalgia pain include pregabalin, duloxetine, and milnacipran, all of which currently require prior authorization. HFS identified approximately 8,000 participants with fibromyalgia alone or with unspecified rheumatism with fibrositis or myalgia and myositis in 2015. Approximately 36,000 participants had a diagnosis of myalgia and myositis. Many HFS participants with fibromyalgia have conditions/medications that may cause symptoms similar to those in fibromyalgia and many have concomitant conditions (anxiety disorders, depression, gastro-intestinal disorders, headaches, and insomnia). Review of medication use in HFS participants with fibromyalgia noted primary use of narcotic analgesics, gabapentinoids, NSAIDS, skeletal muscle relaxants, SSRIS, corticosteroids, and limited use of SNRIS or milnacipran. Although opioids are predominantly used and may provide a centrally-mediated reward, these medications are not effective in alleviating fibromyalgia symptoms. Opioids can cause hyperalgesia, augment pain perception, contribute to nonrestorative sleep, fatigue, sedation, and mental clouding, and worsen irritable bowel due to opioid-induced constipation. Practitioners should not start opioids in patients with fibromyalgia, should use tramadol for rescue analgesia without escalating doses, and should prevent opioid overuse. The DUR Board discussed available treatment options. They suggested HFS work with the Drugs and Therapeutics Committee to re-evaluate preferred drug list status of FDA-approved agents for fibromyalgia to enhance medication access. Dr. Goyal requested clarification whether the HFS review encompassed fee-for-service (FFS) participants only or also include managed care HFS participants. The current review was only focused on FFS participants. Dr. Goyal felt that this might underrepresent the issue, since about 2/3 of the HFS population is now under managed care. Dr. Goyal suggested posting the fibromyalgia slide presentation on the HFS DUR Website because it is a valuable educational tool for prescribers. The DUR Board members agreed. Mary Lynn Moody, BSPharm, will discuss with HFS the current feasibility of making a FDA-approved medication for fibromyalgia available as a preferred agent.

Future agenda items.
Dr. Caskey asked DUR Board members for medication use issues HFS should be evaluating. Dr. Goyal noted that treatment of attention deficit hyperactivity disorder in children may be valuable to address. The DUR Board members may forward additional issues they identify to Christina Petrykiw, PharmD.

Public comments
Dr. Judy King voiced support for making the slide presentations available on the HFS Website and suggested offering continuing medical education for the information. She requested slides be available prior to the meetings, more detail be provided on motions being made during the meeting, criteria for prior authorization be available for public comment, and making meeting attendance via teleconference an option to facilitate attendance by those unable to be onsite in Chicago for the meeting. She also supported incorporating managed care participant information into medication utilization discussions.

Adjournment. Dr. Caskey adjourned the DUR Board meeting at 9:55 am.

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

Approved September 21, 2016 by the Illinois Drug Utilization Review Board.