

Drug Utilization Review Board Meeting Summary

Wednesday, September 21, 2016

The Drug Utilization Review (DUR) Board met on Wednesday, September 21, 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; chairperson; Tim Lehan, BSP Pharm; Anitha Nagelli, PharmD, M.Ed, Vice-chairperson; John E. Tulley, MD.

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

Interested parties: Tom Boyle, Abbvie; Mike Holmes, Sunovion Pharmaceuticals; Michael LaFond, Abbvie; Sara Kinnebrew, Abbvie; Roberta Neuwirth, GSK; MaryPat Petrillo, Janssen Scientific Affairs; Chris Stanfield, Supernus.
*Attendance via teleconference

Call to Order. Rachel Caskey, MD, called the meeting to order on September 21, 2016 at 8:34 am.

Agenda, conflict of interest review, and approval of May 18, 2016 meeting minutes. Illinois DUR Board members had no changes to the September 21, 2016 meeting agenda or the May 18, 2016 minutes. Tim Lehan, BSP Pharm, made a motion, seconded by John Tulley, MD, and the DUR Board unanimously approved the May 18, 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, BSP Pharm, mentioned that HFS will expand availability to therapy for hepatitis C to participants with a Metavir F3 score (previously Metavir F4 score only). Effective October 1, 2016, the HFS Preferred Drug List (PDL) includes Epclusa and Zepatier as preferred agents, and Harvoni will become non-preferred. Criteria and forms for direct-acting antivirals (DAA) for treatment of hepatitis C are posted on the HFS pharmacy Web page.

Prospective Utilization Review

Fentanyl. Christina Petrykiw, PharmD, reviewed fentanyl patch information, including the indication for opioid tolerant participants, pharmacological effects, pharmacokinetics, contraindications, and safety issues. The Food and Drug Administration (FDA) has issued multiple warnings. The most recent warning in March 2016 addressed fentanyl-induced serotonin syndrome and decreased cortisol and sex hormone levels. The FDA reports hospitalizations and death in children due to accidental patch exposure, while the Institute for Safe Medication Practices reports at least 1,890 cases of serious harm, 60% of which were due to medication errors. Harm can be caused by prescribers using the long-acting fentanyl patch for acute pain, post-operative pain, in opioid-naïve patients, and incorrectly dosing it. Patient errors are caused by inappropriate patch placement, wearing the patch too long, and inappropriate storage and disposal. New Centers for Disease Control and Prevention guidelines for prescribing opioids in chronic pain also highlight problems with fentanyl patch use. In June 2016, the HFS Drug and Therapeutics Committee recommended fentanyl patches change to non-preferred on the PDL. Effective August 15, 2016 fentanyl patches became non-preferred. The current preferred long-acting opioids are extended-release morphine oral tablets and abuse-deterrent morphine capsules (Embeda). The Fee-For-Service (FFS) participants who had filled prescriptions for fentanyl patches from June 2015 to June 2016 were evaluated. One percent of fentanyl users had a

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9.21.16 Illinois Drug Utilization Review Board Meeting Summary

diagnosis of cancer or sickle cell disease. Approximately 5% of fentanyl users resided in long-term care facilities. Fewer than 10 fentanyl users were children less than 12 years of age. Approximately 77% of fentanyl users evaluated were no longer using fentanyl, were no longer eligible for Medicaid, transitioned to a MCO, had other insurance coverage, or had died by the effective date for fentanyl patch non-preferred status. At least 9% of fentanyl users were already in the renewal phase of the pain management program for long-term opioid use. Prescribers of 560 participants were notified about the change of fentanyl status via informational faxes and posting of the fentanyl notice in the education section of the Drug Utilization Review Webpage. Temporary approvals were entered for current fentanyl patch users. This fall prescribers will receive a patient-specific *Pain Management Program Letter of Medical Necessity for Long-Term Opioid Use* for participants not already enrolled in the pain management program. On an ongoing basis, prior authorization requests for fentanyl will be processed into the Pain Management Program. Prior authorization criteria for fentanyl were reviewed. Initial prior authorization approval will be for 3 months. Participants who do not meet criteria may switch opioid therapies, taper off opioids, or pay for the fentanyl themselves. The DUR Board members asked about the criteria for chronic opioid therapy and raised concerns about diversion of fentanyl since it is being mixed in with street drugs with deadly results. Members questioned whether recently reported deaths were due to fentanyl, whether chronic fentanyl could be a criterion for limiting a participant to using one prescriber and pharmacy (lock-in) and whether prescribers must submit their Drug Enforcement Agency (DEA) number for prescribing narcotics on prior authorization requests. Mary Lynn Moody, BSPHarm, and Donna Clay, BSPHarm, noted that limitation to one prescriber or pharmacy for only one drug is not possible – it would apply to all prescriptions for the participant. Limiting to one prescriber may be problematic if treated by an Emergency Room provider for an acute issue. Fentanyl should not be prescribed by Emergency Room physicians since they are treating acute, not chronic, conditions. An alert that would flag if the participant is filling all allowed refills at one time would be useful. Dr. Goyal noted that prior authorization criteria should not be generous because that would promote inappropriate use and/or diversion. Prior authorization staff noted that currently the DEA number is not a requested item with prior authorization requests. Dr. Caskey asked which diagnoses required chronic opioid therapy, since few participants had cancer diagnoses. Dr. Petrykiw noted that the number of cancer diagnoses may be under-represented because medical and facility claims are submitted up to 6 months after date of service. The DUR Board members noted that decreasing trends for narcotic prescriptions may be related to culture shifts in pain management in reaction to the over use of prescribed opioids and resulting overdose deaths. Christina Petrykiw, PharmD, asked DUR Board members for input related to the fentanyl contraindication of acute or severe bronchial asthma that is listed in the package insert. If this is the only criterion a fentanyl user does not meet, should therapy be denied? The DUR Board members noted that presence of asthma medications, including excessive use of rescue inhalers, was not sufficient to support a denial. Medication use alone would not provide sufficient information regarding severity or acuity of disease state. Prescribers would need to provide more information in these cases. John Tulley, MD, made a motion, seconded by Tim Lehan, BSPHarm, and the DUR Board unanimously approved the fentanyl criteria for prior authorization.

Methadone. Christina Petrykiw, PharmD, addressed implementation of the methadone prior authorization criteria that were approved at the May DUR Board meeting. In March 2016, at least 307 unique methadone prescribers were called and then received informational faxes about the change of methadone to non-preferred status. Patient-specific *Methadone Use in Pain Management Program Letters of Medical Necessity for Long-term Opioid Use* were faxed to prescribers of participants with non-cancer, non-sickle-cell pain. Since April 2016, at least 48 additional methadone-specific faxes have been sent. Of the total 269 faxes sent, 36% have been returned to date. Of these, 30% were approved. Denials have primarily been for lack of safety monitoring of risk factors for QT interval prolongation or recent urine drug screens, insufficient history of adequate trials of preferred narcotics, non-use of first-line non-narcotic therapies for given indications, or not meeting criteria for chronic opioid use. At least 15% of participants filling methadone are also filling benzodiazepines concomitantly. The DUR Board members asked whether benzodiazepine use was a contraindication to methadone therapy. Benzodiazepine use is contraindicated with methadone use since concomitant use increases risk of respiratory depression and has been implicated in deaths. Concerns were raised about prescribing methadone at doses used to treat addiction. Staff members evaluate methadone doses and indications and verify if the urine drug screen results provided note methadone presence. Illicit drug use evident with urine drug screens may serve as a red flag about abuse potential with methadone. Dr. Goyal asked for an update regarding methadone use as MAT therapy. Mary Lynn Moody, BSPHarm, clarified that currently HFS cannot cover methadone for MAT as a pharmacy benefit because the medication is provided at federal treatment centers via the Division of Alcoholism and Substance Abuse.

9.21.16 Illinois Drug Utilization Review Board Meeting Summary

Retrospective Drug Utilization Review

Attention Deficit Hyperactivity Disorder (ADHD). Christina Petrykiw, PharmD, provided an overview of ADHD deficit, including Diagnostic and Statistical Manual of Mental Disorders version 5 (DSM-V) and International Classification of Diseases version 10 (ICD-10) diagnostic criteria, concomitant disease states, clinical disease course from childhood to adulthood, reasons why ADHD is problematic in the home, school, or work settings, and ADHD treatment guidelines from the American Academy of Pediatrics that address non-pharmacologic and pharmacologic therapy. The Centers for Disease Control and Prevention and the Agency for Healthcare Research and Quality assessed ADHD interventions and provide age-specific recommendations. Medication-related issues including adverse effects were presented, in addition to trends for medication use in foster care and non-foster care children insured by Medicaid and employer-based insurance plans. Impact of medication use in children was addressed. The use of stimulants for the treatment of ADHD in children less than 6 years old insured by HFS has decreased with time, in part due to prior authorization requirements and participant transition to Managed Care. Information was provided about stimulant utilization in adults in state FY10, including percent of stimulant users filling other medications, their alcohol and substance abuse diagnoses, and related Emergency Room use. The majority of state Medicaid programs address psychotropic or stimulant medication use in children and adults. At least half of the programs require prior authorization for pediatric ADHD medications. Medicaid agencies monitor and manage use of select or all ADHD medications by Preferred Drug List placement, age limits, maximum dose or quantity for age, maximum daily dose or monthly quantities, hard edits for duplicate therapy, polypharmacy, concomitant narcolepsy medications, or stimulant-induced sleep diagnosis, retrospective DUR review, indication review, and peer consultation. Washington Medicaid dose/quantity limits and diagnosis-based algorithm were highlighted. The DUR Board members questioned the basis for Washington's limits. They did not favor such an elaborate method for HFS. Mary Lynn Moody, BSP Pharm, informed DUR Board members about the availability of a free peer consultation program called DocAssist in Illinois, which provides prescribers with telephone access to a child psychiatrist at UI Health. Prescribers can get a consult immediately or schedule a convenient time. Currently the program gets 9-10 calls daily. This program may become covered in the future within BPAS. The DUR Board members suggested HFS identify participants by diagnosis and reach out to their prescribers to inform them of the availability of DocAssist. Prescribers of children less than 6 years of age or participants taking more than 6 multiple ADHD medications at the same time should be informed first. Anitha Nagelli, PharmD, suggested a prescription-based approach, for example targeting participants using multiple strengths of short- and long-acting ADHD medications. She noted that although dosing of these medications seems erratic, college students served by the medical center use a shared-decision process with their medical provider and self-adjust the immediate- and extended-release doses of their medications based on symptoms. Voluntary versus required peer consultation was discussed. Required consult was preferred. Most benefit may be for primary care providers in psychiatrist-desert areas to help them make an appropriate diagnosis. HFS is also reaching out to the Child and Adolescent Psychiatry Department at Southern Illinois University for help in addressing needs of participants and prescribers in the middle and southern parts of the state. Dr. Goyal asked about the number of FFS participants using ADHD medications compared to those currently under managed care, particularly the number of total scripts and scripts per patient. Dr. Goyal asked why criteria are currently only for children less than 6 years of age when medications are often used on an ongoing basis, so perhaps HFS should be looking more closely at all children. Donna Clay, BSP Pharm, and Patty Steward, BSP Pharm, noted that services for behavioral health are not always available and there are current budget constraints. Small reimbursement for longer visits that incorporate behavioral strategies is a disincentive. Dr. Caskey reminded everyone not to assume that lack of a claim means there was no attempt to obtain cognitive behavioral therapy (CBT). The current wait list is approximately 9-12 months for an appointment for CBT. If HFS is not paying, then participants must pay for CBT. Mary Lynn Moody, BSP Pharm, suggested getting input regarding criteria from the medical peer consultants at DocAssist that are already familiar with the Washington criteria. Use of DocAssist in a telehealth type of model may partly resolve access to care in the future.

Education

FDA black box warning: concomitant opioid and benzodiazepine use. Christina Petrykiw, PharmD, informed the DUR Board about the FDA's new black box warning about serious risks and death associated with combining opioid-containing pain or cough medicines with benzodiazepines. The warning will be added to labels of prescription opioid-containing pain and cough medicines as well as benzodiazepines. Links to the black box warning and FDA recommendations for health care professionals/patients are posted on the HFS [Drug Utilization Review Web page](#).

Fentanyl provider letter. Christina Petrykiw, PharmD, informed DUR Board members that the fentanyl prescriber informational notice is posted on the HFS [Drug Utilization Review Web page](#).

9.21.16 Illinois Drug Utilization Review Board Meeting Summary

Future agenda items.

Dr. Caskey asked DUR Board members for medication use issues HFS should be evaluating. The DUR Board members may forward issues they identify to Christina Petrykiw, PharmD.

Public comments. Dr. Caskey invited attendees to provide comments. There were no public comments.

Adjournment. Dr. Caskey adjourned the DUR Board meeting at 10:15 am.

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

Approved February 15, 2017 by the Illinois Drug Utilization Review Board.